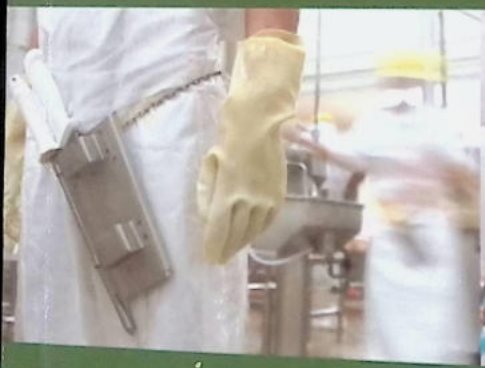
Food Safety Management

III

A Practical Guide for the Food Industry



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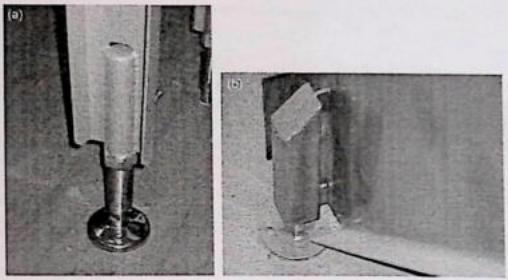


FIGURE 26.29 (a) Pivotal machine leveling mount from which the threaded spindle is completely concealed in a closed pipe that is in-welded in a sheet metal leg. (b) Stair riser legs, totally sealed, with sloped top and set off the riser. *(a) courtesy of Den Rustfri Stålindustris Kompetencecenter. (b) courtesy of Joe Stout.*

rubber used shall be of sufficient low Durometer to provide a tight continuous seal with the flooring material.

Castors

Castors are applicable in those places where equipment has to be made mobile in order to facilitate inspection and cleaning of equipment and process rooms. Transportable equipment (e.g. conveyors) also allows the layout of process lines to be changed so that products can be altered to suit demand (e.g. frozen vegetable industry). However, a castor assembly must not be used in the product zone. As an example, containers designed for elevated dumping shall not be equipped with attached castors if, when raised, the castors are over the product zone.

Castors should be made of a material that suits the floor quality, the expected loading and the frequency of movement. If underspecified castors are used, the body of their wheels can break up due to being overloaded. In general, the heavier the load, the larger the wheel required for the castor. Large wheels roll more easily, are generally more maneuverable and ride better over obstructions and floor cracks, tracks and ruts than smaller wheels. Large wheels also provide sufficient clearance between the lowest part of the equipment and the floor for easy cleaning and inspection.

Although cast iron wheels are virtually indestructible and are able to withstand the highest loads, their use in the food industry is not recommended (not acceptable), because they are prone to general corrosion and can damage floor surfaces. Castors manufactured from zinc-plated mild steel should be avoided, because the coating on the wheel may wear away, resulting in corrosion and increased friction between the wheels and the castor forks (horns). Paint shall not be used as a coating. Castors manufactured from zinc-plated mild

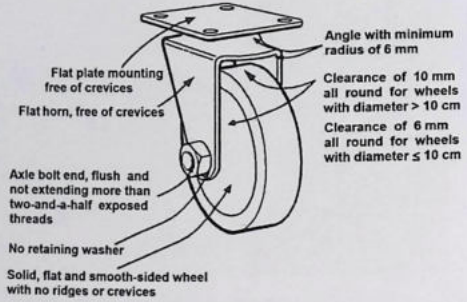


FIGURE 26.30 Hygiene design requirements that castors in the food industry must meet (APV Baker, 2001).

steel require the swivel bearing and wheel axle to remain lubricated to prevent them from corroding. Hence, lubrication of the swivel bearings and wheel/axle surfaces should be regularly and properly done, especially because lubricant can be washed away by regular cleaning. Castors (body, mounting plate, etc.) manufactured from stainless steel with stainless steel swivel bearings need no lubrication to prevent corrosion. Stainless steel axles in combination with an outer PTFE bushing provide self-lubrication of the wheel/axle surfaces. However, worn wheels and PTFE bushings still will need periodical replacement.

Thermosetting plastics, particularly phenolics, are widely used in the food industry because they can withstand high temperatures and carry high loads. However, they can become damaged by poor quality flooring and by defects in floors, such as concrete joints and ridges. Phenolic-wheeled castor types are often worn to a flatter profile or their tread can break up causing spalling. Thermoplastic wheels have better impact resistance than phenolic-wheeled castors, but they have poor resistance to higher temperatures. However, these wheels do not need bearings. Where possible, the wheel should have a color (e.g. blue). High temperature rubber-wheeled castors have a high temperature thermoplastic center with a bonded high temperature rubber tire. They will wear and may be damaged by poor or abrasive surfaces, acids, oils, chemicals and other substances that may be harmful to rubber. These soft tread wheels, however, may ride more easily over bumps, level changes, joints, drainage gullies, etc., and are less destructive to tiled, linoleum, etc. floors.

Swivel castors (Figure 26.30) only function well when they are securely mounted to a rigid frame so the swivel bearing kingpin axis remains vertical at all times. Rigid castors must be mounted (welded, sealed or readily removable) in a way that their axis and wheels are in alignment. All structural members (mounting plate and horn) shall have a minimum of horizontal flat surfaces. The plate mounting shall be constructed to have a flat top surface. The angle between the top surface and the edge of the plate shall be 90° or less.

Mounting holes and other devices provided for installation shall be so designed as to prevent the formation of pockets or areas difficult to clean. The horn assembly or fork shall be constructed so that the surface facing the wheel has no concave surface except that part joining the horn plate. Included angles between all surfaces should have a minimum radius of 6 mm. Kingpin assemblies, which have the nuts or rivets at the bottom, shall have suitable caps covering the ends. The minimum clearance between horn assembly and wheel for wheels having a diameter should be 6 mm all round, while the minimum clearance should be <10 cm all round for wheels with diameter >10 cm. Brakes and locking devices should comply with the hygienic requirements mentioned above.

Preference should be given to single-wheeled castors because dual-wheeled castors are more sensitive to contamination, and are more difficult to inspect and to clean. Castor wheels should be constructed so as to have no concave surfaces facing the horn assembly except that part which joins the hub. The included angles between all vertical and horizontal surfaces shall have a radius of not less than 6 mm. Wheels should have solid webs, smooth sided, without ridges or crevices, and their tread face should be smooth and flat. Rubber-wheeled castors should have a tire from which tread and shoulder are free of lugs, voids and indentations wherein foreign matter can penetrate. If bolted, axle bolt ends should be flush and should not extend more than two-and-a-half exposed threads beyond the retaining nut. Excess threads should be cut off and covered with a "dome"-type nut. The use on the axle of cotter pins or castellated nuts to keep the wheel attached to the horn assembly is not acceptable. Two PTFE washers (combination seals) can be fitted, one either side of the wheel, to prevent direct contact (e.g. metal-to-metal contact) between the wheel and the castor body. Although it is expected that the life of these washers should almost be as long as that of the wheel, the washers can become worn and must be replaced immediately. In general, washers (retaining washer under a nut) should not be used between the horn of the castor and the axle retaining nut, because there they are more exposed to impact from the outside.

Roller or ball bearings should be used. Roller bearings can carry heavier loads, while ball bearing wheels roll more easily but carry lighter loads. All bearing arrangements must ensure that no crevices or dead areas are present which could adversely affect cleanability and/or functional life. If no self-lubricating bearings (stainless steel with PTFE bushing) are used, they should be lubricated every 6 months. In corrosive environments, lubrication of bearings should occur once a month. In the food industry where the lubricant is washed away by daily cleaning, lubrication is sometimes required after each washing. Bearings in castors (wheels and swivel horns) should preferably be of the sealed type. These seals used to contain the lubricant oil or the grease in the bearings will wear, ultimately allowing leakage. Their integrity must be regularly checked and they should be replaced at defined maintenance intervals. If "open" ball-race bearings are used, they must be cleanable and, when required, capable of being disinfected and re-packed with food grade grease as necessary.

Belt Conveyor

Conveyor frames should have an open structure (Figure 26.31) with a minimum of hidden areas/surfaces. But guards are required in places where a drive station, a pulley, rollers or the conveyor belt may cause injury. The guards, however, should be easy to dismount to allow for complete cleaning. Solid cross-members as structural members are preferred over

FIGURE 26.31 Conveyor frames should have an open structure without horizontal surfaces and with a minimum of hidden areas/surfaces. At the outside, the framework consists of vertical plate members positioned longitudinally, which also serve as a lateral belt guide. The conveyor frame is an all welded construction with solid round cross-members, welded at the outside framework. The use of bolts and nuts for fastenings is reduced to a minimum. The cross-members not only act as structural frame members, but also as belt supports. The weld-on flat cross-members are provided with gaps to accommodate the freely located plastic wear strips that help to support the conveyor belt. No bolts, holes or nuts were used for fastening the ultra-high-molecular-weight (UHMW) polyethylene wear strips. To minimize cleaning time, these belt supports are easily lifted out of the frame by means of a quick tension-release arrangement and without manual tools. The cut-outs in the frame allow spraying and cleaning of the inside of the conveyor without lifting the belt. The conveyor shown is provided with a swivel-mounted roller that releases tension, providing improved access to the space between belt and bearing strips for cleaning and disinfection. The frame member closest to the point where the belt runs onto the drive roller sprocket also serves as a guard. Stand-off legs keep fasteners out of the food zone. *Courtesy of Dorner Conveyors.*

hollow section members, although completely sealed hollow section members are still more preferable over open profile angle or channel sections, to minimize horizontal ledges and crevices. Hollow sections should be sealed by welding.

Conveying surfaces shall be supported by a minimum amount of carrying surface or bed as required (Figure 26.32b). The use of solid plate that expands the whole top surface of the conveyor table to provide support to a belt is likely to increase contamination problems and cause excessive wear of the belt (Figure 26.32a). Non-removable bearing surfaces for belts cannot be cleaned easily. Rollers shall be used where practical, or line supports that are easily removable for cleaning. The conveyor belt should have minimal debris retention, and running under a turned-over section of side cladding (overhanging belt edges) is not allowed because the whole surface of the belt cannot be cleaned, and the belt cannot be lifted up to allow cleaning and inspection of internal surfaces and support members. Also, pivoted covers cannot be cleaned easily. The use of fixed hinges is not recommended because of the great difficulty of removing debris and microbial slime from between the hinge segments (Figure 26.32a). Side guides used to contain product should be capable of being removed. However, removable guides may cause problems because of the possibility of the fastening system working loose. The conveyor frame must be designed so that the sides of the belt are turned up to form an integral guide to the belt. Besides this guide cladding can be made removable allowing for effective cleaning (Figure 26.32b).

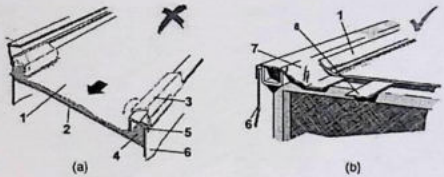


FIGURE 26.32 (a) The use of solid plate (2) expanded over the whole top area of the conveyor table to provide support to a belt (1) is likely to increase contamination problems and cause excessive wear of the belt. The non-removable bearing surface (2) for belts cannot be cleaned easily. The conveyor belt should have minimal debris retention, and hence running under the turned-over section of side cladding (overhanging belt edges) is not permitted as the whole surface of the belt cannot be cleaned (4), and the belt cannot be lifted up to allow cleaning and inspection of internal surface and support members. Side guides used to contain product should be capable of being removed. But removable guides also may cause problems because of the possibility of the fastening system working loose. Pivoted covers (3) cannot be cleaned easily, and the use of fixed hinges is not recommended because of the great difficulty of removing debris and microbial slime from between the hinge segments (5). (b) The conveyor frame (6) must be designed so that the sides of the belt are turned up to form an integral guide to the belt (7). Besides, this guide cladding can be made removable allowing for effective cleaning. The conveyor belt shall be supported by a minimum amount of carrying surface or bed (8) as required. Rods, slats, rollers or similar supports shall be used where practical (CFPRA, 1983; Hauser et al., 2004b).

The drive motor of the belt conveyor should not be positioned over the product flow, as this may result in contamination of the product by lubricants discharged from the drive system. Otherwise, an adequately sized drip tray should be fitted. However, motors should rather be located below the line of the product flow because the exposed motor may have a fan that will scatter dust and dustborne microbes. The motor, gears and the chain must be covered to avoid any contamination of food product (e.g. enclosed in a hygienically designed and hermetically sealed housing). However, a chain guard (essential from an occupational safety point of view), when open, may provide a place where product may accumulate, allowing microbes to multiply to large numbers and so posing a contamination risk for the food product on the belt (Figure 26.33).

Also notice that drive motors installed below food products are quickly splashed and difficult to keep clean. The motor is also often of a type that cannot be washed with a high pressure hose using water and cleaning agents. In that case, if installed below the line of the product flow, the gears and motors of belt drives must be covered. Alternatively, cleanable and sealed motors (wash down or easy clean motors), which do not require ventilation or housings, can be used. Where needed, the motor, gears and the chain should be enclosed in a hygienically designed enclosure or hermetically sealed housing (Figure 26.34a). IP55/54/67 motors can be easily cleaned and drained of water around the motor, if they are provided with enough air space for cleaning and disinfection, maintenance and repair. Where possible, use drum motors (motorized pulleys) (Figure 26.34b) that are fully closed, non-ventilated, conveyor belt drives where motor and gearwheels are inside, submerged in a bath of food

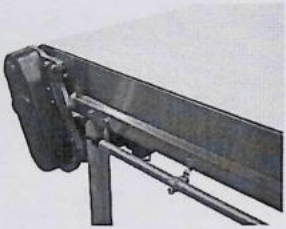


FIGURE 26.33 Motors should rather be located below the line of the product flow. Gears, chains and motors of belt drives must be covered to avoid any contamination of product. However, a chain guard (essential from an occupational safety point of view), when open, may provide a place where product may accumulate, allowing microbes to multiply to large numbers and so posing a contamination risk for the food product on the belt. *Courtesy of Dorner Conveyors.*

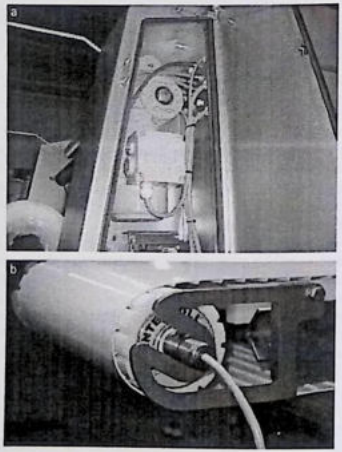


FIGURE 26.34 (a) Where possible, the motor, gears and the chain should be enclosed in a hygienically designed enclosure or hermetically sealed housing. (b) An even better solution is applying a direct-driven (drum motor) instead of a chain-driven system. *(a) Courtesy of Den Rustfri Stålindustris Kompetencecenter. (b) Courtesy of Interroll.*

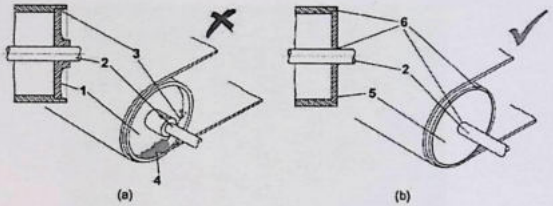


FIGURE 26.35 (a) Pressed-in roller ends (1) create dead areas and crevices (3), where residues of product and soil (4) may accumulate. (b) Flush roller ends (5) which are properly welded (6) to the roller and to the shaft (2) avoid any hazard and can be cleaned easily (CFPRA, 1983; Hauser et al., 2004b).

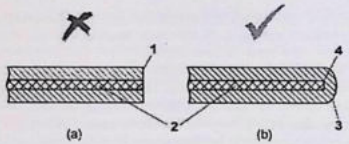


FIGURE 26.36 (a) Cut edges of belts (1) which incorporate reinforcing materials (2) are prone to penetration of liquids into the interior by wicking (capillary action). (b) Therefore, embedded reinforcements, as well as fabric backing materials (2) in conveyor belts, must be covered to avoid contact with the product. The edge should be suitably sealed and covered in a way that the covered edge (4) is shaped like a round rim (Lelieveld et al., 2003; Hauser et al., 2004b).

grade lubricant, providing at the same time lubrication and cooling. Drum motors make gears and chains redundant. (Den Rustfri Stålindustris Kompetencecenter, 2006a).

The design of rollers, pulleys and sprockets shall be free of end recesses and shall be closed if hollow. A welded construction should be preferred to a sealed design (Figure 26.35).

Embedded reinforcements, as well as fabric backing materials in conveyor belts, must be covered to avoid contact with the product. Cut edges of belts which incorporate reinforcing materials must be sealed to prevent penetration by wicking (capillary action) of liquids into the interior (Figure 26.36).

Covers and Guards

It is difficult to obtain motors, gearboxes, etc. that meet the recommendation of EN 1672-2. Protecting any of these items by means of covers or guards is recommended. These guards must also protect the food product from contact with drive parts such as lubricated chains, sprocket wheels, etc. The requirement of guarding machinery to ensure safety in operation

FIGURE 26.37 Example of a hygienically designed guard. *Courtesy of P.T. Group.*

may easily conflict with hygiene requirements unless considerable care is taken in its design, construction, installation and maintenance. However, the housings or guards should be removable to provide access for cleaning. From a hygienic and safety point of view, totally removable covers, guards or cladding should be avoided. They may not be put back, creating a hazard for the operators in the environment of the process equipment and exposing the food product to risk. Covers and guards also may become damaged during removal. Bars, perforated/punched sheet and weld mesh (Figure 26.37) stainless steel guards with an open area of 40–50% give good protection from moving equipment parts, and permit access for cleaning and disinfection by spray nozzles or hosing down procedures. For good drainability, covers should always have an angle and should be free of panel joints.

Where possible, hinged covers and guards that pivot outboard should be used. But use as few hinges as possible, with the least number of parts. In view of cleaning and disinfection, continuous and piano hinges are not allowed. Block or pin hinges are a possible option, but should have removable hinge pins or be the lift-off type. Finally, the exterior of enclosures is easier to clean if internal hinges are used.

Maintenance Enclosures

Maintenance enclosures (e.g. electric control panels, junction boxes, pneumatic/hydraulic enclosures) must be designed, constructed and maintainable to ensure that the product water or product liquid does not penetrate into, or accumulate in or on, the enclosure. The cabinet and operator panel are mounted where they will be least exposed to splashes. Electrical control cabinets mounted on the exterior of the equipment shall be watertight and sealed to the supporting member with food standard silicon seal, or spaced sufficiently away from the member to permit cleaning of all surfaces. A minimum of 20 mm between the control and supporting member shall be provided. Electrical enclosures can also be sealed to a wall (with food

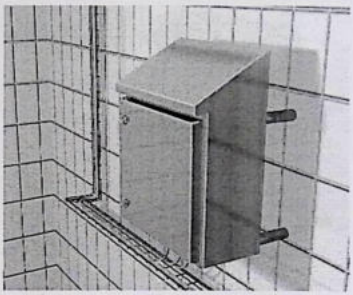


FIGURE 26.38 Electrical enclosures can also be sealed to a wall (with food standard silicon seal), or shall be spaced at least 30 mm away or at a distance equal to one-fifth of the shortest dimension of the electrical enclosure parallel to that wall, to prevent a soil trap being created at the rear of the enclosure and to allow for adequate access for cleaning. Suspending members should be constructed of a solid steel round tubing to prevent the formation of a flat horizontal surface whereupon dirt may collect. *Courtesy of Rittal.*

standard silicone seal), or spaced away at least 30 mm or at a distance equal to one-fifth of the shortest dimension of the electrical enclosure parallel to that wall. The distance between the cabinet base and the floor should be no less than 0.3 m. Horizontal surfaces should be minimized or avoided by installing a top roof with a minimum 30° inclination towards the front to allow water to run off and prevent tools being placed on the top. The front edge of the inclining cabinet top should reach beyond the front door and the seal (Figure 26.38). To prevent condensate dripping from the field box into the product, field boxes should not be placed in or above the contact area. Furthermore, field boxes should be located such that easy access for maintenance and cleaning is practicable. All connections (e.g. cable ladders or wire trays, trunking, conduit, cable, etc.) to cabinets or field boxes should be made via the bottom side of the cabinet. Connections of cables and wires to housings must be sealed (Moerman, 2011a).

The control and indicator devices must be constructed of durable and mechanically stable (unbreakable, resistant to steam, moisture and the actions of cleaning and sanitizing agents, abrasion and corrosion resistant) material. Commonly used food grade plastics for the construction of control devices and indicator lights are polyamide (PA), polycarbonate (PC), polyoxymethylene (POM), silicone and acrylonitrile butadiene styrene (ABS). Control devices and indicator lights in contact with food should be shaped so as to avoid the accumulation of dirt and bacteria, and to facilitate cleaning (Figure 26.39). The device heads must have smooth and crevice-free surfaces that are easy to clean. Device head to front panel transitions must be smooth, without corners and edges. Push buttons, when touched, should not penetrate deeply in the front panel far beyond a (protruding) frame edge surrounding the button. Connections must be conceived in such a way that protruding parts, strips and concealed corners are restricted to a minimum. The connections of inside

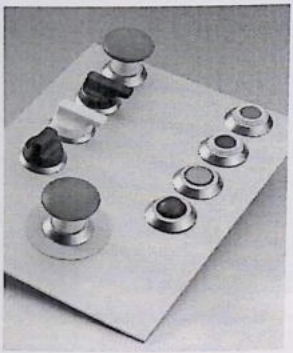


FIGURE 26.39 Control panel with hygienic control and indicator devices. Seals should fill the gaps between the fixed and moving device parts, to avoid the ingress of product residues, lubricants and organic materials. A perfect, hermetic seal is also required to prevent the ingress of moisture, dust and dirt within the control panel. Adequate space should be provided between control and indicator devices for easy cleaning. *Courtesy of Elan-Schmersal.*

surfaces must be made with curves of sufficient diameter. Seals should fill the gaps between the fixed and moving device parts, to avoid the ingress of product residues, lubricants and organic materials. A perfect, hermetic seal is also required to prevent the ingress of moisture, dust and dirt within the control panel. An IP67 or IP67K ingress protection rating for control panel enclosures is highly recommended. Control panels with control and indicator devices shoud be installed in vertical or declining position, such that fluids (splashed food and cleaning solutions) are able to flow from the control panel. Adequate space should be provided between control and indicator devices for easy cleaning. Further hygienic alternatives to control panels with push buttons and selection switches are membrane panels with a ≥2% inclination or touch screen displays.

HYGIENIC DESIGN CLOSED EQUIPMENT FOR PROCESSING OF LIQUID FOOD

Process and Utility Lines

Hygienic Design of Process and Utility Lines

To avoid the formation of standing "pools" of liquid that can support the growth of microorganisms, process and utility piping runs should be sloped to at least 3% in the direction of flow and should be properly supported to prevent sagging (Figures 26.40 and 26.41).

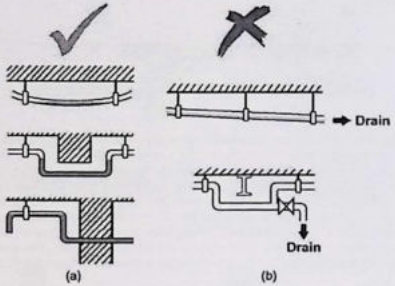


FIGURE 26.40 (a) Sagging of piping must be avoided because standing "pools" of liquid can support the growth of microorganisms. Changes in the level of horizontal runs of pipelines should be avoided otherwise there will be an undrainable section. Horizontal runs of pipe which are routed vertically up and then down to by-pass beams, doorways or other obstructions will allow air to collect in the raised section. (b) Process and utility piping runs should be sloped to at least 3% in the direction of flow. Piping must be installed in a way that air does not collect in the raised section. While automatic air release valves can be installed (on top of elevated horizontal pipe sections) to remove trapped air, the resulting dead leg may cause contamination and/or cleaning problems. Where liquid collects in a lower horizontal pipe section, fitting a valve in a shortened tee allows that liquid to be drained (CFCRA, 1997).

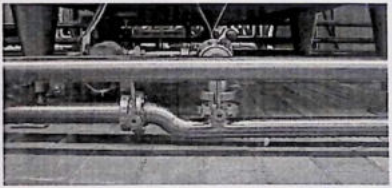


FIGURE 26.41 Non-drainable pipe (Hauser et al., 2007).

Blanked-off tees should be avoided where possible as they constitute a potential hazard. A dead space, being an area outside the product flow, where liquid or gas can become stagnant and where water is not exchanged during flushing, is formed. An air pocket may be present if the branch of a blanked-off tee is pointing vertically upwards (Figure 26.42a). Hence it will prevent liquids (cleaning solutions, disinfectant solutions or hot water) from reaching all surfaces to be treated, with the result that cleaning-in-place and decontamination processes will be unsatisfactory. Drain points pointing downwards that act as a dead

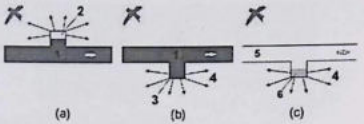


FIGURE 26.42 (a) When cleaning and disinfection solutions (1) flow through the piping, an air pocket (2) will be formed if the branch of a blanked-off tee is pointing vertically upwards. This will prevent the solutions from wetting the surface in the dead leg. (b) Drain points pointing downwards (3) again act as a dead leg, providing an area of entrapment which may not be reached by cleaning or sterilizing procedures, and hence they lead to contamination of the product. Moreover, during a hot water treatment, the hot water also will stagnate in the downwards pointing pocket, so that the temperature of the surfaces in the dead area may be lower than required as the consequence of heat loss (4). (c) A downwards pointing dead area also will collect condensate (6) due to heat loss (4) during steam sterilization (5), with the result that again the temperature of the surfaces in the dead area may be lower than required. Blanked-off tees should be positioned such that they are a few degrees above the horizontal (Lelieveld et al., 2003; Hauser et al., 2007).

leg (Figure 26.42b) are not acceptable because they provide an area of entrapment which may not be reached by cleaning or sterilizing procedures, and hence they lead to contamination of the product. During a hot water treatment, the hot water will also stagnate in the downwards pointing pocket, so that the temperature of the surfaces in the dead area may be lower than required as the consequence of heat loss. A downwards pointing dead area will also collect condensate during steam sterilization (Figure 26.42c), resulting again in the temperature of the surfaces in the dead area being lower than required.

The direction of the flow of food product has a significant influence on the residence time in the dead leg. When the food product flows in the direction as indicated in Figure 26.43a, b and c, part of the product will stand still in the dead leg, especially if the length or depth of the T-section is too long. If the length of the T-section is equivalent to the diameter of the main pipe, a flow velocity of 2 m/s in the main pipe already results in a reduced velocity of 0.3 m/s in the T-section. This decrease in flow velocity provides a relatively stable pocket or dead leg in which product residues can accumulate and microorganisms begin to multiply. Long T-sections outside of the main flow of cleaning solutions are also very difficult to clean. During cleaning there is much less transfer of thermal (heat), chemical (detergent and disinfectant chemicals) and mechanical energy (action of turbulent flow) to the food residues in the zones and T-sections which are further outside the main flow of cleaning liquids than to the soil in the main flow. Notice that flow away from the dead leg (Figure 26.43a and c) gives rise to more contamination problems and problematic cleaning, as velocities in these dead legs are even much lower.

A properly designed food processing line should not have unnecessary dead legs, and where they cannot be excluded, they should be in the correct position for the selected cleaning and decontamination process and should be as short as possible. For pipe diameters of 25 mm or larger, T-sections should have a depth/length preferably under 28 mm, while for smaller pipe diameters this length should be smaller than the diameter. Blanked-off tees should be positioned such that they are a few degrees above the horizontal. The dead leg will then be drainable but not necessarily cleanable even if made as short as possible. If a sensor must be installed in a process line, it should be installed in a bend on a shortened tee in a position so that the flow of cleaning fluid is directed into the tee (Figure 26.43e and f). Where

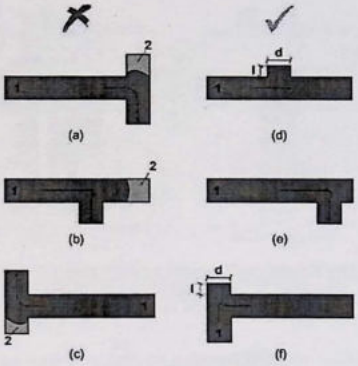


FIGURE 26.43 When the food product flows in the direction as indicated in (a), (b) and (c), part of the product will stand still in the dead leg, especially if the length or depth of the T-section is too long. Long T-sections outside of the main flow of cleaning solutions are also very difficult to clean. For most liquids, the dead leg should be positioned as shown in (d), (e) and (f). The configuration in (f) is quite acceptable if $l \leq d$, because the flow directed into the short dead leg provides sufficiently high velocities for proper cleaning. If the dead leg is very short ($l \leq d$), configuration (d) is acceptable, although flow across a dead leg results in much lower velocities within it and thus only provides moderate cleaning. Configuration (e) may not be suitable, if products contain any particulate matter that may accumulate in the dead leg (CFCRA, 1997; Lelieveld et al., 2003; Hauser et al., 2007).

an angle valve is installed in the process piping circuit, this valve must also be mounted in a shortened tee so that no or a minimum of annular space above the side branch is formed. Again the flow of cleaning solution must be directed into the tee.

For most liquids, the dead leg should be positioned as shown in Figure 26.43e, d and f. The configuration in Figure 26.43f is quite acceptable, because the flow directed into the short dead leg provides sufficiently high velocities for proper cleaning. If the dead leg is very short, configuration Figure 26.43d is acceptable, although flow across a dead leg results in much lower velocities within it and thus only provides moderate cleaning. The configuration in Figure 26.43e may not be suitable if products contain any particulate matter, which may accumulate in the dead leg. In all cases, the cleaning procedure must take the presence of the dead leg into account.

Flow diversion should not be done in a way that would cause part of the product to stand still in a dead leg. The two-valve system for flow diversion (Figure 26.44a) creates a dead leg towards the closed valve. The correct type of valve is shown in Figure 26.44b.

For horizontal piping, eccentric reducers should be used instead of concentric reducers, because the latter provides a dead spot where condensate and dirt may collect (Figure 26.45).

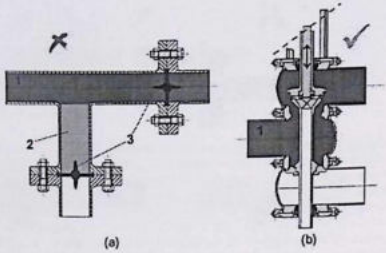


FIGURE 26.44 (a) Flow diversion should not cause part of the product (1) to stagnate in a dead area (2). The system of two butterfly valves (3) for flow diversion creates a dead area (2) towards the closed valve. (b) The correct type of valve is shown on the right (Lelieveld et al., 2003; Hauser et al., 2007).

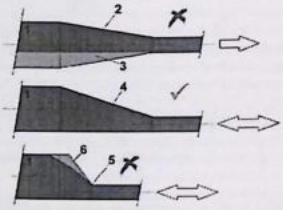


FIGURE 26.45 Changes in pipe diameter should be made by the use of reducers to ensure a smooth transition of the product flow. In vertical piping, a concentric reducer is fully acceptable for food product (1) to flow. However, this is not the case for horizontal piping, where the concentric reducer (2) prevents full drainage if product flow is in the wrong direction. A dead spot is created where condensate and dirt (3) may collect. For horizontal piping, eccentric reducers (4) are preferred. The reducers should be long enough (4) to avoid shadow zones. If a short eccentric reducer (5) is applied, a potential shadow zone (6) will be created (Lelieveld et al., 2003; Hauser et al., 2007).

Hygienic Integration of Process and Utility Piping in Food Factories

Welding of attachments on food processing support piping is not recommended. They can cause stress on the pipe and the part of the supporting anchoring structure. All hangers and supports have to be designed in such a way that they either move together with the pipe (roll or slide) or they can swing without exposing any stress either on the pipe or on the part of the supporting anchoring structure.

All process and utility piping should be grouped together in pipe trains whenever possible. All these process and utility piping should preferably be positioned in a way that all exterior surfaces are readily accessible, to allow cleaning from all sides. The points of

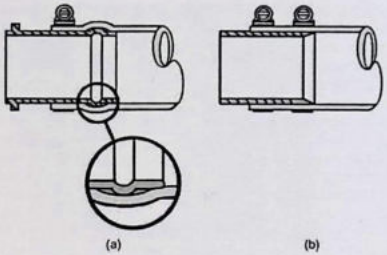


FIGURE 26.46 (a) Incorrect and correct installation of hoses on fixed pipes. (b) Hoses attached to stainless steel pipes should be clamped at the very end of the pipe to minimize the amount of dead space between the clamped portion and the end of the pipe. *Courtesy of Huub Lelieveld, personal communication.*

use should also be grouped in an attempt to minimize individual ceiling drops. Vertical entrance of piping into the equipment is more hygienic than horizontal piping runs. Running of process and utility piping over open equipment in food preparation areas is unacceptable, and nesting of ductwork should be avoided.

Hoses

The use of hoses is not recommended, because failure of hoses can occur due to overstretching, kinking, rough handling, mechanical impact, ageing, fatigue, abrasion, corrosive atmospheres, etc., and because the chance that leakage of liquid occurs is much higher than when fixed piping is used. Therefore, hoses need regular inspection for damage, deterioration and cleanliness. They should be cleaned and maintained in good mechanical condition. Braided (woven wire or fabric) covers on hoses should not be used.

Out of service hoses must be hanging without touching the floor, and must never hang over open process equipment. Hoses attached to stainless steel pipes should be clamped at the very end of the pipe to minimize the amount of dead space between the clamped portion and the end of the pipe (Figure 26.46). Hoses should not exceed 3 meters in length. When not in use, the ends of the hoses should be covered or capped to maintain proper hygienic conditions.

Pipe Joints

Welded Pipe Joints

It is strongly recommended that the number of joints, whether welded or detachable, is minimized. Cold bending of pipes is highly preferable to the use of prefabricated bends which have to be installed using joints. Although more hygienic, this is still true for welded joints as they are the weaker places in a process system.

Welding is the preferred method of joining, provided that it is done correctly. Stainless steel sanitary tubing joints should be made by automatic orbital welding (Figure 26.47) where possible

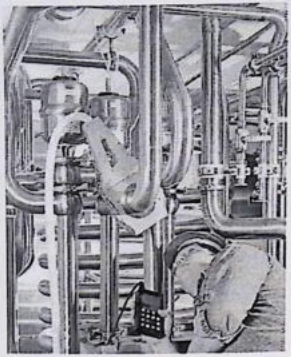


FIGURE 26.47 Stainless steel sanitary tubing joints should be made by automatical orbital welding where possible (Kupitz[illegible] et al., 2006).

and hand welding in those places that are difficult to access. However, those welds that are difficult to access should wherever possible be completed in the workshop prior to installation in the plant. The applied materials should be easily weldable, and a higher alloyed filler metal in comparison to the welded material should be used to improve the corrosion resistance. Piping with the correct interior diameters should be applied because any mismatch in diameters or thickness may result in misalignment introducing a step in the wall or bore. If the diameters of the pipes to be joined are not the same, then the smaller pipe should be expanded to match the larger. Misalignment can also be due to incorrect fitting up (missed coincidence between the axes of the two coupled components) prior to welding. Alignment and clamping tools are available to ensure accurate alignment. Misalignment tolerance must be limited to less than 20% of the wall thickness.

For proper welding, the parts to be welded should be adequately prepared. Cutting should be done with a mechanical mill or saw to ensure that the cut face is exactly at right angles to the longitudinal axis of the pipe. Any burrs must be removed with either a file or emery paper. Care must be taken not to remove the corner edges of the pipe, as this can give rise to problems with fusion of the root of the weld. The pipe surface 25 mm either side of the weld should be roughened up with a stainless steel wire brush, or emery paper. Then both pipe ends and roughened surface area should be degreased with a solvent and cleaned of contaminants. Any organic substances remaining on the metal surface are vaporized during the welding process and form bubbles (porosity) in the weld metal that may trap product.

After two deburred pipe ends are aligned and butted together to a gap of less than 0.25 mm between both pipe faces, a butt weld joint is made by fusing together the two stainless steel edges with the aid of filler material. If the gap during the joint preparation is too wide, a crack running along the weld metal itself may result (centerline cracking). Full penetration welds

should be used whenever possible to avoid pockets where volumes of gas or contaminants can be trapped. Single pass welds should be utilized instead of multi-pass welds to avoid trapped volumes. The weld metal should exactly fill the joint and remain flush with the surface. Underpenetration leaves a crevice at the joint, while excessive overpenetration can give rise to hold-up of product in pipework once taken into service. The weld metal in the joint must be fully fused to the parent, otherwise a crevice will form at the interface between weld and plate. Weld zones should be continuous, smooth and flush with the parent metal. Welding should always occur with sufficient weld seam protection, because insufficient inert gas shielding or no internal purge will result in roughened welds of lower corrosion resistance that are prone to increased adhesion of soiling and difficult to clean. Typically, where inert gas shielding was inadequate, significant discoloration or carbonization in the heat-affected zone is observed.

Weld slag and debris generated within the pipe must be removed from the inside and outside of the weld by proper maintenance and cleaning practice with an alkaline detergent solution prior to the start of the production process. This is followed by rinsing with water of good microbiological quality, usually chlorinated water to 2 ppm available chlorine maximum. After draining, the access points should be covered and sealed. In some circumstances there is an additional requirement to passivate the weld area on the product contact side. The welds may be mechanically polished (outside) or electro-polished (inside and outside), but air leakage should be monitored after the polishing procedure.

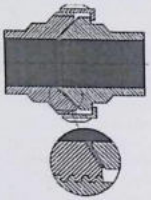
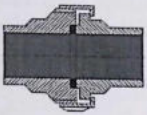
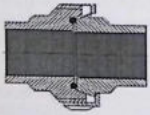
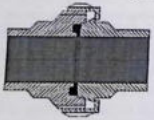
Finally, weld seams should be visually inspected for any discoloration and surface-breaking defects, usually by endoscopy and aided by dye penetrant tests that highlight these defects. Inspection personnel should be trained and act with caution to avoid internal surface damages while handling endoscopic tools (Hauser et al., 1993; Kopitzke et al., 2006).

Detachable Pipe Joints

Pipework may be designed for rapid regular dismantling to permit cleaning, or the plant may be designed for cleaning-in-place (CIP) or sterilizing-in-place (SIP) without dismantling the plant. In such equipment it is important to avoid crevices and gaps where product residues can accumulate and potentially begin to decompose. Therefore, from a hygiene point of view, the use of threaded piping is not recommended, because it provides crevices and areas where bacteria can adhere and proliferate. To make detachable joints the use of conventional O-ring grooves is not recommended, because these groove designs leave a considerable free space in the groove. Other hygienic requirements for detachable joints include coaxial alignment of the two mating bores, axial stop for controlled compression of the seal, room for thermal expansion of the seal and avoidance of sharp edges such that seals are not damaged. Where there are depressions and steps of more than 0.2 mm in the pipework, the flow of cleaning fluid may not thoroughly wash the surface and proper draining of the piping will be hampered. Hence, when making bolted flange fittings, a lot of care should be taken to avoid offsets, gaps, penetrations and voids. A further aspect to be considered is that the seal material must be compatible with both the system product and the cleaning fluids which may be at a much higher temperature.

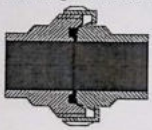
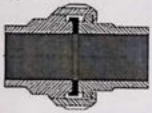
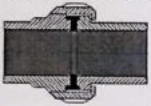
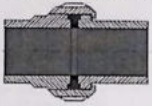
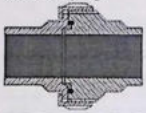
A number of specific pipe couplings and seal arrangements have been developed for hygienic applications. Some types are covered by national, international or internal company standards, but many of these have been in use for some considerable time and are not considered to be compatible with current requirements in some areas of the food and drink industry (Table 26.2).

TABLE 26.2 Several Well-Established Couplings have been Assessed for Applications in the Food Industry (CFCRA, 1997; Lelieveld et al., 2003; Hauser, 2008b)

Type	Hygiene Characteristics	Application
3-A coupling – ground seat 	When these surfaces become permanently damaged, it becomes more difficult to obtain a tight seal after every disconnection. The metal-to-metal seat does not prevent the partial penetration of low viscosity liquids or the ingress of microorganisms. Even if the joints are not visibly leaking, the ingress of microorganisms is possible. Furthermore, the seal obtained is very unlikely to be continuous at the interface with the product. More likely, the actual seal follows an irregular line between the inside and outside. The resulting annular crevice will trap product.	Not recommended for use in hygienic plant pipelines and CIP installations, because the internal annular crevice may retain product during production and/or after cleaning in-place. It is widely used in situations where a gasket is unacceptable.
3-A coupling – gasket seat 	When correctly fitted and assembled a smooth, crevice-free internal surface is obtained.	Suitable for handling most products and for cleaning in-place.
Dairy coupling DIN 11851 – standard gasket 	There is an internal annular crevice between the ends of the coupling parts and the bore of the gasket. Product may be retained during production and/or after CIP. An additional potential problem with the design of this fitting is that it has a clearance on the cone fitting; as a consequence the two pipes are not automatically aligned. This could give rise to a potential step in the pipe joint. Does not comply with 3-A or EHEDG sanitary design criteria.	Often found in the food industry (pipes and tanks) due to the fact that it is reasonably priced. Not considered as suitable for CIP, which means that the fitting should only be used where the pipework is manually cleaned.
Dairy coupling DIN 11851 – non-standard collared gasket 	It provides a smooth crevice-free internal surface when correctly fitted and assembled. However, because of the mobility of this type of coupling and of the alternating expansion and contraction of the gasket, this gasket may be damaged by shear. Does not comply with 3-A or EHEDG sanitary design criteria.	Not recommended for use in hygienic plant process lines and CIP installations. Expensive and does not fulfill standard hygienic design criteria.

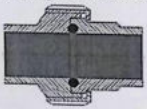
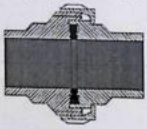
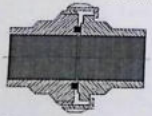
(*Continued*)

TABLE 26.2 (Continued)

Type	Hygiene Characteristics	Application
Dairy coupling DIN 11851 – alternative gasket with SKS ring 	With support of the steel ring the gasket remains flush with the surface. The special designed gasket fills all dead areas in the coupling and will expand to the outside in cases of high temperature. At elevated temperatures, expansion of the seal to the inside is limited. This solution takes all critical points of a DIN 11851 coupling away. Complies with 3-A or EHEDG sanitary design criteria.	Stainless steel center ring and a gasket is an easy solution to upgrade a DIN 11851 coupling to a hygienic status. As a smooth surface gives excellent cleanability.
IDF coupling ISO 2853 with L-gasket 	When the coupling is correctly fitted and assembled, a smooth continuous bore and internal surface without crevice is obtained, so that cleaning may be performed without any problems.	This coupling is recommended for applications where CIP is normally practiced. Widely used for pasteurized circuits where dismantling is infrequent.
IDF coupling ISO 2853 with non-standard T-shaped gasket 	When properly made up, the joint is crevice free and has a smooth bore, flush with the pipe walls. If overtightened, the gasket may expand into the bore of the pipe, which creates a step where product can become trapped. Unless the nut is tightened correctly, the coupling will not be bacteria tight.	Most suitable for permanent or semi-permanent installations that are going to be cleaned in-place. If the seal material is suitable, then it can be sterilized.
IDF coupling ISO 2853 with metal-backed T-shaped gasket 	By supporting the seal with a stainless steel ring, both axial stop and centering can be achieved, allowing the connection to meet the requirements of hygienic design. The rubber is specifically shaped to give a flush interior joint when the union is tightened.	Most suitable for permanent or semi-permanent installations that are going to be cleaned in-place. If the seal material is suitable, then it can be sterilized.
Recessed ring joint type (RJT) screwed coupling 	There is an internal annular crevice between the liner and the male part and the bore of the joint ring. Hence, product may be trapped and retained between the two metal components during production and could cause problems if certain products are handled. Does not comply with 3-A or EHEDG sanitary design criteria.	This type of coupling is recommended for use where piping systems are frequently dismantled, but is not suitable for CIP.

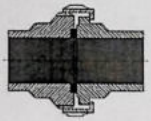
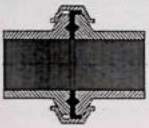
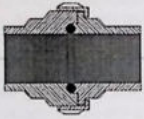
(Continued)

TABLE 26.2 (Continued)

Type	Hygiene Characteristics	Application
		It is used in the brewing and dairy industry in applications where pipework is manually cleaned. Excellent for flow plates, owing to wide dimensional tolerance on mating bends.
Coupling DIN 11864 form A 	A smooth interface within the pipe work while simultaneously achieving a metal-to-metal seat behind the joint. A sufficient gap is created between the seal and the product space to facilitate rinsing in cleaning processes. This gap also serves as an expansion space that can accommodate volume expansions in the material as a result of heat or the influence of media without forces that can result in shearing. The groove is designed to minimize protrusion of the O-ring into the pipe bore. Complies with EHEDG and 3-A design criteria.	Optimal for aseptic operations because they are successfully tested for CIP-ability, steam sterilizability and bacteria tightness.
Coupling DIN 11864 form B 	The volume of the functional part of the gasket (diamond section) is minimal to limit the effects of thermal expansion. A small area of the gasket is exposed to the product. The width of the gasket is only 1 mm. The block of elastomer behind the seal will accommodate the thermal expansion, relieve stress build-up on the sealing faces and limit expansion into the product stream to a minimum. The small functional part of the gasket can expand in two directions. To prevent air from being trapped between the gasket shoulder and the male part groove small slits are provided on the outside, acting as vents.	Optimal for aseptic operations because they are successfully tested for CIP-ability, steam sterilizability and bacteria tightness.
Standard SMS 1145 coupling  (DS coupling is similar to this coupling)	Standard SMS couplings are not hygienic because an internal annular crevice is formed in which product may be retained during production and/or after cleaning-in-place. The bore of the gasket may retain product. L-profile gasket is available but does not provide self-centering. A later version when correctly fitted and assembled provides a smooth crevice-free internal surface. Does not comply with 3-A or EHEDG sanitary design criteria	Only the latter version is suitable for handling viscous products and for in-place cleaning.

(*Continued*)

TABLE 26.2 (Continued)

Type	Hygiene Characteristics	Application
SMS 1145 coupling – alternative gasket 	When correctly fitted and assembled gives a smooth crevice-free internal surface.	Suitable for handling viscous products and for in-place cleaning.
Clamp coupling ISO 2852 	The seal is considered to form a smooth crevice-free joint between the liners, which makes clamp-type couplings suitable for CIP duties. Some users have indicated a preference for clamp fittings rather than screw-type couplings because in the event of a spill, screw threads cannot be decontaminated effectively. Clamp-type couplings are perceived to have the advantage that in the event of a product spillage at the fitting there is no thread to become filled with product that may be difficult to clean.	Often found in the food and pharmaceutical industry (pipes and tanks). Not considered as suitable for CIP.
Varivent® flange coupling 	Varivent® flange coupling ensures a smooth transition, free of dead space. It complies with EHEDG and 3-A design criteria.	Successfully tested for CIP-ability. Suitable for aseptic processes.
Neumo Bioconnect® 	The seal is almost completely encapsulated. The highest press-on power is found at the transitions to wetted areas, preventing dirt and germs from penetrating into the sealing space behind the sealing element. Dead volume is minimized. Complies with EHEDG and 3-A design criteria. Successfully tested for CIP-ability.	Optimal for aseptic operations because it has been successfully tested for CIP-ability, steam sterilizability and bacteria tightness.

Hygienic Design of Pumps

Hygienic Design of Centrifugal Pumps

While it is often convenient for the arrangement of pipework to orientate the casing of a centrifugal pump so that the outlet port is pointing vertically up, this will result in the pump casing retaining liquid up to the level of the inlet port. The pump casing is drainable through the outlet port if the pump's outlet is arranged to point horizontally at the

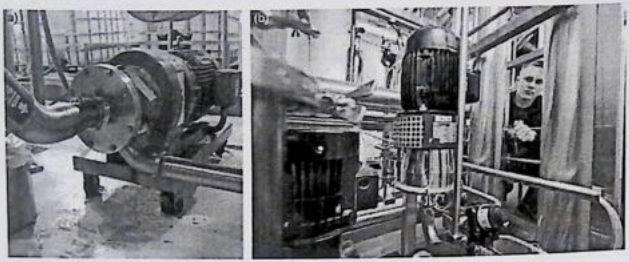


FIGURE 26.48 (a) The pump casing is drainable through the outlet port if the pump's outlet is arranged to point horizontally at the bottom. (b) Now the centrifugal pump is installed in a vertical position, and hence fully drainable through its suction port. *(a) Courtesy of Patrick Wouter, Unilever. (b) Courtesy of Hilge.*

bottom (Figure 26.48a), or the pump casing can be made drainable through its suction port if installed in vertical execution (Figure 26.48b).

Hygienic Design of Rotary Lobe Pumps

Rotary lobe pumps having unhygienic design features can only be cleaned effectively after dismantling. To avoid any introduction of contaminants into food product and to allow for CIP without dismantling, rotary lobe pumps should be hygienically designed. Metal-to-metal joints should be eliminated by hygienic application of O-rings; O-ring groove design should be improved and O-rings should be positioned more appropriately, or alternatively gaskets having controlled compression should be used; sharp corners must be rounded to a minimum radius of 3 mm; the length of the annular space within the mechanical seals should be reduced by changing the design of these mechanical seals (e.g. the elements of the mechanical seal should be reversed and the radial distance increased); any exposed threads (e.g. threads of the rotor shafts, Figure 26.49a) should be covered by crevice-free domed retainer nuts; or even better, the rotors and shafts should be designed as an integral construction so that rotor retaining nuts and associated metal-to-metal joints can be eliminated, so that the inside of the front cover can be made completely flat and free of space holes for rotor retainers.

Some types of rotary lobe pumps are traditionally positioned in such a way that draining is impossible without dismantling but the same type of pumps can also be designed for installation in a drainable position. As an example, the inlet and outlet ports of rotary lobe pumps have been arranged traditionally in the horizontal position as this has again been convenient for connecting the pipework. This results in the retention of liquid in the casing up to the level of the inlet and outlet ports. Nowadays there are well-designed hygienic rotary lobe pumps available with the ports arranged in the vertical plane (Figures 26.49b and 26.50) so that it is possible to drain the casing.

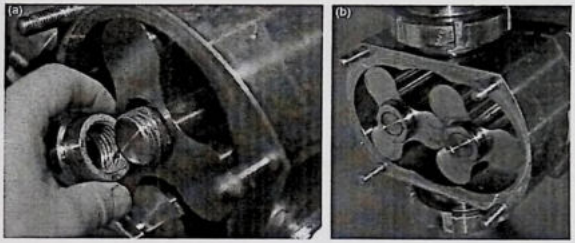


FIGURE 26.49 (a) Ingress and retention of product and/or microorganisms in the threads of the rotor retaining nuts should be avoided by making use of crevice-free domed retainer nuts and by application of O-rings. (b) In an improved version, the rotors and shaft should be designed as an integral construction. With the ports arranged in the vertical plane, it is possible to drain the lobe pump casing. *Courtesy of Burggraaf & Partners, www.burggraaf.cc.*

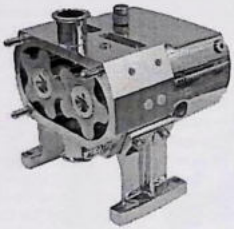


FIGURE 26.50 Nowadays there are hygienically designed rotary lobe pumps available with the ports arranged in the vertical plane. *SPX Flow Technology – brand Johnson Pump.*

Sensors and Instrumentation

Incorrect mounting of sensors in process lines will result in large dead areas which are unacceptable (Figure 26.51). Instrument branches, which could become a dead leg when not properly installed, should be installed vertically upwards to keep condensates, debris, suspended solid particles, flakes, etc. from collecting in the sensor or from falling into the sensor and the measurement system. However, the length of the dead area must be as short as possible and its cleanability must be demonstrated. For all pipe diameters the length of the upstand should be smaller than its diameter ($l \leq d$).

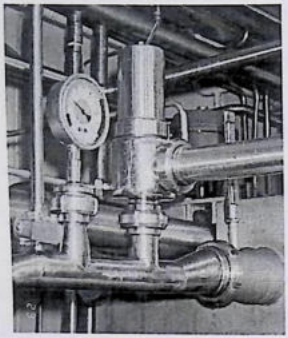


FIGURE 26.51 The pressure gauge is mounted on too long a tee branch such that an unacceptably large dead area is created. *Courtesy of Huub Lelieveld, personal communication.*

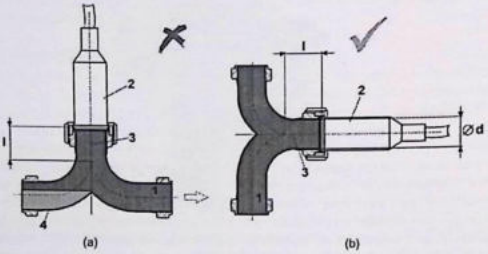


FIGURE 26.52 Incorrect mounting of sensors (2) in process lines (1) may give rise to tees with closed ends (3) that if too long will result in large dead areas. (a) But a swept tee if mounted in a horizontal pipeline may impede drainage (4). (b) Swept tees should be mounted in a vertical pipeline. Dimension l must be as short as possible relative to dimension d, maximum $l = d$ (Lelieveld et al., 2003; Hauser et al., 2007).

It is possible to avoid such dead areas by mounting, e.g., the pressure transmitter on a swept tee (Figure 26.52). However, swept tees must be used with caution, as a swept tee in a horizontal pipeline could hamper draining. Swept tees should be mounted in a vertical pipeline. Dimension l must be as short as possible relative to dimension d, maximum $l = d$. Alternatively, pressure transmitters with tubular membranes, with the same inner diameter as the adjacent pipelines, can be installed in standard spherical valve bodies welded into the

FIGURE 26.53 The pressure transmitter with tubular membranes, having the same inner diameter as the adjacent pipeline, can be integrated into the process, installed by means of a clamp fitting in a standard spherical valve body welded into the piping. The stainless steel diaphragm is sealed by O-rings fitted into grooves such that there is no metal-to-metal joint on the product side. This way of mounting a pressure transmitter provides a dead space-free, flush transition from the process line to the pressure transmitter. *Courtesy of WIKA.*

piping by means of clamp fittings. The stainless steel diaphragms are sealed by O-rings fitted into grooves such that there is no metal-to-metal joint on the product side (Figure 26.53). This way of mounting of pressure transmitters provides a dead space-free, flush transition from the process line to the pressure transmitters.

Temperature measurement is usually based on electronic detection of a change in resistance. The actual temperature sensor elements used integrate either platinum thin film resistors (Pt100, etc.), or employ other sensing elements with a varying electrical resistance against temperature (NTC or PTC resistors). Also semiconductor devices are common. The temperature sensor element itself is covered by a protective sleeve, a highly polished, closed tube typically made of stainless steel. Only one surface of the thermowell has fluid contact, the sensor being installed inside. For these temperature sensors, a close thermal and mechanical contact to the liquid to be measured is needed. Therefore, often a paste with high thermal conductivity is used inside thermowells.

Temperature sensors should not be mounted on too long a tee branch because an unacceptable large dead area is then created. Thermowells with flanged process connection (Figure 26.54) can be integrated into the process, installed by means of clamp fittings in standard spherical valve bodies welded into the piping. The sheath of the probe is welded into one of two blanks which are sealed to the spherical valve body by O-rings fitted into grooves such that there is no metal-to-metal joint on the product side. This way of mounting of a temperature sensor provides a dead space-free, flush transition from the process line to the blank containing the thermowell.

A surface probe with the inner diameter of its pipe the same as that of the adjacent piping is, from a hygiene point of view, an excellent choice. However, the thermowell can also be directly fitted via an orbital welded pocket (Figure 26.55). Attention should be given to the quality of the weld, which must be smooth and continuous. Furthermore, to avoid shadow areas, the direction of the flow must be as indicated.

For temperature measurement in tanks and larger vessels, the thermowells can be continuously welded to the tanks with welding balls or welding collars, after which the inner

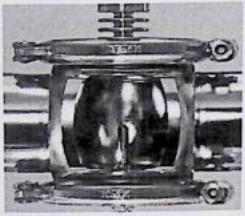


FIGURE 26.54 This thermowell, having the same inner diameter as the adjacent pipeline, is integrated into the process, installed by means of a clamp fitting in a standard spherical valve body welded into the piping. The sheath of the probe is welded into one of the two blanks which are sealed to the spherical valve body by O-rings fitted into grooves such that there is no metal-to-metal joint on the product side. This way of mounting a temperature sensor provides a dead space-free, flush transition from the process line to the blank containing the thermowell. *Courtesy of WIKA.*

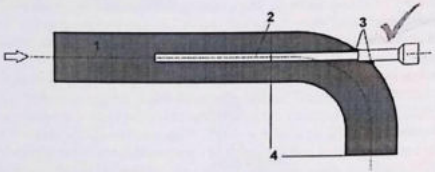


FIGURE 26.55 To avoid dead areas, the pocket for the temperature probe (2) may be welded in the product flow (1) through the pipeline. Attention should be given to the quality of the weld (3), which must be smooth and continuous. Welding of the temperature probe into the bend may be done off-line, after which the bend can be built permanently (by welding) or with dismountable joints into the piping system. In the latter case, the bend section is detachable (4) (Lelieveld et al., 2003; Hauser et al., 2007).

welding seam is polished and passivated after welding. Sensors also can be installed via a hygienic process connection sandwiched (detachable seal joints such as O-rings) into the pipeline (Figure 26.56). The dimensions of the O-ring and the design of the groove to be used for mounting sensors are critical to achieving controlled compression of the seal. The O-ring needs periodic maintenance with an inspection of the O-ring upon dismantling. Used O-rings should not be reinstalled.

Valves are used to change the direction of the flow of product or cleaning solutions (selection of the product routing) to regulate the flow and pressure to protect a process system against overpressure. The cleanability of a valve is largely determined by its internal geometry, the way in which the inlet and outlet connections are made, and the seal between the fluid and the external environment. The seals may be under a static load or dynamic with linear or rotary motion. Valves must have the following properties:

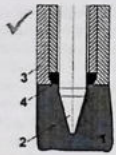


FIGURE 26.56 In the product area (1), a sensor (2) can be installed via a weld-in adapter (3) and a hygienic process connection sandwich into the pipeline. The detachable seal joint (e.g. O-ring, 4) is almost completely enclosed with the surrounding metal protecting the non-product side from the product contact area (Lelieveld et al., 2003; Hauser et al., 2007).

- Be fully drainable, without the need to dismantle;
- Be resistant to wear and easy to maintain;
- Have the minimum number of seals, positively retained and flush with adjacent surfaces;
- Dynamic seals on valve shafts in contact with product must provide an absolute barrier between the product and the environment to prevent microbial recontamination;
- Where unavoidable, springs in contact with product should have minimum surface contact area;
- Allow rapid visual detection of internal leakage.

The following are hygienic requirements for different types of valves (CFCRA, 1997; Schonrock, 2005):

- Diaphragm valves used as back pressure valves need visual detection of leakage (usually there are leakage holes in the valve bonnet), because damage to the diaphragm can result in product leaking through into the non-product side. Such an event may give rise to contamination, and cleaning and disinfection will become nearly impossible. To avoid premature rupture, they should be replaced at regular intervals depending upon the operating conditions. Diaphragm valves must be installed for full drainability.
- Butterfly valves comprise a disc and a rubber seal clamped between the halves of the body providing both a seat for the disc to close on and a seal for the disc spindles. If properly designed, they are hygienic low-cost valves, with the properties of low resistance to flow and their appropriateness to be automated and cleaned in-place. Butterfly valves with a streamlined disk free of external ribs are hygienic. However, product containing fibrous material may build up on the leading edge of the disc, and butterfly valves are suitable as long as the seals are not worn. Seals can wear and break down after a period of time due to the frequent opening and closing of the butterfly valve. Product can also migrate along the shafts due to product pressures in the system. Therefore, butterfly valves should preferably be disassembled for manual cleaning. If butterfly valves are in use, appropriate cleaning and maintenance schedules must be implemented.
- Traditional ball valves are considered unsuitable for process installations that are cleaned in-place. Due to the presence of crevices in their internal construction, the area between

ball, housing and seal face is uncleanable. Food product is transferred in the annular dead space when the valve is operated from its open to its closed position. When the ball valve is then rotated back from its closed to its open position to allow CIP, the food product trapped in the annular space between the sphere and the housing will not be removed by cleaning-in-place. Moreover, ball valves may retain condensate in their internal cavities. Often the design incorporates cavity fillers or encapsulating seals to prevent product flow around the exterior of the ball but product may still find its way under the seat surface and become an area for bacterial growth. Ball valves in existing installations must be disassembled completely for manual cleaning. However, the design and construction of a ball valve are such that it is not easily dismantled for cleaning. Certain ball valves with improved design allow for cleaning-in-place, especially in a half open position. For some applications, connections have been made to the housing so that the annular space may be continuously purged with steam throughout production.

- Plug valves are unsuitable for CIP, because product is carried around the clearance between the plug and the body during the rotation of the plug. Three-way plug cock valves allow 90° changes in flow direction of both food product and cleaning solutions. They have the disadvantage that they neither can be automated or cleaned in-place. However, plug valves can be easily manually cleaned after dismantling, which – due to their simple design – can be done very easily.
- Pressure relief valves are valves where the valve head is lifted off its seat when the product pressure exceeds that at which the valve has been set. Product then may be discharged to drain through the discharge port. To flush the inside of the valve body and the discharge port during cleaning-in-place, the valve must be opened by moving the lever through 90°. The valve body must be installed in a position so that it is fully drainable to the outlet side, and should be mounted on a short tee to avoid a large dead leg in which product will be retained throughout the production.
- Check valves with springs, hinges and flappers should be avoided as they quickly become contaminated and could give rise to cleaning problems. When spring-loaded check valves are used, the coil springs having product contact surfaces shall have at least 2 mm openings between coils, including the ends when the spring is in a free position. Spring-loaded check valves must be fully disassembled for manual cleaning. The use of ball-type check valves is the preferred practice. Springless floating ball check valves have a streamlined internal design which may reduce the potential for material to clog or hang up. Check valves must be installed in a position that allows full drainage of the check valve.
- Tank outlet valves should be installed as close as possible to the product vessel to reduce the dead leg formed by the stub pipe that connects the bottom valve with the vessel. They may be manually or mechanically operated and cleaned depending upon their design features.
- Mixproof valves are an essential part of automated processing, not only separating two different products but also preventing product contamination from cleaning fluids during mechanical cleaning. The valve uses double seats that can be operated independently, separated by a self-draining opening to the atmosphere between the valve seats. The vent space must also be cleanable and avoid a pressure build-up in case of a leak from a seal. The outlet from the vent line must be visible so leakage can be easily detected. A steam or sterile barrier may also be applied in the atmospheric opening (vent) to prevent ingress of microorganisms.

- Linear plug and stem valves may incorporate a lip seal to limit microbial contamination via the reciprocating shaft. This seal is easily cleanable but will not prevent the ingress of microorganisms. A hole is required to detect product leakage when the lip seal wear becomes excessive. Arrangements incorporating an O-ring seal are less hygienic because product can enter the clearance around the stem and become trapped in the O-ring groove from which it cannot be removed by cleaning in-place. For aseptic processing applications where ingress of microorganisms must be prevented, the shaft may be sealed by means of a diaphragm and bellows. In the case of the diaphragm type, the diaphragm must be replaced at regular intervals and a leakage hole must be provided that indicates failure of the diaphragm. With respect to the bellows sealed linear plug and stem valve, the bellows will rupture after a period of service and needs to be replaced at regular intervals. Moreover, if the product contains particulates, there may be a cleaning problem because particulate material may become trapped in the convolutions of the bellows. A steam barrier between the atmospheric and product sides of the valve stem is another method of preventing ingress of microorganisms.

INSTALLATION OF THE FOOD PROCESSING EQUIPMENT IN THE FOOD FACTORY

Clearance with Respect to the Floor, Walls and Adjacent Equipment

There should be enough clearance under the machine to allow for adequate cleaning and inspection to be carried out effectively. With that purpose, the process equipment should be installed as high off the ground as possible. The minimum height should be a function of the depth of the bottom surface above the floor (indicative: 150–300 mm). For large sized equipment, greater distances apply (at least 0.5 m from walls), as it is necessary to be able to walk around such equipment with at least enough room to facilitate cleaning. If the equipment is sealed against the mounting surface, care must be taken to avoid gaps, cracks or crevices where insects or microorganisms can remain/survive after cleaning.

Installation of large equipment (e.g. freezing equipment, meat curing chambers, etc.) on feet is technically not always possible. An alternative is sealing the equipment onto the factory floor. Proper sealing of the perimeter between the equipment and the subfloor must prevent water from accidentally getting into this space. But sealing, especially with silicone, has not always proven to be successful in excluding wet and unhygienic conditions.

Equipment must not be mounted beneath tanks or vessels so that maintenance and cleaning are impeded but must be easily accessible. Increased elevation of tanks and vessels facilitates cleaning and maintenance operations beneath them but water and condensation running down their sides may allow microbial growth and certainly must not fall onto exposed product.

Raised Walkways and Stairs

Raised walkways or stairs (Figure 26.57) over exposed product should be avoided because dirt may be transferred from clothing or footwear onto product lines beneath. The use of

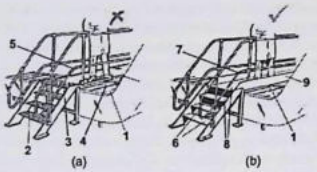


FIGURE 26.57 (a) If not appropriately designed, walkways and stairs over open product (1) may contaminate it. Open-mesh steps (2) that are not enclosed by vertical risers (3), the absence of a cover over the product area (4) and the handrail and its mountings hanging (5) over product area put the open food product at risk. (b) Now, the steps are enclosed (6), the handrail is mounted inside the walkway (7), solid anti-slip steps and floor plates are used (8), and fully welded, continuous kick plates are in place to prevent the open product from getting contaminated (Hauser, 2004b).

covers and hygienically designed walkways should be both considered. The decking of platforms and steps (crossovers on conveyor systems) should be constructed from solid plates containing a raised anti-slip material as deck. The steps can be given a small inclination for improved drainability. Mesh must be avoided to prevent soil from being transferred into the product. Further, fully welded continuous kick plates should be in place, designed as a one-piece construction. Platforms and stairs should have generous radii in the corners of kick plates, etc., to allow cleaning and disinfection. Handrails should not overhang the walkway and must be attached to the inside of the walkway. Risers of staircases must be enclosed and the steps should be constructed of the same anti-slip material as the deck.

HYGIENE PRACTICES DURING MAINTENANCE OPERATIONS IN THE FOOD INDUSTRY

Maintenance and Repair, a Necessary Evil

Physical equipment in any field or in any plant or industry is susceptible to failure through breakdown, deterioration in performance owing to wear and tear over time and to obsolescence due to improvement in technologies. Therefore, machinery should be regularly checked with respect to its performance. Equipment maintenance checks should include an assessment of the equipment's overall condition and integrity (e.g. is it working properly?), the sources of physical contaminants (e.g. damaged, lost or worn parts, rust, loose/flaking paint, broken parts such as needles and blades, loose parts on equipment prone to vibration, polymeric deposits, friction, fatigue, chemical reaction, etc.), the microorganism harborage sites (e.g. worn or frayed hoses, gaskets or belts, porous welds, product contact surfaces). Increase in noise, lubricant consumption, temperature rise or increased leakage is usually the consequence of failure of equipment and its components. Worn parts should be replaced as soon as practical, not only to ensure that production is maintained but also to prevent debris from worn or broken parts entering the product or contaminating the production line.

The operator must ensure equipment used for critical measurements is calibrated and uniquely identifiable. It must be used within its design and capacity (e.g. accuracy, calibration range, conditions of use). Items requiring calibration could include thermometers, temperature recorders, scales, test weights, metal detectors, gas analyzers, pressure or heat sensors, chemical assessment equipment, flow meters, etc.

Scheduled Preventive Maintenance

Scheduled preventive maintenance should be preferred over inefficient "breakdown" maintenance and repetitive repair. No longer does the maintenance department have the luxury of extended periods of available equipment downtime in order to carry out maintenance. Instead the maintenance function is moving toward a more predictive approach. If the failure characteristics of the equipment are known, predictive maintenance can detect the failure well in advance and appropriate actions can be taken in a planned and organized manner. Predictive maintenance makes use of a group of emerging scientific technologies that can be employed to detect potential failures: vibration analysis, thermal imaging, ultrasonic measurement and oil analysis. The maintenance technicians should be skilled to use these diagnostic tools, and they must have detailed knowledge of the operating characteristics of the equipment to make the correct failure diagnosis. By means of a risk analysis, the manufacturer may define which parts of the system are critical and allowing the necessary treatment (which interval, which time point, and which measures). The maintenance schedule should be frequently reviewed during the initial operating period of an installation to establish the optimum maintenance frequency (Jha, 2006).

Proper *a Priori* Design, Installation and Working Practices that May Reduce the Occurrence of Unhygienic Conditions during Maintenance and Repairs

Proper design and installation of the processing equipment and utility services, and common-sense measures create the appropriate conditions to keep up a sanitary process environment during maintenance and repairs (Moerman, 2011b):

- Equipment should be of such a design that the need for physical entry into the system is minimized. Enough space and clearance should be provided so that all equipment parts and components are readily and easily accessible for inspection, maintenance and troubleshooting.
- Mechanical, electrical, pneumatic, hydraulic and electronic components, together with distribution conduits, valves, pumps, pressure reducers, gas cylinders, vacuum sources, compressors, etc., should be relocated to a technical room or technical corridor adjacent to the production room, so that maintenance personnel can access the technical area without special gowning or disruption of the cleanliness of the high hygiene space below.
- Lamps with high light output should be used so that the factory staff can perform inspections of the food processing equipment and the process environment more easily and profoundly, enhancing the detection of grease, leaking oil, failures, maintenance residues, etc. Torches to light dark places with process equipment should be resistant to breakage.

- Maintenance managers and supervisors should implement "Maintenance Best Practice," eliminating the sources of breakdown and contamination that cause downtime, quality holds and lost profits.
- Correct maintenance attitudes must help to ensure that the production area and products are kept free from contamination by undesirable microorganisms, filth, debris or machine parts. Regular audits should be done to verify if the maintenance staff or contractors have adopted the correct hygienic practices during maintenance operations.

Maintenance and Repair Operations according to the Principles of Hygienic Design

Maintenance and repairs should occur according to the principles of proper hygienic design to ensure that safe food is produced once production is resumed. The following recommendations should be followed (Moerman and Degraer, 2003; Den Rustfri Stålindustris Kompetencecenter, 2006b; Moerman, 2011b):

- The construction materials used during maintenance and repair must be compatible with the food product or process aid they contain, and may not introduce contaminants that would present a risk to food safety. Piping and components should be constructed out of the same materials to prevent contact corrosion between dissimilar metals.
- Work in black steel and stainless steel must always be kept separated. Spare parts should be pre-packed in plastic, stored segregated from other non-stainless steel products.
- Stainless steel equipment components should be (shrink) wrapped with plastic film to protect them against corrosion in contact with black steel (particles), and their inlet and outlet connections should be fitted with protective caps to prevent ingress of impurities, insects and small animals (Figure 26.58).
- Prior to use, process equipment and components should be examined for debris, oil or grease; and if necessary should be cleaned.
- The body and internal parts must be handled carefully to ensure that the machined surfaces are not damaged.
- Use as much piping as possible with the same internal and external diameter over the whole factory, in particular to avoid misalignment (missed coincidence between the axes of two coupled pipe components) prior to welding.
- Reassemble piping and equipment components using a new seal, and check for leaks and retighten as necessary.
- All fastening devices should be secured firmly.
- If old insulation containing asbestos has to be removed, all precautions should be taken to avoid the spreading of asbestos fibers in the food processing environment.
- For insulation work, preference should be given to rigid foam rather than fibrous materials that have already proven to be an excellent harborage of dust, insects and rodents. Afterwards, the insulation should be covered with properly sealed cladding of appropriate thickness that resists tear and abrasion.
- When a new cable has to be installed, it should not be supported from a previously installed cable because a hygienically unacceptable entangled cable bundle may be formed. The cables should be fastened individually at a distance no less than 25 mm from each other to allow for proper cleaning.

FIGURE 26.58 Stainless steel equipment components should be (shrink) wrapped with plastic film to protect them against corrosion in contact with black steel (particles), and their inlet and outlet connections should be fitted with protective caps to prevent ingress of impurities, insects and small animals. *Courtesy of Zhejiang Jugang Pipe Co., Ltd.*

- The use of temporary devices, such as tape, wire, string, etc., should be avoided. If strips are the only option, they should preferably be of a stainless steel type that can be detected by means of a metal detector. Alternatively, a plastic strip of a color that is not omnipresent in the food product and food factory could be used. Temporary fixes should be replaced in a timely manner by permanent repairs.
- Always determine the correct installation situation and direction of fluid flow. Install for maximum cleanability and drainability.
- Calibrated equipment that is non-conforming (i.e. broken, expired calibration period) must be identified as non-conforming, and further recalibrated, repaired or replaced.

Personal Hygiene Practices During Maintenance Operations in the Food Industry

Before the onset of maintenance and repair operations, all maintenance workers shall comply with the requirements for personal hygiene appropriate to the area where maintenance and repairs will be executed (Holah and Taylor, 2003; Smith and Keeler, 2007; NZFSA, 2009):

- Both the food manufacturer's own maintenance staff and contractors should follow the food manufacturer's guidance with respect to personal safety and hygiene.
- It is recommended to encourage the maintenance staff or contractors to fill out a health questionnaire before allowing them to enter the food production area. The food manufacturer must restrict access of any person with obvious health problems such as flu, colds, skin lesions, uncovered sores or wounds, etc. All personnel are in fact responsible for reporting any such condition to their supervisor before beginning or continuing work.
- The use of cosmetics, medical substances (ointments, plasters or Band-Aids for wound healing, safety pins) or other chemicals (suntan products, etc.) on the skin are not allowed.

- Eating, drinking, chewing (gum, toothpicks, straws, etc.) and smoking are not allowed during maintenance operations.
- Maintenance staff or contractors are not allowed to enter the food production area with their casual clothes. These should be stored away from the production area. Protective clothing shall be worn, not only to safeguard the person's casual clothes during work but also to protect the food product. In order to avoid contamination of work surfaces, maintenance personnel should wear clean coveralls.
- Maintenance workers who work in a less clean area which has high microbiological activities (raw materials) must change their garments prior to entering a cleaner area where sensitive food products (e.g. finished products) are produced. Hair nets, headbands, caps, bump hat, hard hats, beard nets or other devices must be worn to control hair lost in the food, onto food surfaces and into packaging.
- All piercings, jewelry and watches should be removed.
- Hands should be washed thoroughly, including in between fingers, before entering a food processing area and after eating, drinking, smoking or using the restroom. The use of gloves may be advisable. Gloves are to be maintained in a clean, sanitary and intact condition. Gloves used in less hygienic (raw material) areas of the plant must not be used in more hygienic areas.
- Footwear should be clean. If it is necessary to stand on or over machinery, the process equipment shall be covered to prevent footwear dirt and debris from contaminating the surface. It is also recommended to cover footwear with overshoes just prior to walking on the process equipment.
- Maintenance staff or contractors must remove all unsecured objects, such as pens, pocket notebooks, small screwdrivers, non-attached earplugs, nuts and bolts in shirt pockets, etc., which could fall into the product. These items must be stored in the tool box or the carrier used to bring parts to the work site.

Hygiene Practices during Maintenance Operations in the Food Industry

Recommended Hygiene Practices to be Taken before the Onset of Maintenance and Repair Operations

The following measures and actions will create the appropriate hygienic conditions to execute maintenance and repair without compromising the safety of the food produced with that equipment when production resumes (Jha, 2006; Smith and Keeler, 2007; NZFSA, 2009):

- Work such as drilling or welding will inevitably produce debris and dust. Where possible, production operators should remove food processing equipment from the processing room before repairs are made. Coverings such as tarps or plastic sheeting (polyethylene or equivalent film) can be draped over equipment to reduce contamination.
- Maintenance could be done in a separate room outside the food processing area.
- If entry in process equipment is required, a plastic cover film must be laid down on the bottom of the process equipment.
- Where practical, maintenance tools should be dedicated for use in specific areas of their operation to avoid cross-contamination.

- Tools used for repairs and maintenance must not come in contact with, or compromise the hygienic status of, any product or packaging material. The maintenance tools must be free of rust, peeling paint, niches and threads, and not have wooden handles or knurling soft rubber grips. They should be non-corrosive, easy to clean and inspect, with smooth finish and hard plastic grips, and with fitted heads for equipment longevity. They must be designed in a way that they cannot damage the process equipment.
- The maintenance tools must be clean and used with care so that they cannot be left in the production equipment.
- Maintenance equipment and tools must not transfer microorganisms from a hygienic area into a less hygienic area.
- Ordinary steel wool or steel brushes should never be used on stainless steel surfaces as particles of steel may become embedded in stainless steel surfaces and rust.
- Debris from engineering workshops (such as swarf and other unwanted materials) must be prevented from entering processing or support areas. This is especially important where engineering workshops have access ways (e.g. doorways) that lead into processing or support areas. This may be achieved by keeping doors closed, using swarf mats, boot washes, etc.

Recommended Hygiene Practices during Maintenance and Repair

The following hygiene practices should be followed during maintenance and repair (Smith and Keeler, 2007; NZFSA, 2009):

- During maintenance operations, light sources used to provide the necessary light for proper maintenance and repair should not be placed above open process equipment, or the lamp should be housed in a shatter-resistant fixture to avoid shattered glass falling into the open processing equipment during its maintenance. By using a protective PTFE coating, one may also maintain the integrity of the lamp in the event of breakage. Light sources used during maintenance operations should not contain mercury.
- Opening the distribution system will expose it to particles from the outside environment. The contamination risk can be minimized by using strict specifications on how to conduct activities, such as cutting pipework, and handling pipes and components before the actual installation. Precautions should be taken to prevent the distribution of any contamination residues or mechanical damage residues in the surroundings. Vacuum cleaners should be applied to extract maintenance debris at the place where the maintenance takes place, and drip pans should be used to collect oil, etc. Equipment openings must be protected to maintain the interior of the process equipment and components free from any external contamination.
- Equipment components subjected to maintenance, spare parts and tools should not be placed on the ground or walking surface (e.g. deck), but on a plastic pallet, in a receptacle, a box, a carrier or a trolley provided with a plastic cover. In the food processing area, no wooden pallets should be used to store new or replaced equipment components.
- Whenever parts and tools are stored in the production area, they should preferably be kept in rooms or lockers reserved for such use.
- Equipment components in service should be clearly indicated and/or placed in quarantine.

- Care must be exercised not to lose nuts, bolts, etc. when removing them from machinery. Because small parts easily can be misplaced, loose bolts, nuts, screws, rivets, washers, etc. should be stored in maintenance receptacles.
- Bolts, nuts, screws, etc. of a lower alloy composition may not be left behind on stainless steel because they may induce corrosion.
- Maintenance personnel should not walk on the cladding of insulated piping so as not to damage it.
- Food grade maintenance chemicals (lubricants, heat transfer liquids, etc.) that do not provoke corrosion should be used.
- Personnel must be trained and suitably skilled in the correct access, handling and use of approved maintenance compounds, or have access to documented directions.
- Maintenance products (oils, greases, lubricants, ammonia, glues, chemical products, etc.) should not be left in the food processing environment when maintenance operations have ceased (e.g. during the night, during weekends, during collective holidays, etc.). They shall be stored separately from food products in clearly labeled (identifying the maintenance compound) and closed containers (e.g. bulk supply) in dedicated secure storage facilities.
- Maintenance compounds that are "in use" or for "immediate use" may be stored in processing and support areas, but only in quantities necessary for immediate use. When transferred from their original container (e.g. bulk supply) to a new container (e.g. "in use" or for "immediate use"), the latter must be labeled with the name of the maintenance compound.
- Empty maintenance compound containers must not be reused in a way that food product could be contaminated. All containers/implements should be labeled "for chemical use only."
- Excessive lubricant and grease should be removed to prevent them coming into contact with the product or food contact areas (Figure 26.59).
- Avoid placing dirty, greasy, oily hands on any surface with which the product comes into contact.

Recommended Hygiene Practices after Maintenance and Repair

After maintenance and repair operations, the following practices should be followed (Smith and Keeler, 2007; NZFSA, 2009):

- Maintenance tools or machinery must be removed or returned to storage without delay once maintenance or repair work is completed. Therefore, maintenance technicians must verify that all maintenance tools and components are removed after maintenance and repair to ensure nothing is left where it may enter the product or damaged equipment. An inventory can be made of all tools prior to maintenance.
- Any maintenance waste and other refuse (e.g. packaging materials, broken components, failed parts, dirt, dust, spilled oil) must be regularly removed immediately to a suitable storage area.
- Equipment that could be a source of contamination must be physically isolated from processing lines and product, or removed from processing areas. Damaged or decommissioned equipment that remains in processing areas must be clearly identified as

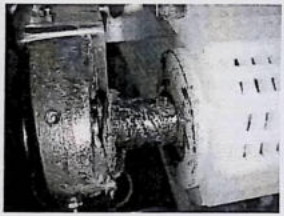


FIGURE 26.59 Avoid over-lubrication. Excessive lubricant and grease should be removed to prevent them from coming into contact with the product. *Courtesy of John Butts, Land O'Frost.*

such, to ensure that it is not used. Decommissioned equipment may be stored outdoors, but should be placed on a hard standing (e.g. concrete, sealed or paved area) and covered.

- If emergency repairs were required during production, any product that may have been left sitting for long periods of time or become contaminated during repairs should be disposed of.
- The operator must have a procedure to ensure that equipment returned to use (e.g. after repairs and maintenance, recommissioning or having previously been idle) is not a source of contamination to product because of bad maintenance or repair, because repair does not conform to rules of appropriate hygienic design, or because maintenance debris remains.
- Maintenance debris (e.g. abraded particles, swarf) must be flushed from the system after maintenance and repairs.
- When it was necessary to "break in" to the system for maintenance or inspection, equipment should be thoroughly cleaned when maintenance or repairs of any type are performed in a food processing facility. The equipment and area should be cleaned with solutions of detergents and disinfectants in the right concentration, then rinsed and finally dried prior to resuming production.

Evaluation of the Quality of Maintenance Work Done and Record Keeping

Before production resumes, the food manufacturer must evaluate whether finished maintenance operations and repairs meet the expectations with respect to the quality of the maintenance and repairs. In this perspective, the following practices should be followed:

- Equipment must be subjected to a pre-operational check before processing recommences. Are all technical problems solved? Are maintenance and repairs done in a way that the process equipment allows to produce safe food products once production resumes?
- Equipment operating under validated conditions must be revalidated if the repairs and maintenance activity will affect its validated status (e.g. replacing temperature probes/sensors in ovens/freezers).

- Maintenance records or job sheets (including when and how the defect/breakdown was repaired, who conducted the work, who has signed off that it was completed and that appropriate equipment return to use procedures have been followed) must be provided. Comprehensive maintenance records will assist the operator to verify that the repairs and maintenance program are working correctly.

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CHAPTER

27

Development of a Comprehensive Cleaning and Sanitizing Program for Food Production Facilities

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OUTLINE

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INTRODUCTION: CLEANING AND SANITIZING OPERATIONS IN FOOD PROCESSING FACILITIES

Effective cleaning and sanitizing, whether automated or manual, requires an understanding of these operations and how to properly validate cleaning and sanitizing procedures to ensure a safe food environment. Primarily, procedures must focus on where soil and microbial contamination can reside in a food processing system. Cleaning and sanitizing procedures that fail to remove soil from food contact surfaces can lead to build-up of microbial agents and be a potential source of contamination of subsequent food production. Prevention of such contamination can be accomplished by food processors focusing on development of efficient Sanitation Standard Operating Procedures (SSOPs) by implementation of HACCP and ISO 22000-type standards (Arvanitoyannis, 2009).

Sanitation Standard Operating Procedure Development

SSOPs are documented procedures for the cleaning and sanitizing of a given piece of equipment or area in a food production facility. A verification procedure ensuring that a cleaning and sanitizing operation was actually completed should be documented in the SSOP. Each SSOP, once written, should be "validated" or proven to actually function as required. An example of a SSOP structure can be found in the United States Department of Agriculture (USDA) Code of

TABLE 27.1 Ten Principles of Sanitary Design

1. Cleanable
2. Made of Compatible Materials
3. Accessible for Inspection, Maintenance, Cleaning and Sanitation
4. No Liquid Collection
5. Hollow Areas Eliminated or Sealed to Avoid Liquid or Soil Collection
6. No Niches (also to Avoid Liquid or Soil Collection)
7. Sanitary Operational Performance (Demonstrated Ability to Execute All Aspects of Sanitation Procedures)
8. Validate Cleaning and Sanitizing Protocols
9. Separate Processes Wherever Possible
10. Meet Personnel Hygiene and Sanitation Requirements

Federal Regulations, Title 9 Part 416 (http://www.usda.gov/wps/portal/usda/usdahome). A more detailed discussion on developing a validation protocol can be found below.

Food Production Facility Cleaning Based on Sanitary Design Principles

Despite the very broad range of food systems and very specialized equipment developed for many food production and packaging operations, cleaning and sanitizing systems should be designed using standard principles. An example of these principles adapted from the American Meat Institute is shown in Table 27.1 (AMI, 2002).

Cleaning methods, manual or automated, cannot overcome poorly designed production equipment and facilities. For example, even sealed hollow areas in support structures or walls have been known to develop cracks and become microbial harborage points.

Hygienic design standards for food processing equipment and facilities, and even "hygienic zoning" concepts (designing facilities to provide "hurdles" to microbial or allergenic contamination transfer from raw food areas to post-processed food areas), should be used for all new equipment, new buildings or new sections to existing structures of food processing facilities to minimize food safety-related recalls (Lelieveld et al., 2003, 2005; Holah and Lelieveld, 2011).

Types of Cleaning and Sanitizing Systems: CIP, COP and Environmental

Cleaning systems for food plants are generally separated into three categories, clean-in-place (CIP), clean-out-of-place (COP) and environmental cleaning:

1. CIP is the automated cleaning of equipment with minimal dismantling of food production equipment prior to the cleaning and sanitizing operation.
2. COP is the removal of food production equipment or portions of the equipment as well as related food production tools to an external area for cleaning, sanitizing and drying prior to reassembly.
3. Environmental surfaces are those external to food processing equipment within the food production facility. Cleaning and sanitizing of all environmental systems is generally accomplished manually but in some cases automated cleaning systems have been utilized.

In all three categories, cleaning is usually followed by sanitizing although sanitizer chemistry and procedures will differ based on regional regulatory requirements. The methods

used for cleaning and sanitizing can also vary significantly depending on the food type food additives and processing temperature used to make the food.

Cleaning Factors

Four factors are generally accepted as being important to ensure effective cleaning and sanitizing. Cleaning time, temperature, chemical activity and mechanical energy all need to be defined for all cleaning and sanitizing programs as described below:

1. **Time to clean and sanitize** is often misunderstood, especially when chemical cleaning is involved. Optimizing the time for a cleaning operation to ensure effective soil dissolution and emulsification (tying up soil in solution to avoid redeposition) is generally a high priority for food producers. Rushing a cleaning operation can result in poor cleaning and the potential for food contamination. Improper use of cleaning chemistry, temperature or mechanical action can result in an inordinately long cleaning time.
2. **Temperature effects on cleaning and sanitizing** will vary depending on soil type and water quality. A rule of thumb is that for every 10°C increase, cleaning chemical activity doubles resulting in fatty soils, sugars and starches and many other types of food soils being more easily removed with increased temperature. High temperatures (>145°F/65°C) will kill microbes but if used properly, lower temperature cleaning and sanitizing programs can be used to achieve effective microbial kill. Increasing cleaning temperature in some cases will precipitate proteins or hardness ions (calcium or magnesium) and create difficult to remove scale deposits.
3. **Chemical activity** is important as cleaning chemistry is built to dissolve soils from the surfaces to be cleaned and emulsify these soils to avoid redeposition. A sanitizing step will kill or inhibit microbial contamination that remains after the cleaning step. Chemical activity is impeded when:
   a. Cleaning or sanitizing solutions do not reach the soils due to lack of solution flow (dead zones).
   b. Chemical concentrations are too low (cannot dissolve soils) or too high (precipitate out or react with soils).
   c. Inappropriate chemical systems are used and are not effective at cleaning or sanitizing the food processing equipment.
4. **Mechanical action** is required to move soils away from a surface. In the absence of manual cleaning, automated cleaning systems generally rely on pressurized water or air to provide mechanical force for soil removal. The need for mechanical force can be minimized if temperature, time and/or chemical activity can be optimized to permit better soil dissolution but some force is always required to move the soil away from a surface to prevent soil redeposition.

CIP BACKGROUND (FIGURE 27.1)

In practice, a standard CIP system will recirculate cleaning solution automatically through enclosed food processing equipment such as tanks, ovens, fryers, conveyors and cooling systems and the associated food transfer piping. Recirculating a cleaning solution

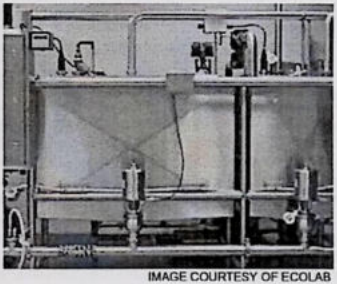

IMAGE COURTESY OF ECOLAB

FIGURE 27.1 CIP cleaning solution and sanitizing solution tanks: this single-use CIP system includes two medium-sized tanks for detergent and rinse/sanitizer, a steam heat exchanger, and programmable logic controllers to automate the cleaning process.

permits measurement and control of temperature, flow rate and chemical concentrations. Such a CIP operation, run for a time period sufficient to ensure all surfaces are free of contaminants, is generally completely automated to:

1. Ensure consistent cleaning results.
2. Minimize labor compared to manual cleaning.
3. Provide electronic documentation that a cleaning program was run as desired (Jennings et al., 1957; Gibson et al., 1999; Schmidt, 1997).

For a CIP system, the mechanical energy is provided by circulation systems. Liquid impingement on surfaces or turbulent flow through piping generally cannot match the mechanical energy provided by manual scraping and scrubbing. To overcome this mechanical energy deficit, the other cleaning factors – temperature, chemical activity and time – must be emphasized. As an automated and enclosed CIP system does not expose operators to chemical mixtures, stronger chemical activity and higher temperatures can be safely used in cleaning and sanitizing. Cleaning times can also be lengthened as labor can be distributed to other tasks while an automated CIP is in operation.

Food CIP systems and beverage CIP systems (such as milk, beer or soft drinks) use essentially the same cleaning and sanitizing solution transfer and spray technology but can vary greatly in the required chemical strength, water temperature and cleaning time for removing light versus heavy, aged and/or burnt on food soils. Use of automated cleaning and sanitizing CIP systems has advantages over manual cleaning in the following ways (Lowry, 2010):

1. Reduces the amount of time and labor spent on sanitation operations (increasing food production run times).

2. Decreases the impact of sanitation operations on water consumption, energy utilization and wastewater processing.
3. Reduces overall wear on process equipment due to decreased manual cleaning.

CIP – Line Circuit Cleaning

The line circuit portion of CIP cleaning is focused on ensuring proper turbulent flow at rates to provide mechanical "scrubbing" by the cleaning solution. Critical to the success of cleaning line circuits is removal of all "dead zones" where cleaning solution cannot flow and residual food product can build up and result in microbial contamination. CIP circuits can often be extremely complicated, especially when using a single CIP system to clean numerous circuits (sometimes simultaneously). Careful design of each CIP piping circuit, especially when new food processes are added to existing equipment is suggested to ensure elimination of these dead zones.

Optimizing time, temperature and chemical concentration is important after ensuring optimum mechanical action based on solution flow rates. Flow rates will need to increase with increasing pipe diameter (see Table 27.2). Care must be taken where line circuits contain multiple pipe sizes as pressure/velocity drops will occur going from smaller to larger diameter piping and inadequate cleaning of the larger piping can result. It is common for tank and lines to be cleaned in the same CIP operation and optimizing both types of CIP programs in conjunction is required.

CIP – Tank Circuit Cleaning

The tank circuit CIP program relies on a spray device or spray ball to achieve mechanical action. At a minimum a tank cleaning spray device must be designed to ensure all tank surfaces are reached by the cleaning solution. Fixtures within tanks such as mixing blades or drain valves on tank surfaces can block spray from reaching soiled surfaces. Multiple overlapping spray devices are often required to overcome such blockages. Flow rates out of a

TABLE 27.2 Flow Rates in Feet/Second (ft/sec) and Gallons/Minute (GPM) for Different CIP Line Sizes

Line Size*	Desired Velocity	Minimum Flow Rate	Drain Capacity**
1"	5 ft/sec	15 GPM	22 GPM
1.5"	5 ft/sec	24 GPM	40 GPM
2"	5 ft/sec	43 GPM	75 GPM
2.5"	5 ft/sec	69 GPM	115 GPM
3"	8 ft/sec	163 GPM	190 GPM
4"	8 ft/sec	288 GPM	350 GPM

*- Assumes Standard Sanitary Pipe.
**- Maximum drainage through the pipe.
(Courtesy of Ecolab Inc.)

spray device typically are on the order of 3 gallons per minute per foot of circumference of a cylindrical tank.

Single Versus Multi-use CIP Designs

CIP circuits can be designed to be (1) single use with cleaning solution dumped directly to drain after completion of the CIP cycle or (2) reuse or multi-use systems. Multi-use CIP systems are often designed to recover final rinse water for use to make up subsequent cleaning solutions. Some or all of the cleaning solution itself can also be saved and reused to minimize chemical usage. In all CIP designs, any final rinse or sanitizing rinse would not be reused in that function but fresh final steps would generally be required by food processing regulations in most regions.

Single use systems, where all cleaning, sanitizing and rinse solutions are used once, are simple to design and result in the highest level of sanitation. These single use systems would be required for food production equipment having very high soil loads or allergenic material and thereby avoid the potential for cross-contamination. Facilities with very limited space for additional equipment would also benefit from such a system.

Recovery of rinse water is a popular choice for CIP as there is little chance of soil redeposition resulting in system contamination. Multi-use systems where the cleaning chemicals are reused require a fairly complicated CIP design and a high level of understanding of the CIP circuit to avoid soil redeposition. There are many of these systems in use, some of which have automated make-up water and cleaning chemical additions to achieve equilibrium in a cleaning solution and can run weeks or months without the need to dump the cleaning solution.

COP CLEANING

Cleaning out-of-place (COP) is the cleaning of removable parts of food processing equipment after disassembly or any ancillary food production tools. Typically COP systems are open tanks where a given cleaning solution can be heated and recirculated. As with CIP systems, automation is possible with a recirculation step (permitting the monitoring of solution temperature, chemical concentration and flow rate) so that "push button" COP systems are common. The use of numerous distribution headers in COP tanks are used to create turbulence to aid in soil removal via mechanical action.

COP cleaning and sanitizing programs require:

1. Appropriate tank design:
   a. Sized for application.
   b. That can contain shelves or hangers for parts to maximize number of parts loaded while still maintaining separation between parts to ensure full access to cleaning solutions.
   c. With a recirculation system and associated headers sized to ensure tank turbulence.
2. Cleaning solution chemistry, temperature and cleaning time balanced to ensure full cleaning of the toughest to remove soils.
3. A rinse step to ensure removal of residual soil and cleaning solution.

4. A sanitizer step to kill off any residual microbial contamination.
5. Proper parts storage program to ensure complete drying and avoidance of cross-contamination prior to reassembly.

ENVIRONMENTAL CLEANING

Cleaning and sanitizing environmental surfaces in a food production facility is a critical part of a full food safety program. Poor design of a cleaning program for environmental surfaces cleaning (sometimes termed open plant cleaning) can leave microbial contamination that can migrate into food product (Samelis et al., 2001).

Environmental cleaning in a food processing environment is the cleaning of equipment's external surfaces, walls, floors, ceilings, elevated walkways, drains, piping and conduit in addition to ancillary equipment (such as motors, electrical boxes, etc.) that generally cannot be cleaned by CIP or COP methods.

Typically, cleaning environmental areas of a food production facility is done manually by first removing food debris followed by wet cleaning and sanitizing steps. Emphasis is on removing as much soil as possible before a wet cleaning operation to limit the biological load on the wastewater treatment system.

Environmental cleaning programs for food processing facilities should remove as much water as possible after completion of cleaning and final rinse steps and return to as dry a state as possible prior to resuming food production. Focusing even wet cleaned areas on maintaining as dry a state as possible will help limit microbial growth in the environment, thereby reducing the potential for microbial cross-contamination into food product.

Systems used to support environmental cleaning include the following.

Foaming or Gelling Systems

Cleaning and sanitizing with foam or gel-based chemistry increases the dwell time of chemical on the surface to help dissolve soils for cleaners or provide increased microbial kill efficacy for sanitizers. Foam generators mix a chemical solution with air to create a foam or gel. This solution is then sprayed under pressure onto the surface to be cleaned. Often entire rooms and all accessible surfaces of the food production equipment are foamed (with chemically sensitive equipment being wrapped prior to foaming).

High Pressure Cleaning Systems

High pressure air, water, steam or particle blasting systems can be used for cleaning the exterior parts of equipment, floors and some building surfaces when mechanical action is required for soil removal. Soil types dictate which type of mechanical action will be most effective. For example, particle blasting works best on brittle food soils while hot steam can clean by liquefying soils. Steam can also be used to sanitize surfaces (care must be taken that all surfaces are heated to an appropriate temperature for a reproducible time period to ensure the desired microbial kill).

Pressurized air or steam injection systems generally operate with nozzle pressures between 60 and 170 psi. Cleaning effectiveness is dependent largely upon the force of the cleaning system against the surface and will be a function of both operating pressure and nozzle design. It must be emphasized that high pressure air or water systems (especially centralized systems) must be free of microbial contamination. Additionally, care must be taken that these high pressure cleaning systems do not scatter soil (which may contain microbial or allergenic contamination) into adjacent food production systems.

Ancillary Cleaning Equipment

Programs should be developed for cleaning ancillary food production tools as well as ensuring that cleaning tools themselves have appropriate cleaning procedures to avoid the potential for microbial or allergenic cross-contamination. Strategies often involve using color-coded cleaning and waste removal equipment specific to either food contact or non-food contact surfaces. Procedures to clean, dry and store equipment after a cleaning operation is completed and isolation of equipment are used in areas where raw food products are stored separately from areas where finished food products are stored.

Master Sanitation Schedule

Development and implementation of a master sanitation schedule is highly recommended for all food production facilities. A facility's environmental areas that are not normally cleaned on a daily basis should have a strict cleaning schedule at some regular time frequency to ensure these areas are not overlooked and become sources of food product contamination. Not only cleaning activities but maintenance of equipment, sealing of roofs, wall and floor cracks where water may enter a facility as well as identification and elimination of any microbial harborage points or pest activity is recommended on a regularly scheduled basis.

CLEANING OF ALLERGENS

Food allergies affect as many as 6% of young children and 3 to 4% of adults (Sicherer and Sampson, 2006). Exposure of some individuals to very small amounts of allergenic proteins can be life-threatening. Moreover, allergen contamination makes up a significant portion of all food recalls. Control of allergens in any food facility that produces both allergen- and non-allergen-containing foods must be accompanied by a stringent allergen control program. Potential for cross-contamination of allergens into allergen-free foods can include: (1) mislabeled raw material entering the food process facility, (2) mislabeling of materials by facility staff, (3) cross-contamination from allergen-containing food remaining on food production equipment or tools and (4) mislabeling of a final product containing allergens. There are many manufacturers who have separate production equipment or even separate manufacturing facilities to avoid the potential for such cross-contamination to occur (Vierk et al., 2002).

CLEANING OF DRY OR LOW MOISTURE FOODS

Low moisture or dry food production areas are usually cleaned without water for the purpose of minimizing growth of microbial pathogens. Some of these low moisture foods include milled grains, bakery goods, cereals, chocolate, dry dairy, nuts, spices and fried or baked chips. Food facilities that have dry processing areas (in some cases the entire production facility will be dry) have been historically more concerned about pest issues than microbial contamination.

Unfortunately, recent food recalls involving food contaminated in dry food production facilities have increased the need by these food producers to identify ways to provide sanitation breaks in their facilities. *Salmonella* is the main concern in these environments due to its persistence on dry foods and in food manufacturing facilities. *E. coli* O157:H7 and *Listeria* also remain of major concern in these areas.

Developing dry cleaning and sanitizing protocols using little or no water becomes a challenge as there are few government regulations addressing such cleaning and sanitizing methods. For most dry food facilities, dry raw material delivery, storage and internal facility transport systems are rarely cleaned completely and almost never sanitized (relying on dry environment to inhibit any microbial growth).

Some examples of such dry cleaning include traditional sweeping, scraping and vacuuming coupled with sanitizing with quick drying alcohol solution applied directly to surfaces or using sanitizing wipes. Sanitizing with steam and heat also provides low water alternatives to water-based sanitizers. More unique methods include "rinsing" with the new lot of food product itself to remove any traces of older product. Non-allergenic food material such as rice or salt might also be used to rinse out systems and then tested to demonstrate removal of microbial contamination. The final "rinse" would consist of food product from a new production lot (to be discarded until all traces of a rinse raw material are removed).

CLEANING CHEMISTRY

Chemical cleaners are required where dissolving and emulsifying soils is more efficient at cleaning food processing equipment than manual cleaning would be. Food soils of concern to most food processing facilities will vary depending on food type and additives, temperature and type of food processing as well the condition of the water used in food production and cleaning. To effectively clean these soils requires an understanding of the functions of different chemical components in a cleaning system. An overview of the properties of chemicals used in cleaning procedures is provided below. A more comprehensive review of these technologies can be found in the work by Stenga (Stenga, 2010).

The pH of a cleaning solution is defined by the relative level of hydrogen cation (acidity) or hydroxyl anion (alkalinity) in a solution and is a key factor in the cleaning ability for most food soils. The chemical structures of food soils such as fats and oils, proteins, sugars and starches as well as minerals all have some ionic features under some or all conditions. A cleaning solution must be built from components that maximize the breakdown of soil residues on food facility equipment and associated environmental surfaces while minimizing

the amount of chemical used for cleaning. The goal of an optimized chemical cleaning system is to use the cleaning solution to wet the soil, dislodge it from a surface to be cleaned and then emulsify it (hold the soil in solution) so it will not redeposit.

When choosing a chemical cleaning system for a given food soil the cleaning time, cost, compatibility with equipment, safety for facility operators as well as regulatory requirements for wastewater discharge and environmental sustainability are all factors that must be considered to ensure an optimum system.

Personal Protective Equipment and Safety Programs for Chemical Usage

The use of personal protective equipment (PPE) when using any chemical cleaning or sanitizing system is highly recommended. A proper sanitation program should include operator training on safety issues at the core of its training program. Continuous monitoring of compliance with all safety procedures for all employees and a safety review of all new procedures should be a part of any new SSOP development program. All chemical materials brought into a food production facility should have an easily accessible material safety data sheet (MSDS) available. These MSDS documents describe how to safely handle and dispose of the chemical as well as the appropriate PPE to be worn by any employee or contractor using the chemical.

Environmental Issues with Chemical Cleaners

Understanding regional and local regulations regarding use and discharge of chemical cleaning and sanitizing systems is important for proper operation and long-term viability of a food production facility. As regulations are constantly changing, care needs to be taken by a business to be aware of regulatory changes that might affect business practices.

Typically, a facility will be most concerned with local wastewater treatment facility requirements as chemical discharge can have almost immediate effects on a water treatment program, and discharge limits on phosphorus or nitrogen, for example, or sanitizing chemistry discharges that wipe out a bacterial culture used to break down organic waste at a water treatment facility can result in significant fines for a food production facility. Use of non-compliant chemical systems can also result in economic issues for a facility as well as environmental damage from such chemical systems.

Alkalinity

Alkaline cleaners use alkalinity to break down and solubilize fats, proteins and starches. Alkaline salts provide hydroxyl anions to an aqueous cleaning solution and can be strong alkaline (high pH) or buffered to alkalinities down to a pH below 10 (where neutral chemical components start to provide the major cleaning effects).

Sodium or potassium hydroxides are the common caustic additives that provide high strength, high pH cleaning effects. These solutions will turn fats into soaps (saponification) and are commonly used for dissolution of protein soils, especially proteins that have been denatured, precipitated or polymerized by heat. If used alone, without added buffering or

threshold sequestrant components, the pH of alkaline solutions can change rapidly due to dilution by rinsing. Such pH swings for an alkaline solution can result in extremely rapid soil redeposition or scale depositing onto food production equipment.

There are many other alkaline sources effective at cleaning including alcohol amines such as monoethanolamine (MEA), silicates, used for safe cleaning of soft metals and phosphates and polyphosphates that act simultaneously as an alkalinity source, a sequestrant and anti-redeposition agent.

Reuse of alkaline solutions is common in order to save water and chemical costs in CIP systems as described above.

Acidity

Acidic cleaning products provide hydrogen cations to a cleaning solution primarily for the dissolution of inorganic scale deposits. Scale forms from precipitating metal salts such as calcium, magnesium and other multivalent metal ions and can be a problem especially in heated solutions, as calcium and magnesium salts become less soluble with increasing temperature.

Scale can result from minerals precipitating from foods (such as calcium phosphate or milk stone and calcium oxalate or beer stone), from hard water used in food production or from the cleaning step itself. Care needs to be taken in all these processes to ensure scale build-up is carefully controlled as some scales, if they become too thick, may be extremely difficult to remove. Silicate scale from food or plant water sources, for example, can be especially difficult to remove if not controlled and in some cases require the quite hazardous hydrofluoric acid to dissolve.

Certain anions interacting with hardness ions can induce scale precipitation. Stearate, oleate and laurate from fatty acids, oxalate from vegetable sources and inorganic anions such as phosphate, sulfate, fluoride and carbonate from food or water sources can induce scale under certain conditions and must be controlled to ensure equipment can be properly maintained.

It is important to note that strong acid washes can still be responsible for scaling food processing equipment. This happens when using hard water for rinsing the acid. When the acid concentration in the rinse falls below a level where the scale ion concentration is soluble, these ions will precipitate. In order to avoid such scale precipitation during an acid wash, threshold inhibitors are often added to acid cleaning products.

Acids generally are poor detergents as they tend to make soils hydrophobic and, therefore, difficult to wet and dissolve. Surfactants are often added to acidic cleaning formulation to provide some wetting ability. Surfactants can also be formulated into acid cleaners to provide visible foam for environmental cleaning.

A common cleaning practice involves washing with an alkaline cleaning solution followed by an acidic cleaning solution to ensure removal of organic soils and inorganic scale, respectively.

Strong acid cleaners (phosphoric, nitric and sulfuric blends) are the most cost-effective cleaners but have to be used carefully as they may damage many soft metals and some plastic or rubber materials. Organic acid-based cleaners (such as citric, oxalic, lactic, etc.) are more expensive but are more ecologically sound (by not contributing phosphorus or

nitrogen to wastewater as well as being biodegradable) and they are generally safer to use on soft metals.

Chelants and Sequestrants

Chelants or sequestrants are chemical compounds designed to bind dissolved metal salts. Sequestrants are added to cleaning formulation for two basic functions:

1. For dissolving scale on equipment surfaces; and
2. To keep hardness ions such as calcium and magnesium from precipitating out of solution.

While acids act to dissolve scale as a separate step, as discussed above, neutral and alkaline cleaning formulations often need to be built with sequestrant components for one-step cleaning applications as well as to ensure hardness ions do not precipitate during cleaning.

Some sequestrants can work by ensuring each hardness ion is complexed (or kept bound) by a sequestrant molecule (stoichiometric sequestrant). Stoichiometric sequestrants are required for many cleaning systems, especially when cleaning solutions are reused, ensuring long-term stability of the solution against the precipitation of scale.

Other sequestrants can also work as threshold agents. A threshold sequestrant molecule effectively impedes the growth of a scale crystal in solution so that a small number of sequestrant molecules can stabilize a large number of scale forming ions. A threshold agent is added to alkaline or acid formulations to guard against scale formulation during a rinsing operation where hard water is used or where the cleaning solution has solubilized a great deal of scale during cleaning.

The strongest sequestrants, such as ethylene diamine tetraacetic acid (EDTA), or organic acids, such as gluconate or citrate, do not act as threshold agents. Tripolyphosphate, phosphonates and carboxylate polymers can act as both stoichiometric and threshold agents and can be used individually or with strong sequestrants depending on the specific cleaning requirements.

Surfactant and Solvent Systems

Surface modifying additives to cleaning formulations are also generally known as surfactants. Solvents used in food cleaning systems are essentially low molecular weight surfactants and are effectively used for the same purpose: to dissolve food soils and emulsify them into the cleaning solution. All surfactant molecules have a "water-loving" hydrophilic portion that is water soluble and solubilize ionic soils. They also contain an oily hydrophobic portion that will dissolve oil- or fat-based soils. Surfactants are added to cleaning formulations to provide:

1. Soil wetting or solvating capabilities that assist the delivery of other cleaning components (such as acidity, alkalinity or sequestrants) into the soil.
2. Emulsification of oils in order to keep oily soils from redepositing during cleaning.
3. Modification of cleaning solutions by introduction of foaming or defoaming features as required by different cleaning methods (see CIP and COP discussions above).

Proper use of surfactants can significantly reduce the requirements for other cleaning components in a formulation. Often very small amounts of surfactants can have a very large effect on a cleaning operation as these molecules only need to interact with soils on the interface or surface of the soil to be effective and not dissolve the entire soil. Solvents generally require much higher concentrations than surfactants to have an effect on cleaning but can be much better overall cleaning solutions at those concentrations.

Caustic-Oxidizer

Oxidizing agents are generally used with alkaline cleaning solutions to break down soils such as protein, much more effectively than without the oxidants. Chlorine and hydrogen peroxide are the most common oxidizer additives in alkaline cleaners and act by breaking apart and solubilizing food protein molecules. Protein soils, especially heat-deposited proteins, can be extremely difficult to remove and can build up in food production equipment over time if the equipment is not properly cleaned and leading to harborage sites for microbial contamination.

Oxidizers such as nitric acid and hydrogen peroxide are also commonly used for stainless steel passivation which keeps equipment surfaces from oxidation damage (ASTM A380-06).

Enzymes

Enzymes in biological systems are extremely efficient at breaking down biological molecules at relatively low body temperatures. Outside of biological systems, enzyme-based cleaners are designed to break down very specific soils: proteases for proteins, lipases for fats and amylases for starches, for example. These cleaners are generally limited to lower temperature cleaning and are designed specifically for a given soil type. Enzymes are easily denatured by the wrong pH range, high temperature or various contaminants. Enzymes are especially useful in cleaning equipment such as membranes that are sensitive to temperature and many cleaning chemicals.

Cleaner-Sanitizers

In applications and/or regions where a cleaner-sanitizer single step meets regulatory requirements, such an operation can be used to clean soils as well as remove microbial contamination. In some cases a cleaner-sanitizer can be formulated to provide both functions or a wash step can be followed by heat sanitizing.

COMMON CLEANING PROBLEMS IN FOOD PROCESS ENVIRONMENTS

Issues at food production facilities involving difficult to remove soils vary significantly depending on the food being produced. Proteins, starches, fats/oils and metal ion scales can all be difficult to remove depending on the food production method, processing

temperature, time between cleanings and accessibility to food soils. Effective cleaning methods depend in part on whether the equipment was built to be cleaned (which is not always the case).

Protein Cleaning Problems

Protein soils can form difficult to remove soils especially if left behind after other components (such as fats, starches and inorganic scale) are removed by the cleaning operation. Usually, protein soils from such foods as milk, eggs or meats that undergo heat treatment or are exposed for a significant amount of time to air oxidation will denature, precipitate or polymerize to form soils that can build up over time and create harborage sites for bacteria and associated biofilms.

High cleaning temperatures and poor choice of chemistry (inappropriate alkaline, oxidizer, chelant or acid levels) can precipitate or denature a protein soil and make it more difficult to remove. Each protein source will have different optimized cleaning requirements due to the wide range of protein types found in food products.

Protein cleaning is usually best using alkaline oxidizing chemistry at temperatures that support cleaning without precipitating the protein from the cleaning solution.

Fats and Oils

Oily soil from fats or vegetable oils generally will clean better with increasing temperature and use of appropriate surfactant emulsifying cleaning solutions. If unsaturated oils polymerize due to heating in the food production process, these oils can create varnish-like coatings on food equipment surfaces. Dissolving these coatings can be very difficult and can require fairly concentrated chemistries or high levels of manual labor to remove.

Cleaning Starches and Polysaccharides

Starches from food sources, gums, pectins and other thickeners are usually water soluble but when heated can dry out and become very difficult to rewet. These polymeric soils can also be held together in some cases by inorganic mineral scale. Built alkaline cleaners with oxidizers (hydrogen peroxide or chlorine) are often required to remove these soils effectively and, in some cases, pretreatment with acid followed by alkaline cleaning may result in more efficient cleaning.

Scale Removal Problems

Different scale types might require a specialized cleaning program to ensure complete removal of food production equipment scale. Examples of some important food-produced scales include:

1. Calcium oxalate or beer stone is formed from foods containing tannins, seeds, fruits or vegetables. Tea, beer, tomatoes and especially vegetables treated in a blanching process can form these difficult to remove calcium oxalate scales. Removal methods include

alkaline peroxide-EDTA-based cleaners followed by nitric acid washes to dissolve. (EDTA is often the best chelant system but in some regions must be replaced by less optimal chelants due to regulatory restrictions.)

2. Calcium phosphate or milk stone is formed from high phosphorus-containing foods such as milk. Alkaline or alkaline peroxide, EDTA or other chelants can be used as cleaners followed by a separate nitric acid wash would be a typical cleaning system.
3. Calcium soaps can form by reaction of fats with calcium from milk, meats or other processed fat or seed oil-containing foods. Acid washes of these hydrophobic organic scales are much less effective than with inorganic scales. Strong chelant systems such as EDTA and alkaline peroxide-type cleaners will be required for cleaning these soils.

Cleaning Sensitive Equipment

The food industry has a broad range of customized and unique production and packaging equipment systems all of which should be designed with sanitary principles in mind. Unfortunately, there are many applications that require complicated equipment designs that can be extremely difficult to properly clean or contain materials of construction that can be damaged by conventional cleaning chemistries.

Corrosion issues on metals and plastic degradation can occur as a result of strong acid or alkaline chemistries or other high salt (especially chloride-containing) solutions. Surfactants or solvents can damage specialized equipment, especially plastic parts or rubber gaskets. Membrane separation systems, such as reverse osmosis (RO) or ultra-filtration (UF) membranes used, for example, for process water treatment and concentrating whey and milk in the dairy industry, are very effective production systems but can be easily damaged by many standard cleaning and sanitizing chemistries.

It is highly recommended that, prior to building or purchasing new equipment or systems, facility engineering work with quality groups to evaluate the special cleaning needs required for those devices is carried out. Many facility problems can be avoided by designing equipment so it can be effectively cleaned and does not contain materials that are incompatible with the cleaning process.

SANITIZING CHEMISTRY

The US EPA defines antimicrobial agents as substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms whether bacteria, viruses or fungi on inanimate objects and surfaces. Definitions of each type of antimicrobial agent are described in the EPA Fact Sheet on their website (EPA Fact Sheet):

Sterilizers (also sporicides) "will destroy or eliminate all forms of microbial life including fungi, viruses, and all forms of bacteria and their spores."
Disinfectants are used "on hard inanimate surfaces and objects to destroy or irreversibly inactivate infectious fungi and bacteria but not necessarily their spores" (these require a final rinse if used on food contact surfaces).

Sanitizers will "reduce, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations." Sanitizers used in food processing plants in the US generally are non-rinse agents, safe for food contact surfaces when used according to the product label requirements.

It is important to understand that for different food processing facilities, government regulations will differ based on region. An operator using sanitizers and disinfectants for direct and indirect food contact surfaces needs to follow regulations for both sanitizer and disinfectant products. For example, in the USA, any antimicrobial or chemical sanitizer used on food or for treating food contact or other surfaces in a food production facility must be registered at the EPA. The US Food and Drug Administration (FDA) regulate the use of antimicrobial agents used on food or food contact surfaces. All approved no-rinse food contact surface formulations and associated usage levels used in the USA are listed in the FDA 21 CFR 178.1010 Code of Federal Regulations. In some regions applications may require a final rinse for all sanitizer chemistry applications.

Sanitizing Systems

Chemical sanitizers fall into a number of categories based on whether they are oxidative or non-oxidative. These chemical sanitizers can be delivered as liquids, gases or in vapor/mist form depending on the application. A comparison of the different chemical sanitizers for stability, foaming, corrosivity, pH stability and efficacy against microorganisms can be found in a review by Richter and Cords (Richter and Cords, 2001).

For food processing operations, a sanitizing step in a cleaning program can be accomplished using chemical, non-chemical and combinations thereof to achieve the level of sanitization required for a given process.

A brief summary of these systems is described below.

Thermal Sanitizing

While not a chemical system, thermal sanitizing is used in many operations and often in conjunction with chemical sanitizers. A thermal sanitation process must follow some basic principles which, if not followed, can result not only in the potential for a food contamination incident but also in a thermally tolerant microbial biofilm that affects all food production through a contaminated system.

Bacterial contamination can generally be eliminated by a pasteurization step (>160°F or 70°C) for 15 seconds. Spores generally will require steam to induce the opening of the spore and temperatures on the order of >250°F or 122°C for several minutes to have acceptable kill levels (5 log or 99.999% reduction of the spores). Depending on the organism of concern and the level of microbial kill required for a given process, heat sanitizing functions need to ensure correct time, temperature as well as humidity levels (if sanitized with hot air rather than hot water) to obtain acceptable microbial kill. Equipment where there exists the potential that not all surfaces will be heated equally can leave cooler portions of the system improperly sanitized. Such areas could be dead head pipes with minimum flow for

an aqueous thermal process or thicker or more intricate internal structures with high heat capacity if steam or hot air is used to sanitize.

Oxidative Sanitizers

Commonly used oxidative sanitizers include chlorine, iodine, hydrogen peroxide, peroxycarboxylic acids and chlorine dioxide.

Chlorine

Chlorine is one of the earliest sanitizers used in food processing plants and is used in sanitizing solutions in the form of aqueous sodium hypochlorite or hypochlorous acid. Chlorine can be purchased as a gas, in a stable liquid form (bleach), as a chlorine producing solid (calcium or magnesium hypochlorite as well as in the trichloroisocyanuric acid form) or produced from the chloride salt on site in an electrolytic cell (White, 2010).

As a sanitizer chlorine has the advantage of being generally inexpensive and broadly effective against all types of microorganisms and is thought to act primarily through disruption of cellular proteins and enzyme activity. It is most desirable to sanitize with chlorine in the pH 6–7.5 range as it becomes ineffective as a sanitizer above pH 9 and will evolve dangerous chlorine gas when combined with acid. Disadvantages include loss of activity in the presence of an organic load as well as being highly corrosive to stainless steel and elastomers (especially when not completely rinsed and permitted to dry onto these surfaces). Chlorine also will react with organics to form carcinogenic trihalomethanes (THM) and is restricted for use in some regions.

Iodine

Iodine-based sanitizers (iodine stabilized with surfactant iodophors), like chlorine, have broad spectrum kill of microorganisms and are effective even against difficult to kill bacterial spores. Iodine sanitizers can be used at acidic pHs which is important for scale removal function in dairy and brewery applications, for example. They are effective at lower concentrations than chlorine and can generally work at a higher organic load. Iodine can be somewhat expensive in practical use and it cannot be used hot as iodine will not remain in aqueous solution above 115°F (45°C). Corrosion can be a problem, especially at higher temperature, and staining of equipment and some starchy foods are common complaints in the use of iodine compounds (Gottardi, 2001).

Chlorine Dioxide

Chlorine dioxide is a gas at room temperature with only slight solubility in water but it is a very effective sanitizer even at low concentrations. The main advantage of a chlorine dioxide solution over chlorine is that chlorine dioxide will work effectively against a broad spectrum of microbial contaminants even under a high organic load and is one of the most active antimicrobial systems against biofilms. Chlorine dioxide (ClO_2) is considered to be more environmentally friendly than chlorine as it does not form THM compounds. ClO_2 has 2.5 times the oxidizing power of chlorine and, thus, less chemical is required. Typical use concentrations range from 1 to 10 ppm.

Care must be taken when using chlorine dioxide as some corrosion issues have been reported for some metals and electronics although the formation or co-delivery of salts at the metal surfaces contacted is thought to be responsible for a significant portion of the corrosion effect (proper water rinsing to remove salts should minimize this risk if rinsing is possible). Chlorine dioxide is explosive in nature, degrades rapidly above temperatures of 122°F (50°C) and when exposed to light. Therefore, chlorine dioxide is usually produced on-site, used as a gas in very carefully controlled conditions or charged into water as a sanitizer or disinfectant, also under carefully controlled conditions. As chlorine dioxide has very low solubility in water, care must be taken to avoid unsafe atmospheric concentrations for workers due to off-gassing (EPA Guidance Manual).

Acidified Sodium Chlorite

Acidified sodium chlorite (ASC) is an oxychlorine mixture formed by acidification of sodium chlorite to form a chlorous acid intermediate chemical species. The chlorous acid supports active concentrations of strong oxidants (i.e. chlorate, chlorite, chlorine dioxide). ASC has broad antimicrobial efficacy and is able to be used, as is iodine, at acidic pH which is valuable for scale removal. ASC has US FDA approval for most equipment and environmental sanitizing applications. ASC solutions have also been approved by the US FDA as a "secondary direct food additive permitted in food for human consumption" permitting antimicrobial surface treatment of red meat, poultry, seafood and raw agricultural commodities (Allende et al., 2009).

ASC is most popular in food tissue spray applications where it can be used to provide antimicrobial reduction compared to a normal water wash step. Corrosion can be a problem as with any halide salt-containing system. Care needs to be taken to ensure proper equipment rinsing as a dried acidic salt on metal surfaces can result in pitting corrosion if not properly rinsed.

Peroxides

Hydrogen peroxide and peroxycarboxylic acid-based sanitizers are oxidizing sanitizers that have an advantage over halide oxidizers with similar effects against bacteria and viruses but are more effective in the presence of organic loads (especially proteins). These sanitizers break down into non-hazardous by-products. Hydrogen peroxide and the peroxycarboxylic acids are non-corrosive to stainless steel and the standard elastomers commonly used in food processing facilities. While hydrogen peroxide is odorless, it generally requires a fairly high concentration to deliver acceptable sanitizing results in a food process environment. Peroxyacetic acid, the most common peroxycarboxylic acid, has an odor associated with it and can have a higher use cost but is effective at a much lower concentration than hydrogen peroxide.

Other peroxycarboxylic acids, such as peroxyoctanoic acid, provide additional efficacy as sanitizers over peroxyacetic acid alone and due to the lower vapor pressure will have less associated odor in use (Fatemi and Frank, 1999).

Non-oxidizing Sanitizers

Non-oxidizing sanitizers typically used in food processing facilities include quaternary ammonium compounds (quats), acid anionic surfactant systems and fatty acids.

Quaternary Ammonium Compound

Quaternary ammonium compounds (Quats) are surfactants containing a positive charg which will be effective at binding at the negative charge of a bacterial cell wall and thereb delivering its antimicrobial effect. Quats are very stable compounds, are tasteless and odo less in solution, non-corrosive to common food processing facility surfaces, are non-irrita ing to skin and can leave a bacteriostatic coating on surfaces to inhibit microbial growt after treatment. Quats can also have activity against viruses through interaction with th negatively charged lipids on virus envelopes covering their protein capsids.

Quat compounds most used in recent years have consisted of blending multiple quats fo increased efficacy as well as using polymeric quats for decreased toxicity. These quats ge erally have increased hard water intolerance and lower sensitivity to anionic compounds a was the case for older quat structures.

Disadvantages of quats are the need for a relatively high concentration to obtain a germ cidal or bacteriostatic effect; they have limited activity against Gram-negative bacteria an can have limited activity in the presence of water hardness or anionic surfactants commo in detergent systems and relatively slow biodegradation rate.

Fatty Acid Sanitizers

Fatty acid sanitizers are popular due to their low environmental impact and use at a acidic pH (also effective for scale removal). They generally require higher active concentra tions than other sanitizer systems which can affect the organic wastewater limitations o some food processing facilities (Marriott and Gravani, 2006).

Acid Anionic Sanitizers

Acid anionic surfactants are negatively charged surfactants which have antimicrobia properties similar to Quats. They have a negative charge but are used at such a low pH tha the bacterial cell surface switches to a positive charge resulting in binding and antimicrobia activity.

Alcohol Sanitizers

The use of alcohols for sanitizing and disinfecting in a food processing facility is usually done only as a manual, spot sanitizing, step as the alcohol concentration (the most popular being ethanol and isopropanol) is usually on the order of 60% or greater to obtain complete efficacy.

Miscellaneous Sanitizing Systems

Other unique sanitizing systems such as UV radiation, filtration, cold plasma, high pressure and pulsed electric field can provide alternatives to heat and chemical sanitizer strategies for providing microbial reduction (Gachovska et al., 2008). Careful research into proper system design and rigorous validations of desired sanitizing efficacy for these systems is recommended. As with any sanitizing system, but especially with automated applications relying on complex technology, a proof of delivery for each application in conjunction with a good verification program is recommended to demonstrate continued efficacy.

APPLICATION OF SANITIZERS IN FOOD PROCESSING FACILITIES

A sanitizing operation is generally performed after a thorough cleaning operation for CIP and COP systems as well as for all environmental areas. Automated CIP/COP sanitizing would use a non-foaming sanitizer while a foaming sanitizer would be used for environmental surfaces (discussed above) as foam provides contact time for vertical surfaces as well as a visual confirmation of sanitizer application. (In the case of sanitizers that are approved for no-rinse applications, such foam would break and leave no visible residue.)

Any manual sanitizer application should not rely on mechanical action or scrubbing to assist the sanitizing operation (using the cleaning operation for such removal). If applicators, such as fabric or mop systems, are used for sanitizer application, care must be taken that these applicators are themselves thoroughly cleaned, sanitized and stored separately from equipment used for cleaning operations to avoid cross-contamination. It is usually recommended that cleaning equipment be color coded and stored in dry areas zoned against the possible contamination of food product by cleaning equipment.

CLEANING VALIDATION AND VERIFICATION TECHNOLOGY

There are three main components to developing a cleaning program for any food production area:

1. A **cleaning and sanitizing protocol** needs to be developed that is based on the specific legal and safety requirements for the food processing business.
2. **Validation** of that cleaning and sanitizing protocol requires development of tests for every point in the cleaning process to prove that the process can meet regulatory standards.
3. A **verification** program needs to be instituted (usually consisting of a subset of the validation test methods) in order to demonstrate the implemented cleaning and sanitizing programs are effective.

Too little focus has been given in most food production facilities to validation of cleaning and sanitizing protocols. Without proper validation of a cleaning and sanitizing protocol, there can be no assurance that a cleaning program will be effective in providing contamination-free, safe food product. An example validation program description that can be used in a food processing facility is shown in Table 27.3.

When a cleaning and sanitizing program is identified, the following steps are needed to ensure a successful program:

1. The validation program must determine the points in the process that will be the most difficult to clean and sanitize (Scipioni et al., 2002).
2. Cleaning and sanitizing methods should be evaluated specifically for the ability to effectively remove all soil types from these tough to clean and/or sanitizer areas.
3. A set of verification tests must be agreed upon to prove soil removal actually occurs in the difficult to clean areas. (These validation tests are generally much more rigorous than the final verification portion of the final SSOP document to ensure the program successfully cleans and sanitizes all potential failure points.)

TABLE 27.3 Components of a Typical Food Processing Validation Program

SCOPE OF VALIDATION PROTOCOL
Equipment and Area to be cleaned Makeup of Validation Team Critical Requirements for validation success Timeline for completion
RECOMMENDED REPRESENTATIVES FOR VALIDATION TEAM
Sanitation Quality Maintenance Engineering
SANITATION STANDARD OPERATION PROCEDURE (SSOP)
Contains cleaning and sanitizing program for system under review Basis for validation design SSOP reviewed and edited by Validation Team on completion of validation
DEFINE SANITATION REQUIREMENTS
Cleaning and Sanitizing equipment/chemicals Personnel required for sanitation operation Timeframe to complete sanitation
DEFINE QUALITY PROGRAM
Visual inspection program Microbiological and/or allergenic tests to be used Collection program of representative samples confirming removal of soil and/or microbial contamination Acceptance Criteria Response to failure of acceptance criteria Addresses short and long term cleaning, sanitizing and repair requirements (Master Sanitation Plan)
IDENTIFY TRAINING REQUIREMENTS FOR SSOP
Sanitation team meetings for each sanitation event in addition to higher level monthly/yearly training Includes safety training, chemical usage associated training on personal protection equipment
DEVIATIONS AND INVESTIGATIONS
Unforseen SSOP issues requiring changes in validation protocol Equipment or facility repair required to meet validation acceptance criteria
FINAL REPORT
Contains data demonstrating effectiveness of SSOP Sign off from validation team representatives and plant management Insure report is accessible to other validation teams

4. Multiple cleaning trials must be evaluated using the developed validation protocol to prove that soil and microbial contamination are removed from the most difficult to clean areas.
5. If this is a new procedure for an old system, a baseline study using the old cleaning and sanitizing protocol and the validation test procedures is recommended to understand whether the new protocol is actually providing a better result than the current protocol.
6. The validation team should evaluate data from the trials, optimize the cleaning and sanitizing method and then determine verification tests and testing frequency required to ensure long-term success of the validated protocol.

Allergen Validation: Prototype for Validation of Food Cleaning and Sanitizing Operations

Validation for cleaning of food allergens can be used to define best practices for cleaning in food production facilities due to the similarity in goals between removal of allergen and removal of microbial contamination (Jackson et al., 2008). As with microbial contamination, allergen contamination can be distributed uniformly throughout food production equipment or it may be inhomogeneously distributed in hard to reach, inaccessible areas in the equipment (examples would be nut particles for allergens or biofilms for microbial contamination). Like allergens, a biofilm contamination may slough off equipment into food products resulting in large but difficult to detect product contamination.

As described above, allergen issues in the general population have required development of new cleaning techniques to ensure the safe removal of allergen proteins. Rigorous validation programs were required in order for the food industry to meet the regulatory requirements (such as the US Food Allergen Labeling and Consumer Protection Act of 2004 and similar strict labeling regulations in many other countries). Current guidelines require certain proteins to be removed to less than a 2ppm residual – a level that is not always measurable by available protein test methods for some allergens.

When a food manufacturer produces an allergen-containing food, a fully validated sanitation procedure needs to be implemented when switching back to production of non-allergen food products. Such a validation of allergen removal, cleaning and sanitizing protocols not only has to take into account uniform allergen residue but also inhomogeneous pieces of an allergen that may not be detected by a general allergen swabbing technique. Standard cleaning methods often fail to remove detectable levels of allergens and special procedures must be developed to completely eliminate residual allergens.

Allergen validations must include evaluation of the complete allergen program. For example, if allergen cleaning is effective but the raw material handling program can permit unintended allergen contamination into a food product (due to labeling issues, employee error, etc.) the work of an allergen validation can be negated.

As with unintended microbial cross-contamination discussed above, a full allergen protection program in a facility requires a carefully planned program to place "hurdles" in front of a contamination source to significantly lower the probability of a contamination incident. In many cases, manufacturers have opted to build separate facilities and developed highly sophisticated raw material labeling and shipping programs to avoid any possibility for contamination.

Setting up a validation protocol to ensure effective cleaning and sanitizing methods for allergen systems usually will require careful planning and a cross-functional team that includes engineering, maintenance and raw material handling personnel in addition to food safety and quality teams to ensure all potential allergen contamination sources are addressed.

It is important to point out that standard cleaning and sanitizing methods can often fail to completely remove allergen soils and that a purging of a system with a non-allergenic food product can often be the only effective way to remove all traces of a contaminant.

Validation of a Cleaning and Sanitizing Protocol

Validation of cleaning and sanitizing protocols for general food production systems should be done with the same level of scrutiny as allergen systems to ensure microbial contamination is not an issue. A full HACCP program is recommended that includes a validation program with appropriate verification tests.

It is important to understand the validation process is, at its core, an experimental process:

1. Validation of a cleaning and sanitizing protocol must identify both the soil to be removed and the pathogen of concern.
2. The validation team needs to make experimental conjectures about what specific cleaning and sanitizing methods will successfully provide hurdles to pathogen contamination of food product.
3. The validation team then needs to ensure that the verification tests represent the most appropriate tests.
4. The areas to be tested for microbial contamination should represent the most difficult areas in the process to clean.

Additionally, validation may require proof that a certain level of microbial kill is delivered throughout the food production area targeted. If a pathogen were to enter accidently into a food production process, would the validated method destroy that pathogen at all process points down to an undetectable level? Such validation testing could use the actual microbial pathogen in the testing but in many cases such testing would be too hazardous to a facility and its personnel and a surrogate system can be used in the validation protocol.

Use of Surrogates in a Sanitizing Validation Protocol

To represent pathogenic contamination, the use of surrogates in a validation study is a common way to ensure a validation protocol will meet regulatory requirements for a cleaning and sanitizing procedure (Kvenberg and Schwalm, 2000). Surrogates are chosen to provide features of a bacterial contamination without having the hazards associated with that pathogenic species introduced into a food production facility. Often food grade microbial species such as yeasts or probiotic bacteria can be directly used to demonstrate a microbial kill step. Other, non-microbial methods can include the use of food dyes, food particles or food grade inorganic particles (calcium carbonate, for example) that are easily detectable visually or can be detected by sensitive chemical or electronic detection methods thus proving contamination can be removed using the cleaning and sanitizing protocol being tested.

Surrogate validation tests need to be well thought out as microbial species should have similar temperature and pH stability to a target microbial species. Non-microbial methods should have a similar dissolution or removal rate as the food soil in the chosen cleaning and sanitizing system being tested. Delivery of the surrogate can be through manual application or added to a food product during manufacture.

Dry Food Production Cleaning Validation

As discussed above, food produced in a dry process environment provides an especially difficult challenge to food producers globally wanting to ensure pathogen-free food product. A sanitation break defines a specific time where food processing equipment has been completely cleaned and sanitized. For a dry food process, a sanitation break has not always been considered to be a required step in a food production process as the lack of water in these environments inhibits microbial growth. Many dry ingredient storage and delivery systems in these food production facilities have gone for years without sanitation breaks (with the focus instead being on elimination of pests). As a result of these practices there is no distinguishable raw material lot that can be used to determine an appropriate recall date for food produced with that raw material.

Validation of a dry sanitation break is critical to permit lot definition for food production (GMA, 2009). A dry process cleaning method, using little or no water and resulting in a sanitation break, would be focused on removal of microbial contamination and not necessarily all evidence of a dry food soil. Validation of such a dry process cleaning method would effectively involve the same validation steps as with wet cleaning. Verification testing on food contact surfaces and environmental surfaces needs to be rigorous and focus on areas most likely to harbor microbial contaminants. The special emphasis in dry facilities needs to be on ensuring water contamination does not occur and that effective sanitizing programs exist when water inadvertently is introduced into these dry environments. The sources of water contamination include unintended sources such as roofs, walls and floor leaks, water piping leaks, condensation inside and outside food production equipment as well as water intentionally brought into a facility by standard food production practices.

To ensure dry process cleaning and sanitizing methods eliminate microbial contamination in the food production equipment itself, surrogates for pathogens (as discussed above) can be especially valuable. For difficult to disassemble areas, sampling of these surfaces during a validation project can be used to prove the surrogate can be removed with a dry cleaning program or deactivated with a dry sanitizing step. Many food grade materials can be spiked into food products, placed in difficult to clean sites and subsequently detected by various methods at high sensitivity (such as proteins, inorganics or flavors) and biologically active but safe food grade yeast and bacterial cultures can be spiked into a food process and detected by standard plating techniques. The use of surrogates can, therefore, provide a safe way to demonstrate that a dry food cleaning and sanitizing process has been effective.

Cleaning Verification Tests

There are numerous verification tests to determine allergen and microbial contamination on food production equipment (Brown, 2009). The Association of Analytical Communities

AOAC Research Institute provides a wide array of validated methods for both allergens a pathogens (AOAC International). These verification tests or similar validated tests shou be used in a validation program to ensure elimination of the desired contaminant.

Sampling for contaminations is typically done using swabbing techniques on hard su faces and analyzing the swabs using the various applicable allergenic or microbial detectio methods. Other techniques include testing rinse water or using air sampling techniques.

Some allergen verification tests include highly sensitive tests that can detect peanuts, gl ten and related grain proteins (gliadin, secalins, hordeins), mycotoxins such as deoxynival nol (DON) in cereals and aflatoxins common in cereals, spices, tree nuts and oilseeds (esp peanuts and raw almonds).

The common bacterial tests include measurements of general bacterial populations suc as total plate count (TPC), total viable count, standard plate count (SPC), aerobic bacte (APC), Gram-positive cultures, thermoduric count, coliforms, Gram-negative bacilli as we as more specific tests such as *E. coli* O157:H7, *Salmonella*, *Listeria*, *Bacillus anthrasis* (anthrax Enterobacteriaceae, *Staphylococcus* and Campylobacters. In addition yeast and mold tests a commonly used in food processing verification, especially for air quality assessments.

Verification tests can be general or specific. Common general tests demonstrate the pre ence of soil in areas of food production facilities and can be very sensitive. Use of genera verification tests are based on the understanding that if no soil is detected, no contaminatio is present. Such sensitive tests include total organic carbon (TOC) which will detect any typ of organic soil. Adenosine triphosphate or ATP-based detection technology will detect an type of food or microbial contaminations (from cell ATP content) but is not specific to th sources of the ATP. The ATP from cells (living or dead) reacting with the luciferase enzym is the basis of swabbing tests that are quick and semi-quantitative, providing a light density based numeric output that can be used for comparative purposes for hard surface soils.

The sensitivity of these ATP detection tests can vary widely, with some extremely sensi tive, and used to detect very low levels of proteins (especially valuable to ensure a low leve of food soil is removed for allergen cleaning verifications). The ATP tests cannot be used t confirm the presence of a specific allergen or pathogen, merely the presence or absence o food or microbial-based soil down to the sensitivity of the specific swab.

Numerous other fluorescence technologies have been employed for identifying pathogens living from dead cells, at high sensitivity. Enzyme-linked immunoassays (ELISA) and enzyme-linked fluorescent (ELFA) techniques have been commonly used for automated detection of specific pathogens. There are numerous techniques for automated testing for specific patho gens and the technologies are getting better and more rapid (Fung, 2002). The ultimate goal for food processing facilities is obtaining test results rapidly enough to permit release of food product from a production facility with minimal need for keeping food product on hold.

CONCLUSIONS

This chapter has reviewed the different aspects of food production facility cleaning and sanitizing programs, SSOP development as well as chemical and non-chemical systems used for cleaning and sanitizing. Automated or manual cleaning and sanitizing requires an understanding of where soil and microbial contamination can reside in a food processing

system. CIP, COP and environmental cleaning systems and the associated cleaning and sanitizing chemistry and procedures for food production facilities are discussed. Additionally, common problems encountered in food production facility cleaning and sanitizing programs as well as validation and verification programs are reviewed. Special topics include cleaning and sanitizing considerations and associated validation programs for allergen issues and dry food environments.

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CHAPTER

28

Personal Hygiene and Health

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OUTLINE

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RISKS OF OUTBREAKS ASSOCIATED FROM INFECTED FOOD WORKERS

Outbreaks Contributed by Food Workers

A food employee or worker is someone who works with unpackaged food, food equ
ment, kitchen utensils or food contact surfaces. A food handler may be perceived
someone who simply handles food but for this chapter all these terms are synonymo
Outbreaks involving infected food workers in many foodservice settings have been wide
reported, with some resulting in many cases and deaths. In fact, food workers have probab
been implicated in spreading foodborne disease ever since food was prepared and serve
The case of Mary Mallon (Typhoid Mary), who was a chronic carrier of *Salmonella* Typh
is an extreme example of the risks of colonized food workers infecting others. She is attri
uted to causing 47 illnesses and three deaths in the New York area between 1906 and 19
During Mallon's temporary confinement from 1907 to 1909, health officials had analyz
stool samples from her approximately once a week. The samples came back with *S.* Typhi
120 of 163 samples tested. In the early 1920s, Tony Labella, a food handler in the New Yor
farming community, may have actually caused more illnesses and deaths, since he was als
a chronic *S.* Typhi carrier. These were the years when typhoid was endemic in the USA, an
there were probably many other undocumented carriers who spread typhoid fever.

A review of foodborne disease outbreaks worldwide shows that food workers hav
been responsible for many of these outbreaks (Greig et al., 2007; Todd et al., 2007a, b
2008a, b, 2009). These authors collected 816 outbreak reports comprising 80,682 cases fro
events spanning 1927 to the first quarter of 2006, with most of these occurring in the las
three decades. These outbreaks were caused by 14 agents: norovirus, Norwalk-like virus
or probable norovirus (338), *Salmonella enterica* (151), hepatitis A virus (84), *Staphylococcu*
aureus (53), *Shigella* spp. (33), *Streptococcus* Lancefield groups A and G (17), and the para
sites *Cyclospora*, *Giardia*, and *Cryptosporidium* (23). It appears from these data that the fre
quency of streptococcal, staphylococcal and typhoid outbreaks diminished over time, thos
involving hepatitis A virus (HAV) saw little change, but those with norovirus and maybe
non-typhoidal *Salmonella* were increasing. The terminology of norovirus has changed ove
time from Norwalk or Norwalk-like or small round structured viruses and may in the pas
have included other similar viruses. Today norovirus (NoV) is the organism of most con
cern, because it is frequently spread person to person in the community, has a low infectiou
dose and has been implicated in many foodborne outbreaks where food workers have been
found to be infected.

In some cases, the worker may have been a victim rather than the cause of the infection
becoming ill at the same time as the customers or later. In other situations, the worker bla
tantly disregarded normal hygienic practices, which may have been a result of inappropri
ate individual actions or the accepted way of doing business in the establishment. Practices
leading to these actions have previously been documented, such as workers being asymp
tomatic carriers and excreting the pathogen unknowingly while working, or they con
tinued to prepare food when it is obvious to them, and sometimes others, that they were
ill with a high probability of contaminating food. Some of the outbreaks were very large
11 involved more than 1000 persons, four with more than 3000 ill. The larger outbreaks

tended to be extended over several days with a continuing source of infections, such as at festivals, resorts and community events, or the contaminated product had been accessed by a large number of customers. There were five outbreaks with more than 100 persons hospitalized, with attack rates ranging from 9.9 to 100%. However, overall, the hospitalization rate was low (1.4%), and deaths were rare (0.11% of the documented 80,682 cases). Many of the deaths were associated with high-risk persons (i.e. those who had underlying diseases, malnutrition, or both, as in a refugee camp, or young children), but a few occurred with apparently healthy adults. Unfortunately, and there is no indication that worker-related illnesses are diminishing. For instance, a study by the Indian Public Health Association in 2012 found *E. coli* on the hands of nearly 11.2% of those who handle food in five star hotels, 47% of chefs and waiting staff in smaller restaurants, and 84.7% of food vendors in roadside eateries (Narayan, 2012). In addition, 11.2% of these roadside vendors carried amebic cysts that can cause amebiasis, the third most common cause of death in India from parasitic infections.

Food Operations and Foods Implicated

An analysis of the settings for the food worker-related events in the above-mentioned study showed that most of the outbreaks came from foodservice facilities (46.1%), followed by catered events (15.4%), the home (10.2%), schools and child care centers (6.0%), and healthcare institutions (5.3%). The single most frequently reported setting was restaurants. Case numbers in outbreaks in homes or at community events are probably underestimated because they are less likely to be reported than those involving commercial establishments.

Large outbreaks frequently occurred because of the continual exposure of large groups to a pathogen, either because the source had not been identified soon enough or because control measures had been insufficient to eliminate the agent, such as at refugee camps or large outdoor events. However, in several other large outbreaks, the amount of contaminated food was so great that thousands of persons were exposed by the same batch of food; this occurred with frosting on cakes, imported raspberries used in a variety of dessert dishes, and items served at large receptions or commissaries. The agents in large outbreaks also tended to be highly infectious, such as *Shigella* or NoV. Because ready-to-eat (RTE) foods are not further processed or cooked, subsequent contamination by infected food workers frequently led to outbreaks. These included produce and baked goods, as well as beverages that would not normally allow the growth of pathogens. However, many of these were of viral origin with sufficient particles to cause an infection without further multiplication. Foodservice outlets, such as restaurants, catering companies and schools that served large numbers of patrons, were the most frequent settings implicated. However, episodes linked to bakeries, hospitals, camps, homes and church meals highlighted the necessity for those who prepare and serve meals in these operations to excuse themselves from food preparation if they are ill or exposed to infected individuals. There were 18 outbreaks associated with commercial travel in air flights, trains and cruise ships over several decades, although only the last seems to be a major concern today. There are several outbreaks every year from cruise ships; often with >2000 passengers per ship, who could be more likely the source of an enteric infection than the crew; staff typically ask illness questions before embarkation and squirt an antiseptic on hands of cruisers before they eat. How effective these practices are is uncertain but they do alert passengers of the risks of spread of foodborne infections in close quarters.

FACTORS CONTRIBUTING TO OUTBREAKS

The most frequently reported factor associated with the involvement of the infec worker was bare hand contact with the food, followed by failure to properly wash hand inadequate cleaning of processing or preparation equipment or utensils, cross-contaminatio of RTE foods by contaminated raw ingredients, and (for bacterial pathogens) temperatu abuse. Many of the workers were asymptomatic shedders or had infected family membe and/or used improper hygienic practices. Outbreaks were sorted into categories based o how many workers were implicated, the origin of the infective agent (outbreak setting or si site), the degree of certainty that the worker(s) were the cause or were victims, whether o not the workers denied illness, the ability of the agent to grow in the food, whether only th workers and not the patrons were ill, and whether patrons were more responsible for the illnesses than the workers. The most frequent scenarios were (1) a single worker causing a outbreak by directly infecting customers; (2) an infected worker contaminating foods fro feces, typically after toileting, that were then temperature abused, leading to an outbreak and (3) multiple workers linked to an outbreak, but with no clear initiating source.

EXAMPLES OF OUTBREAKS CAUSED BY FOOD WORKERS

A few examples suffice to indicate the type of food worker contamination that can lead to outbreaks (Todd et al., 2007a). In 2000, 37 students at a Minnesota college developed gastrointestinal symptoms from 25 April to 1 May, with most on 26–27 April. Illness was associated with consuming any cold salad bar items from the dining service at the college cafeteria on 25–27 April. The index case was a food preparer who reported developing vom iting and diarrhea on 23 April after being exposed to children who also were vomiting and had diarrhea on 22 April. This person called in sick on 24 April and symptoms resolved later that day. The employee then returned to work on 25 April and worked the remainder of the week in the salad bar section of the dining service, with extensive bare-hand contact of salad items during preparation and stocking of the salad bar with lettuce, salad toppings and cut fruit. Additional cases, with onset after the weekend of 29–30 April were likely due to secondary spread of viral infection within dormitories and other campus settings. The Department of Health categorized the agent as viral based on the epidemiological informa tion available, but no specific agent was isolated. An ill call-in log was useful in determining dates that employees were ill and to ascertain the responsible employee.

In Los Angeles County in the same year, an increase in *Salmonella* Thompson infections was noted with most cases dining at a restaurant chain before developing illness (Kimura et al., 2005). A case–control study implicated burgers eaten by 23 individuals at the fast food restaurants. In addition, hamburger buns were also served at a catered luncheon and at three other restaurants where a further 15 *S.* Thompson cases were reported. The index case was a burger bun packer at a bakery that supplied buns for the chain, but she had not eaten at the restaurant chain. This full-time employee was responsible for removing freshly baked bread and buns from the cooling rack, feeding them through an automatic slicer and packaging them for distribution. She did not wear gloves and handled every individual bread item (notably hamburger buns) at least twice with her bare hands. She worked from

the day of illness onset on 13 July until she required overnight hospitalization on 17 July. She resumed work after hospital discharge on 18 July and continued working until termination of employment on 23 July. Although stool specimens were taken during her hospitalization, the results were not reported until 31 July, 2 weeks after onset of illness. The patient's brother, also employed at the bakery, became ill on 17 July, and continued to work while ill until he was removed from work on 3 August. Presumably she infected him either through contact or through consumption of buns handled by her. He was mainly responsible for mixing dough but did some rotation of duties that would allow contamination of bread items. The bakery did not offer any formal training on safe food-handling practices. Furthermore, although many of the employees spoke only Spanish, the procedure manuals were written in English. As indicated above, low water activity does not allow bacterial growth in most baked goods or the ingredients of cake frosting but there were a surprising number of outbreaks, some very large, associated with contaminated icing or frosting on cakes and glazing on pastries. Direct contact between contaminated hands or arms and the ingredients was enough to transfer NoV, HAV, *Salmonella*, *S. aureus* and rotavirus to the products in sufficient quantity to cause illness. Examples of these are: (1) 414 people were ill with NoV after eating pastries served in a Winnipeg hotel; (2) 68 cases of HAV were associated with eating buns and pickles handled by a worker in a Chattanooga fast food restaurant and who was an intravenous drug user; and (3) 12 HAV cases derived from an infected cook who contaminated cream while preparing pastries in a Glasgow restaurant (Greig et al., 2007).

Some outbreaks involving food workers are international in scope (Todd et al., 2007a). For example, *Salmonella* Brandenburg was responsible for illnesses in 232 passengers, 27 cabin staff and 31 aircrew in 45 flights originating in Paris for many parts of the world, including the United States, Canada, the Caribbean, Egypt, Senegal, Japan, Venezuela, Brazil, Russia and eight other European countries in April 1976. The illnesses occurred from 6 to 11 April, and an alert was only triggered when an aircrew on a 9 April flight was concerned about the ill people. However, despite this alert, meals continued to be prepared and served until 11 April, and many more passengers are thought to have become ill than the 290 eventually reported to the authorities. The organism was isolated from a variety of cold foods, primarily fish. Only one of the 200 employees of the catering firm in Paris tested for the pathogen had *S.* Brandenburg isolated from the stools but this person had prepared these cold dishes. Unfortunately, this employee was not recognized by the regular inspection and testing program in the establishment despite the fact that their surveillance program had resulted in 14 suspensions of staff who had infections over the previous 2 years.

More recently, outbreaks from June to September 2005 of norovirus infection in Denmark were linked to frozen raspberries imported from Poland. All outbreaks occurred in institutions or commercial catering settings. A cold dessert dish prepared from frozen raspberries, which had not been heated, had been served one day before the start of each outbreak. In the first five outbreaks, frozen raspberry pieces had been used, which could be traced to the same large batch imported to Denmark from Poland in the spring of 2005. In the last outbreak in September, the frozen raspberries had been supplied by a different Polish producer to a different Danish importer and made into a traditional Danish dessert of buttermilk, fromage frais, sugar, vanilla and raspberries. With 1143 cases in total, these raspberries caused the largest number of foodborne infections attributable to a single vehicle in Denmark in

many years. Delays in the implementation of a recall after the first large outbreak of 450 pe ple in a hospital resulted in a second large outbreak among elderly clients of a meals-o wheels service in early June. An estimated 400 mainly elderly people were affected and least 23 required hospitalization. Surprisingly, three different genotypes of norovirus we found in the six outbreaks. As Polish frozen raspberries were exported to several Europe countries, outbreaks due to frozen raspberries would be expected beyond Denmark but no of Polish origin was reported. Contamination with norovirus may have occurred at fa level by fecally contaminated irrigation water, during harvesting by infected farm worke and/or during processing and freezing by infected workers at company level. The hypoth esis was that several independent contamination events took place, thus explaining the he erogeneous distribution of norovirus strains in the Danish shipments. Infected workers the harvesting or processing of the raspberries in Poland were a likely but not proven sourc

PATHOGENS CARRIED BY FOOD WORKERS

Sources of Pathogens

The human body has several means of transmitting infections from body orifices, p marily fecal, nasal and skin sources (though urine can be a transmitter of HAV), becaus these are exposed to the external contaminated environment through air, water, food an contact with other humans and animals. Sources of pathogens, therefore, include vomitu diarrhea, nasopharyngeal or oropharyngeal secretions, often being transmitted to food o food contact surfaces. The likelihood that workers cause illness in patrons and fellow work ers depends on several factors: the numbers of organisms required to initiate an infection the site of colonization and the length of their carriage in infected persons. Pathogens o nose, throat, skin or fecal origin are most likely to be transmitted by the hands (particularl fingertips and palms), as hands are the parts of the body that frequently touch the mouth skin and anal areas. The pathogens most likely to be transmitted by food workers are Nov HAV, *Salmonella*, *Shigella* and *Staphylococcus aureus*. Unfortunately, such pathogens can be i high numbers in or on the body during an infection. This is particularly true for intestina infections where levels can reach 10^{11} infectious cells or particles per gram of feces, although 10^5–10^9/g is more frequent. Some pathogens appear to be able to infect at doses as low as 1 to 100 units, including viruses, parasites and some bacteria. Although parasitic foodborne episodes of illness are rare, the dose for *Cyclospora*, *Cryptosporidium* and *Entamoeba* may be as low as one cyst/oocyst. Based on outbreak data and other infectious disease studies, other pathogens with low minimum infections doses are *Campylobacter*, *E. coli* O157:H7, *Salmonella* Typhi (and a few other *Salmonella* serotypes), *Shigella dysenteriae*, HAV, NoV and rotavirus (<100 CFU or particles). Interestingly, only rarely have *Campylobacter*, *E. coli* O157:H7 and other *E. coli* serotypes been implicated in food worker-associated outbreaks.

Incubation Periods

For ill persons, these can range from a few hours, e.g. *S. aureus* enterotoxin, to many weeks, e.g. HAV and *S.* Typhi. The longer the incubation period, the more opportunities

there are that an infected person will excrete the pathogen. This is equally important for a worker's contact persons, mostly likely the family or fellow workers, who may be the persons initially infected and excreting. The duration of illnesses is important too. Gastroenteritis symptoms may last many days or even weeks or months, e.g. chronic diarrhea, as in cases of infection with *Salmonella* Typhi, *Shigella* spp., HAV and the protozoan parasites. Since employees want to return to work quickly after illness, and they do not usually receive paid sick leave, they may work while continuing to be ill or only having mild symptoms like occasional diarrhea, without reporting their conditions to management. Post-symptomatic long-term shedding can also occur with *Campylobacter*, *Salmonella*, *Shigella*, *V. cholerae*, *Yersinia*, enteric viruses and parasites.

Fecal Contamination of Hands

Lack of hand hygiene compliance means that fecal contamination of fingers and hands is not uncommon (Todd et al., 2010e). Maybe it is not generally understood that the fecal–oral route is the main source of enteric infection from pathogens present in the feces of ill, convalescent or otherwise colonized persons because no visible feces is present on fingers or hands after normal defecation. It is difficult for managers of food operations to identify food workers who may be excreting pathogens, even when these workers voluntarily report their illnesses (whether there is a policy for reporting illnesses or not), because workers can shed pathogens during the prodrome phase of illness or can be long-term excretors or asymptomatic carriers. Some convalescing individuals have excreted *Salmonella* for 102 days, and most individuals infected with viruses remain asymptomatic while discharging infective particles into their surroundings. Fecal contamination on the hands is linked to the limited effectiveness of toilet paper use. The fecal mass on fingers after defecation has been estimated from $10^{-5.6}$ g to >1 mg (Todd et al., 2008b). This means that there could be 10^{3-4} fecal coliforms present on hands when initially contaminated, and pathogens if present could be in substantial numbers (Table 28.1). There is limited information on carriage rates before, during and after illness and in asymptomatic individuals. Carriage rates range between <1 and 36%, and shedding can occur many days before symptoms appear, making exclusion of excreting employees from the food environment very difficult. The soil matrix, relative humidity and temperature all influence pathogen survival. Declines can be rapid on hands, but most pathogens that cause foodborne illness survive long enough on hands and contact surfaces to allow some transfer to food or fellow workers during a shift. *Salmonella* can survive for several hours on fingertips if they are not washed. Non-enveloped viruses such as NoV, rhinovirus and enterovirus are more stable on skin than are viruses with envelopes, such as the influenza virus.

HYGIENIC PRACTICES OF FOOD WORKERS

Spread of Pathogens in the Food Industry

Personal hygiene is critical to reduce the opportunities for pathogen transmission. This is of particular concern in the food and healthcare industries where food is served and

TABLE 28.1 Levels of Pathogens in Clinical Specimens and Body Excretions

Pathogen	Source of Contamination	Contamination (level/g or ml)
Salmonella	Feces, while ill or early convalescence	10^5–10^7 CFU
	Feces, in late excretion period	10^5–10^3 CFU
	Infants excrete longer than adults	
	Feces, while in convalescence	6×10^3 CFU 15 days after illness $5 \times 10^{2-6} \times 10^7$ CFU (median, 6.0×10^6 CFU) <10 days after illness 1.3×10^2–1.6×10^8 CFU (median, 1.0×10^5 CFU) 10–19 days after illness $<10^2 \times 3.5 \times 10^8$ CFU (median, 2.5×10^4 CFU) 20–25 days after illness 7.0×10^1–1.8×10^5 CFU (median , 1.4×10^2 CFU) 6–35 days after illness 2.0×10^0–3.5×10^4 CFU (median, 5.5×10^1 CFU) 42–50 days after illness $<10^{0-6} \times 10^4$ CFU (median, 2.5×10^4 CFU) 69–102 days after illness
S. aureus and streptococci	Pus in infected lesions	10^7–10^8 CFU (median) for intra-abdominal and anorectal and soft tissue infections (one sample with almost exclusively *S. aureus* and two with beta hemolytic streptococci)
S. pyogenes	Saliva in a sneeze from carriers	Typical person infected with streptococci: saliva 10^0 to 10^6 CFU; <100 CFU/154 sq. cm. 1.5–9.5 feet from sneeze source One carrier sneezed twice (Day 1 and Day 6): saliva 3.2–7.5 × 10^6 CFU; 23–500 CFU/154 sq. cm. 1.5–9.5 feet from sneeze source; 50% of the streptococci remained in the air 10–15 min after the sneeze (10–16 min after sneezing 10^1–10^3 streptococci were cultured 9.5 feet away). A nose blow from a carrier into a handkerchief yielded 2.4×10^7 CFU material from posterior pharynx compared with 3.8×10^4 CFU saliva
S. pyogenes	Saliva in a cough from carriers	10^3–10^6 CFU (1/20 persons infected with streptococci coughed 6 CFU streptococci/154 sq. cm. 9.5 feet from cough source; most of the other 19 did not cough any streptococci)
Enteroviruses (coxsackie virus, echovirus, polio virus, etc.)		10^3–$10^{7.5}$ infectious particles, $10^{8.2}$ infectious particles
Hepatitis A virus	Feces, highest numbers before symptoms begin	10^9 virions 10^8 infectious particles

(Continued)

TABLE 28.1 (Continued)

Pathogen	Source of Contamination	Contamination (level/g or ml)
Norovirus Group G-I	Feces, while ill[a]	2.2×10^4 to 2.9×10^{10} copies/g fecal specimen, median = 8.4×10^5
Norovirus Group G-II		2.5×10^4 to 7.7×10^{10} copies/g fecal specimen, median = 3.6×10^7
Norovirus Group G-I		GI 2.79×10^7 copies/g of stool
Norovirus Group G-I/4		GI/4 2.02×10^8 copies/g of stool
Norovirus Group G-II		GII, 3.81×10^8 copies/g of stool
Norovirus Group G-II/4		GII/4 7.96×10^8 copies/g of stool
Rotavirus	Feces and vomitus while ill	10^{11} particles excreted but only 10^6–10^7 infectious
		100 times more virus in vomitus than feces
		8×10^9–10×10^9 infectious particles
		$>10^{12}$ infectious particles
		10^{10}–10^{12} in feces
Cryptosporidium spp.		10^6–10^8 oocysts in a single bowel movement
		10^6–10^7 oocysts
		3×10^9 oocysts/day
Giardia lamblia/intestinalis		$<10^9$ cysts daily in stools
		1–5 $\times 10^6$ cysts

Information from Todd et al. (2008b); CFU = colony-forming units.
[a]Levels in vomitus not known but assumed to be similar to those in stools.

people and patients touched. An extensive series of reviews of factors contributing to outbreaks by food workers and how they spread diseases revealed a composite list of problems uncovered during the investigations (Greig et al., 2007; Todd et al., 2010d). The major concerns focused on (1) hand washing, (2) sanitation of food contact surfaces, (3) facility-wide hygiene education and training, (4) incentives for workers to report their illnesses, (5) surveillance of the work force by management, and (6) regular professional screening of employees for illness, including nasal and stool samples obtained from staff returning from overseas travel. Food workers have been implicated in outbreaks of foodborne illness, and hands contaminated by human or animal feces are a well-recognized mode of pathogen transfer; sneezes, coughs, infected skin lesions and vomitus also have transmitted pathogens from workers to food, patrons and fellow workers. Physical barriers such as food shields (sneeze guards), utensils and appropriate protective clothing have value but are insufficient to completely prevent contamination of food or food contact surfaces by body secretions. By far the most important action to avoid contamination of food is the cleanliness of the hands.

Widespread lack of attention to any kind of major promotional campaign of hand hygiene was reinforced when the US Food and Drug Administration's (FDA) National

TABLE 28.2 FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant and Retail Food Store Facility Types (US FDA, 2009b)

Facility Type	Proper, Adequate Hand Washing (%)	Good Hygienic Practices (%)	Prevention of Contamination from Hands (%)	Hand-washing Facility, Convenient/ Accessible (%)	Hand-washing Facility, Cleanser/ Drying Device (%)
RESTAURANTS					
Fast food	38.8	22.5	26.3	18.4	15.5
Full service	75.8	24.2	46.3	29.2	29.2
RETAIL STORES					
Delicatessens	52.0	13.3	6.3	17.4	13.3
Meat and poultry	18.4	1.1	0.0	6.1	6.1
Seafood	21.6	5.3	2.9	7.3	7.3
Produce	24.6	9.9	6.3	15.6	17.7
INSTITUTIONAL					
Hospitals	35.6	13.3	9.0	23.3	4.4
Nursing homes	34.4	12.1	12.5	12.9	8.6
Elementary schools	27.5	11.8	8.6	21.5	5.4
Total	**18.4–75.8**	**1.1–24.2**	**2.9–46.3**	**6.1–29.2**	**4.4–29.2**

etail Food Team conducted the third phase of a three-phase,10-year study to measure the occurrence of practices and behaviors commonly identified by the US Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks: food from unsafe sources; poor personal hygiene; inadequate cooking; improper holding/time and temperature; and contaminated equipment/protection from contamination (US FDA, 2009b). FDA Regional Retail Food Specialists collected data during site visits of over 800 establishments representing nine distinct facility types (Table 28.2). Direct observations, supplemented with information gained from discussions with management and food employees, were used to document the establishments' compliance status. The operational areas most in need of improvement were employee hand washing, time–temperature control for safety foods, date marking of RTE foods and cleaning and sanitizing of food contact surfaces. Unfortunately, lack of compliance of personal hygienic practices has changed little over time (Todd et al., 2010e). Auxiliary factors contributing to the lack of proper hand washing were the lack of convenient hand-washing facilities and/or supplies of hand cleanser/drying devices; temporary placement of mobile equipment in front of a hand sink and the use of hand-washing facilities for other purposes. Avoidance of employees eating, drinking and smoking in food preparation areas and working while experiencing persistent coughing and sneezing are critical to prevent pathogen transmission to foods and food

TABLE 28.3 FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant and Retail Food Store Facility Types; Effect of Manager Certification on Compliance of Personal Hygiene (US FDA, 2009b)

Facility Type	Total Observed	% In-Compliance	Total Observed	% In-Compliance	Difference (% In-Compliance)
Hospitals	65	72.3	384	84.6	12.3
Nursing homes	165	85.5	290	83.1	−2.4
Elementary schools	168	86.3	295	84.4	−1.9
Fast food restaurants	186	72.0	319	78.1	6.0
Full service restaurants	**237**	**50.2**	**240**	**67.9**	**17.7**
Delicatessens	**153**	**69.9**	**335**	**83.9**	**14.0**
Meat and poultry	156	91.7	273	94.1	2.5
Seafood	125	86.4	257	93.4	7.00
Produce	127	75.6	265	89.4	13.8

NOTE: Bold facility types had overall in-compliance percentages that were significantly higher in establishments with a Certified Food Protection Manager.

contact surfaces. Improper employee actions could be attributed to a lack of knowledge and/or commitment to proper sanitation and controlling microbial growth.

Reinforcing the importance of hand washing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of hand-washing practices as well as provision of physical infrastructure to facilitate hand washing. Alwood et al. (2004) conducted a survey of retail food establishments to investigate the effect of hand-washing training, availability of hand-washing facilities and the ability of the person in charge (PIC) to describe hand washing according to the Minnesota Food Code on workers' ability to demonstrate food code-compliant hand washing. Only 52% of the PICs could describe the hand-washing procedure outlined in the food code, and only 48% of workers could demonstrate code-compliant hand washing. The most common problems observed were failure to wash for 20 seconds and failure to use a fingernail brush. There was a strong positive association between the PIC being a certified food manager and being able to describe the food code hand-washing procedure, and there was an even stronger association between the PIC being able to describe hand washing and workers being able to demonstrate code-compliant hand washing. Significant associations were detected among correct hand-washing demonstration, physical infrastructure for hand washing and the hand-washing training methods used by the establishment. However, the principal determinant of successful hand-washing demonstration was the PIC's ability to describe proper hand-washing procedure. This is consistent with the results of the FDA studies that the presence of a certified food protection manager is positively correlated to the overall in-compliance percentages in certain facility types, especially in delis, full service restaurants, seafood departments and produce departments (Table 28.3).

Poor personal hygiene, improper holding/time and temperature and contaminat equipment/protection from contamination appear to be the risk factors for which the pre ence of a certified manager had the most positive correlation. This indicates that manag ment can have a positive influence on personal hygiene and other factors relating to foo safety in foodservice establishments. Foodservice and retail food store operators mu ensure that their management systems are designed to achieve active managerial co trol over the risk factors, and regulators must ensure that their inspection, education an enforcement efforts are geared toward the control of the risk factors commonly found to b out of compliance.

Specifically, in the 2009 FDA report of a US national survey of 850 US food establishment for a variety of risk factors reported that observations of poor personal hygiene were exte sive but varied across facility types: restaurants (fast food, 24.2%; full service, 40.9%); reta food establishments (delicatessen departments, 20.5%; meat and poultry departments, 6.8% seafood departments, 8.9%; produce departments/markets, 15.1%); institutional foodse vice facilities (nursing homes, 16.0%; hospitals, 17.1%; elementary schools, 14.9%) (US FDA 2009b).

The types of poor hygienic practices were categorized into five areas. These were (1) proper, adequate hand washing (hands are clean and properly washed when and a required); (2) good hygienic practices (food employees eat, drink and use tobacco only in designated areas/do not use a utensil more than once to taste food that is sold or served/ do not handle or care for animals present; food employees experiencing persistent sneez ing, coughing or runny nose do not work with exposed food, clean equipment, utensils, lin ens, unwrapped single-service or single-use articles); (3) prevention of contamination from hands (employees do not contact exposed RTE food with their bare hands); (4) convenient and accessible hand-washing facilities (hand-washing facilities conveniently located and accessible for employees); and (5) hand-washing facility, cleanser/drying device (hand- washing facilities supplied with hand cleanser/sanitary towels/hand-drying devices). Table 28.2 indicates the out-of-compliance actions related to these. All these were critical issues to avoid transmission of pathogens, and the levels of out-of-compliance observations were mostly too high. By far the most important was inadequate, improper hand washing (184- 75.8%); these were followed by inconvenient or inaccessible hand-washing facilities, contact of RTE food with bare hands and lack of good hygienic practices.

The availability of hand soap and sanitary towels/hand-drying devices, though not directly linked to human illness, is an essential component of the management system needed to ensure proper hand washing. Also, this study shows the difference in attitudes to personal hygiene in the different food settings. Unexpectedly, full service restaurants came off worst compared with other facilities and institutions with over 75% no or poorly observed hand washing, almost 50% seen with bare hand contact with RTE food, almost 30% for hand-washing facilities for employees inconveniently located, inaccessible or not supplied with hand cleanser/sanitary towels or hand-drying devices, and almost 25% for inadequate good hygienic practices by employees in general. Even within retail stores some departments demonstrated better hygienic practices than others; the number of observed inadequate hand washing was twice that for delicatessens than in the other departments; this may reflect the attitude of employees that slicing, handling and displaying deli meats carried less of a risk than working with raw meats, seafood and produce.

PRACTICAL ASPECTS OF HAND HYGIENE

Rationale for Hand Washing to Avoid Transmission of Pathogens

Hand washing removes dead skin cells, sweat, sebaceous secretions, associated resident bacteria, transient microorganisms and any organic material adhering to the hands. The transients are the more important to remove as they include the pathogenic bacteria, viruses and parasites obtained through contact with other persons (and their own body fluids), the environment (including water, sewage and animals), unprocessed food or ingredients and food contact surfaces. An effective hand-wash method should remove most of these, facilitated by the use of soaps, detergents and antimicrobial compounds (Todd et al., 2010c). However, hand washing never achieves sterility because of the presence of the resident skin flora; and hands can become recontaminated with transients immediately after the washing and drying process. The efficacy of microbial removal depends on the type and level of microbial and organic matter contamination present, the use of potable versus non-potable water, the wash time, the type and volume of antiseptic (soap/detergent/alcohol gel) used, the extent to which the fingers, palms, backs of hands, subungual area beneath the nails, and wrists are exposed to the washing process, and the amount and vigor of the rubbing of fingers and palms during rinsing.

Diarrheal and respiratory infections can be reduced where hand hygiene programs focus on frequent washing with soap and water and/or use of alcohol antiseptics. Thumbs, palms, spaces between fingers and fingertips (including the fingernail area) are areas where contamination is most likely to remain. A hygienic water source, typically potable water from a piped system or deep well, is vital for effective hand washing. Even in developing countries with limited resources, spread of disease can be limited by proper hygiene. In regions where sanitary waste disposable systems are limited, safe stool disposal (a primary barrier to transmission) may be more important than hand washing before eating, which constitutes a secondary barrier. Additional information and recommendations for hand hygiene are available from Boyce and Pittet (2002), although these apply to healthcare employees and are not for food processors, preparers or servers.

Removal of Soil

The first step in hand washing is removal of the bioburden, typically visible dirt or contamination with proteinaceous material, blood, other body fluids (e.g. fecal material or urine) or food (e.g. meat protein). Water soluble material is easier to remove than fat, oil or grease, but soaps can facilitate the removal of these lipid substances. Hand hygiene practices of food workers are dependent on the type of work involved and the type and nature of the soil. The contamination level of hands after toilet use, changing diapers or handling contaminated raw foods and food packing material can all contribute to soil containing up to 1 million enteric bacteria per hand. Most surface microorganisms are easily flushed off with washing, but some remain in cracks, crevices, skin folds and nail regions.

To reduce the potential for bacterial transfer, food workers may need to wash their hands for longer than 15 seconds or may need to wash more often. Thorough rinsing is important because this action also removes potential skin irritants and contact sensitizers originating

in food, soaps, metals and facility disinfectants that could lead to dermatitis. Rinsing w hot water (>120°F/49°C) may cause scalding, irritation, pain, removal of the protective l layer, cracking, fissures and possible pathogen colonization, which can discourage fu hand washing and result in subsequent increases in microbial counts on hand surfaces.

Food employees should clean their hands in a designated hand-washing sink approved automatic hand-washing facility and not use other wash facilities such as a s used for food preparation, janitorial purposes or ware washing. Employees may use sin for hand washing in toilets common to both patrons and employees if approved by t health authority.

Hand Hygiene Antiseptic Products

Hand hygiene is a general term that applies to hand washing, an antiseptic hand was an antiseptic hand rub or surgical hand antisepsis. An antiseptic agent is an antimicrob substance applied to the skin to reduce the microbial flora or inhibit the growth of micr organisms (Todd et al., 2010d). Examples include alcohols, chlorhexidine gluconate, chl rine derivatives, iodine, parachlorometaxylenol, chloroxylenol, quaternary ammoniu compounds and triclosan. Antiseptics were formerly called sanitizers in some settings, an the term is still in use today. Soaps loosen dirt and remove microorganisms from hands the home, the healthcare environment and food processing and foodservice operation Soap acts as an emulsifier, suspending oil and dirt and allowing them to be washed aw decreases water surface tension and binds to dirt, oil and bacteria. Hard water reduces th effectiveness of soaps. Detergents (surfactants) are compounds that possess a cleaning actio They are composed of hydrophilic and lipophilic parts and can be divided into four group anionic, cationic, amphoteric and nonionic. Detergents are often referred to as soaps in eve ryday language. Plain soap is a detergent that does not contain antimicrobial agents or th contains very low concentrations of antimicrobial agents that are effective solely as preserva tives. Strong detergents are more effective than soaps for cleaning with hard water becaus these detergents contain a synthetic surfactant and other chemicals that may improve th cleaning ability. Such detergents are not usually used for hand cleaning. Milder detergent are the most frequently used agents for hand washing and are typically called soaps.

Antimicrobial soap (or detergent) contains an antiseptic agent at a concentration suf ficient to reduce or inhibit the growth of microorganisms. These inactivate pathogens more effectively than does soap alone. Triclosan, triclocarban-trichlorocarbamide and parachlorometaxylenol-chloroxylenol are commonly used for their antibacterial and deo dorant activities in consumer cleansing products. However, removal of transient microor ganisms with either plain soap or soap with an antibacterial compound is not significantly different. However, soaps that include a disinfectant are additionally effective at lowering the resident organism population.

Adequate exposure time is also important for soaps with antimicrobial compounds to be effective. For instance, after repeated use over several days, the residual effect of chlorhex idine gluconate (CHG) substantially reduced the normal skin microflora.

When frequent hand washing is needed, a gentle product is required for acceptance by personnel. Soaps should have good lathering ability, acceptable scent and consistency, and should not contain components that will cause skin irritation or dryness. The effectiveness

of these nonantimicrobial soaps can be improved with longer wash time and greater soap volume. Moisturizers and emollients are materials added to hand creams to improve their performance and the feel of the skin. Moisturizers add moisture to the skin, and emollients provide a softening or soothing effect, smoothing dry and scaly skin areas.

Waterless antiseptic agents do not require the use of exogenous water. The term includes different types of hand rubs (liquid formulations, gels, foams, leaflets, towelettes and wipes). An alcohol-based hand rub contains alcohol (in a lotion, rinse, gel or foam) and is designed for application to the hands to reduce the growth of microorganisms. After application, the individual rubs the hands together until the agent has dried and by this process reduces the number of viable microorganisms on the hands. Such preparations may contain one or more types of alcohol with excipients (inactive substances used as carriers for the active ingredients of a medication), other active ingredients and humectants (emollients or moisturizers, e.g. propylene glycol).

Effect of Friction during Hand Washing

Friction is well known as one of the most important elements in hand washing, dislodging microflora from the skin surface during both the washing and rinsing stages. Unfortunately, any aspect of the hand-washing process that decreases friction (e.g. soft water versus hard water, soft bristle brushes versus coarse bristle brushes) and any type of soap by its nature will reduce the mechanical removal of any microflora, particularly when hands are soiled. Wipes also decrease friction.

Cleaning Long and Artificial Fingernails

Outbreaks have been linked to workers with long or artificial fingernails, which are very difficult to clean even with appropriate soaps, hand rubs or gels. The greatest reduction of inoculated microbial populations is obtained by washing with liquid soap plus a nailbrush, and the least reduction was obtained by rubbing hands with the alcohol gel. Because nail polish or varnish can chip off and fall into food, and any cosmetic item that can be brushed or fall off, there should be a policy that no staff are allowed to wear nail polish, varnish, fake fingernails or false eyelashes in food processing and preparation areas. Another reason for banning fingernail polish is because chipped fingernail polish or fingernail polish worn for more than 4 days fosters increased bacterial numbers on the nails. These results indicate that best practices for fingernail sanitation by food workers include maintaining short fingernails and scrubbing them with soap and a nailbrush while washing hands; nails should not be polished. Artificial nail use by food and healthcare workers should be prevented, and the FDA Food Code (US FDA, 2009a) prohibits the use of artificial nails by food workers unless gloves are worn.

Duration and Frequency of Hand Washing

Hand-washing efficiency is affected by two aspects of hand washing: how well (soaps, friction and duration) and how often (frequency) it is done. Both aspects are important for limiting hand contamination. The duration of the hand-washing process is a critical factor for

removing microorganisms, and hand-washing times of 15 to 30 seconds have been recom
mended by different agencies around the world with slightly different emphases. The 20
version of the Food Code states that hands and arms should be washed for at least 20 seconds
with 10 to 15 seconds of vigorous scrubbing, and that individuals must use a paper tow
or other barrier when touching surfaces to prevent recontamination of hands after washi
The World Health Organization states that 40 to 60 seconds total should be used for washi
hands with soap and water, rinsing and drying them, and 20 to 30 seconds for disinfecti
the hands with an alcohol-based formulation. Hand-wash times are sometimes encourag
by suggesting that everyone recite the alphabet or sing "Happy Birthday" or a similar-leng
ditty during washing to obtain maximum pathogen removal. The American Society f
Testing and Materials (ASTM) recommends wetting hands under warm water at 100 to 108
(38 to 42°C), applying 3 ml of hand-washing product and rubbing all hand surfaces vigorous
concentrating on interdigital parts (Guzewich and Ross, 1989). Washing for too long may dam
age the skin, bringing the skin resident flora to the surface, increasing the number of microo
ganisms recovered from hands and damaging the epithelial layer. Unfortunately, observatio
of workers in different settings have revealed that less time is spent on actual washing th
has been recommended, sometimes as low as 9–11 seconds, and soap was not always used.

Hand-washing Water Temperature

Common sense suggests that hand-washing water temperatures should be as hot as
comfortable (between 110 and 120°F/43 and 49°C). However, water temperature has bee
shown not to be influential in hand hygiene efficacy when plain or antimicrobial soaps a
used. No significant differences in bacterial reductions of either resident or transient bacte
ria were found for any of the washing and rinsing temperatures during normal hand wash
ing with a non-antimicrobial soap. Vigorous friction during washing is more effective fo
removal of bacteria than is the type of soap, the length of the wash time or the temperatu
of the water. However, washing and rinsing hands at excessively low temperatures, equiva
lent to those found in a refrigerated cutting room, is uncomfortable and also may result i
poor hand-washing compliance. The 2001 FDA Food Code amended the 1999 version b
decreasing the recommended water temperature for hand washing to 100°F/37.7°C, and ha
remained ever since (US FDA, 2009a). Thus, the temperature of hand-washing water shoul
be comfortable, preferably warm but not hot.

Double Hand Washing

Double hand washing is meant to address residual fecal finger contamination, includin
entrapment of feces in the subungual region of the nails after defecation or contact with toi
let facilities including toilet seats and door knobs or handles. In this procedure, a nailbrush
is used to produce lather on fingertips, hands and arm surfaces during initial hand wash
ing. The hands are then rinsed and relathered, without using the nailbrush, by vigorously
rubbing hand and arm surfaces, thoroughly rinsing and then drying with disposable paper
towels. A double wash has been recommended when employees begin a shift and after the
use the toilet. Although this sequential approach has been considered to enhance the effi
cacy of hand washing, research has shown only a slight gain in cleanliness with the second

washing, but it may be valuable as an alternative to gloving because of the high degree of enteric bacteria removal. However, if a nailbrush is used about 10 times, enough organic material will accumulate in the brush storage sanitizer solution that bacteria could begin to grow, allowing the storage solution to become a source of bacterial contamination for workers' hands. This possible contamination is the reason why nailbrushes are not recommended for use in high-care food handling facilities in Europe (Todd et al., 2010c).

Issues at Hand-washing Stations

A worker can become contaminated from hands and clothing at hygiene stations and automated hand-washing machines from organisms deposited by a previous user on water faucet handles, sink counter tops, door handles and soap dispenser buttons (Todd et al., 2010d). Whereas an ideal hand-washing station has faucets that operate automatically or through use of a knee, foot or elbow, in most restrooms and many food preparation facilities, these types of faucets are not available, increasing the risk of cross-contamination through use of contaminated faucet handles. Thus, inadequate hand washing may actually further spread microbial contaminants, particularly environmentally resistant enteric viruses. One solution to prevent recontamination of cleaned hands is to use disposable paper towels for turning off faucets and opening restroom doors. Another possible source of contamination is from water droplet sprays and aerosols dispersed from the water flow of taps or nozzles and the action of the hands during hand washing. Managers of food preparation operations should be encouraged to check for water droplet transfer by observing the station wetness after use, and modify the faucet system appropriately.

Hand-washing machines have been used as a way to improve hand-washing effectiveness and compliance since the washing time is controlled. Some units are also designed for glove washing. Automated cleansing systems have been considered to reduce variability in hand-washing effectiveness. However, manual hand washing is sometimes preferred by many employees, and less observed use of the automatic sinks by employees would decrease overall hand-washing compliance. There have also been instances of water contaminated with potential pathogens, and some designs of hand-washing machines make contamination of sleeves and already washed hands possible. Nevertheless, the FDA authorizes the use of approved automatic hand-washing facilities.

Drying of Hands

Moist hands transfer microorganisms more readily than dry hands and, therefore, drying is an important step in the hand-washing process, but is often ignored by individuals who do a quick rinse with or without soap followed by a dab on a towel or simply shake the large droplets off. Effective hand drying includes enough time to remove moisture through absorption, and microorganisms on surface skin layers through friction on towels. If pathogens are deposited onto reusable towels, they can survive long enough so that successive users' hands become contaminated. Thus, single-use paper towels are generally considered to be more hygienic than cloth towels. The main issue is that the time taken to dry hands and wrists thoroughly is considered too long. Electric air dryers are increasingly available in both food facilities and public areas, and today's models are much faster at drying. The

concern that microorganisms might accumulate in the driers and create aerosols when the are turned on has not been shown to be the case, and air drying has been shown to produce the highest reduction in the numbers of bacteria and viruses compared with cloth towels.

Alcohol-based Antiseptics and Wipes

Alcohol-based hand rubs (ABHRs) are antiseptics containing isopropanol, ethanol, n-propanol or a combination of these and are now in common use. They are more effective than many non-alcoholic products when hands are relatively clean from soil, provided that enough of the compound is used and the exposure time is not too short (Todd et al., 2010d). They also do not require thorough rubbing as do soap and water and so may reduce the risk of dermatitis. However, there are issues that prevent their complete acceptance, causing dryness of skin and stinging of cuts, and they do not act well when grease or food particles are present. Flammability may be a concern but there are very few reported incidents of the alcohol burning users. There is, however, no residual effect compared with products like CHG or triclosan, and these are sometimes added to alcohols. There can be a 3.5 $\log_{10}$ reduction of bacteria on hands after a 30-second application and 4–5 $\log_{10}$ reduction after 1 minute, but viruses are more difficult to inactivate. Alcohol at 60–95% denatures enveloped viruses but not spores, oocysts and non-enveloped viruses, such as NoV, rotavirus and HAV.

Foam sanitizers may be better than gels in removing microorganisms, but they are more expensive to use. Although they are used more and more exclusively in healthcare institutions, alcohol-based antiseptics should not replace hand-washing and drying policies in the food industry because of a greater variety of soils encountered by employees, particularly with meat, poultry and fish products. Therefore, for most operations, the hands of food workers should be washed before application of hand sanitizers.

Rinsing hands under running water and use of alcohol antiseptic followed by vigorous wiping with a paper towel is the most effective approach to removing viruses. Antiseptic wipes are widely used and typically contain benzalkonium chloride, moisturizers, wetting agents and emulsifiers. Dry tissue wiping combined with antimicrobial moist wipe use without rinsing is at least as effective as washing with soap and water. Again, wipes are most effective for removing microorganisms on clean surfaces, and not where there are many food particles and fecal matter.

Vigilance during Outbreaks

When there are reported community outbreaks, more than the usual number of diarrheal illnesses in confined locations such as army bases, cruise ships and refugee camps, or even family-associated enteric illnesses, food operation managers, employees and home carers must be especially vigilant to avoid the spread of pathogens. Certain microorganisms with low infectious doses have been known for decades to quickly infect exposed persons through direct and indirect contact. Such pathogens include some of the *E. coli* strains, *Salmonella* Typhi, *Shigella dysenteriae*, *Vibrio cholerae* and more recently NoV. Cholera and shigellosis outbreaks are good examples of this.

The 1994 cholera epidemic in Guinea-Bissau, West Africa, resulted in over 15,000 reported cases and 300 deaths. The outbreak of cholera was strongly associated with eating

at a funeral with a non-disinfected corpse and with touching (i.e. transporting, washing) the body. Because a corpse will commonly leak feces, persons handling dead bodies are likely to be exposed to gastrointestinal organisms (such as *V. cholerae*). The cultural practice of serving meals to guests at funerals by the same people who prepared the body was discouraged during this outbreak, and community leaders were informed about the risk of cholera transmission during funerals, that meals should not be served at funerals and that bodies of persons dying of cholera should be disinfected. Although this was done, outbreaks continued in several villages following funerals in some regions of the country. This former widespread practice only rarely occurs today because of education and government action. However, funeral employees may be exposed through direct contact with the victim's body and soiled clothes, and transmission can occur directly through the fecal–oral route. While this should provoke caution in handling the body itself, it is also important to note that equipment used by the funeral industry such as storage facilities, vehicles and stretchers may also be contaminated. Thus, especially during a cholera or any other enteric disease epidemic, disinfection of bodies and equipment must be assiduously adhered to.

The following are six other examples where the rapid spread of disease led to large outbreaks (Todd et al., 2007b); (1) at a resort in Haiti in 1984, a worker infected with *Shigella flexneri* transmitted shigellosis to 1136 guests over a 3-week period where eating a raw or very rare hamburger and having a roommate who was ill and a younger age were significantly associated with acquiring the disease; (2) at the 1987 Rainbow outdoor gathering in North Carolina, many thousands of attendees were infected with *Shigella sonnei* through water, food and person-to-person secondary spread because sanitary facilities were very limited outdoors; (3) at a Michigan music festival in 1988, again mainly outdoors, tofu salad contaminated by infected food workers resulted in 3175 cases of shigellosis caused by *Shigella sonnei* over a 3-week period; (4) in Japan in 1989, thousands of school children ate meals contaminated with NoV prepared in a central commissary; (5) NoV outbreaks twice occurred on two consecutive cruises around the Hawaiian Islands, once in 1990 and again in 1992; and (6) in 1990, Mozambican refugees in a Malawian camp were infected with cholera via contaminated water and food for an undetermined time; hands were placed into stored household drinking water, and there was improper reheating of leftover food. All of these cases reinforce the requirement that during times where there are community outbreaks, or infections at higher levels than normal, food processing and service operators need to be extremely diligent in enforcing personal hygiene and sanitation guidelines, and where necessary have a temporary closure of operations; particular attention should be given to consumption of food where preparation and hand hygiene facilities are limited such as outdoors or in camps.

BARRIERS IN FOOD OPERATIONS TO LIMIT SPREAD OF PATHOGENS

Barriers to Contamination of Food

Physical and chemical barriers to prevent microbial contamination of food are introduced to prevent or reduce the transfer of pathogens to the foods or food contact surfaces from the hands of an employee, from raw meat, poultry, fish/shellfish, fruits or vegetables or

unprocessed ingredients, or from the environment in the facility or from outdoors wh dust and pests may enter. In food processing and service operations, direct contact of fo by hands should be prevented by the use of well-designed barriers, especially when glo are not worn (Todd et al., 2010a; GMA, 2009). Although many barriers have been used decades in food processing and foodservice operations, their effectiveness is sometim questioned or their use may be ignored. Physical barriers include properly engineer building walls and doors to minimize the flow of outside particles and pests to food stora and food preparation areas; food shields to prevent aerosol contamination of displayed fo by customers and workers; work clothing designated strictly for work (these include gow overalls, boots and hair nets), including pathogens from infected family members; and ute sils such as spoons, tongs and deli papers to prevent direct contact between hands and t food being prepared or served. Food processing buildings should be so designed that t opportunities for finished product being recontaminated by the raw ingredients are min mal; this requires a flow of food through different zones to separate those for raw materi and receiving, mixing and other precooking steps, where general good manufacturing pra tices apply, from cooking, packaging and storage areas. Employees should only enter t zone areas they work in, or go from a more contaminated zone to a cleaner one only aft changing clothing and utilizing sanitation steps like boots in disinfectant. Unfortunate contamination can enter rooms from air ducts, fans, eroded flooring, leaky roofs or drain damaged and wet floors, difficult-to-clean equipment, conveyor belts and cleaning an maintenance tools such as mops and buckets.

Cash and paper money, and even credit cards, should be handled separately from an other operation involving preparation or serving of food. This is preferably done by tw workers, or changing gloves and washing hands between handling money and touchin food. In practice, in fast food facilities and small enterprises, this is not always done becaus of convenience and speed required to serve patrons.

Chemical barriers include sanitizing solutions used to remove microorganisms (includ ing pathogens) from objects or materials used during food production and preparation and to launder uniforms, work clothes and soiled linens. Laundering, especially for highly con taminated material, e.g. with feces, blood and vomitus such as in healthcare facilities or in slaughterhouses, may create aerosols of enteric pathogens and not effectively eliminate viral pathogens.

One final point is the food that employees eat. There are no regulations or guidelines on this, but clearly if food workers consume food that is likely to contain pathogens, they are more likely to be colonized and spread these organisms at work. Thus, consumption of raw or minimally processed food items identified as high risk foods should be discouraged. Managers have no control of employees outside the work environment but they can advise them not to eat risky foods and can refuse to serve these, such as steak tartar, alfalfa sprouts and raw milk cheeses, in company cafeterias.

Effectiveness of Gloves

When worn correctly in healthcare environments, gloves have consistently reduced hospital-acquired infection rates and these were adopted later in food operations. Although utensils have hygienic value during food production and preparation to limit contact between

workers and food, for many operations hands need to be in regular contact with food much of the time. Glove use has been emphasized through the widespread distribution of the US Food and Drug Administration (FDA) Food Code (2009a), and their use has increased in hospital foodservice facilities operated under hazard analysis critical control point (HACCP) systems. When gloves are worn properly, the risk of pathogen transmission can be reduced considerably, but careful inspection of gloves must be done to ensure that it is appropriate for the required tasks (Todd et al., 2010b). Hoelzer et al. (2012) consider that gloves can be a major source of *Listeria monocytogenes* contamination in retail deli operations. Their use certainly can be monitored by management and food control agencies by observing the gloves on workers and the discards in trash receptacles, and by reviewing glove purchase invoices. However, it is more difficult to determine their proper use to avoid food contamination, and glove use still is not mandatory in many jurisdictions because of conflicting data on their utility.

Although gloves give some benefit, they do not completely prevent pathogen transfer and hand-washing compliance is less when gloves are worn. Some studies show that indicators of pathogens were similarly present on gloves and hands, and found that the outside of the glove was highly contaminated at the end of a 3-hour period regardless of whether gloves had been changed or hands had been washed, and that bare hands with hourly washes and antiseptics provided a higher level of hand sanitization than did gloved hands with and without washing. Hand washing and glove use were more likely to occur in conjunction with food preparation than with other activities and when workers were not busy, and in general workers who wear gloves do not remove them and wash their hands as often as they should. Gloves are also prone to pinhole leaks or punctures by jewelry on fingers or artificial or long fingernails, as well as operational stress. Occlusion of the skin after extensive use with warmth and moisture build-up can lead to microbial growth, particularly from resident staphylococci. Therefore, gloves should be considered an adjunct to and not a replacement for hand washing for food production and preparation operations.

Arguments for glove use are (1) gloves protect the worker from foods that can cause damage to the skin, e.g. acidic ingredients, (2) gloves protect the food from direct hand contact, (3) glove use is easily observed to verify hygiene compliance, unlike assessing hand-washing frequency and thoroughness, and (4) gloves can be used to cover skin damage or infections. Arguments against glove use are (1) gloves can reduce operational dexterity and increase the risk of injury, (2) higher levels of food contamination are possible in the event of glove failure, (3) a small percentage of gloves have pinhole leaks that are not possible to detect before use, (4) gloves can be worn for longer than they should be, (5) gloves give a false sense of security as a substitute for good hand hygiene practices, and (6) gloves increase the risk of hand irritation. Thus, proper hand hygiene is essential in addition to gloving and other barriers. The best approach is to use multiple hurdles, including gloves, other barriers and appropriate hand washing, to prevent transfer of bacterial, parasitic and viral pathogens to food.

The procedure for removing disposable gloves to minimize contamination of the hands and environment can be done as follows: (1) grasp one of the gloves and pull it part way off so that the glove will turn inside out; (2) with the first glove partially on the hand remove the second glove so that the exposed bare hands or fingers do not touch the outside of either glove; (3) with the first glove over the fingers, grasp the second glove near the cuff and pull it part of the way off to turn the glove inside out, keeping the second glove partially on the hand to avoid touching the outside surface of the first glove with the bare hand; (4) pull off

the two gloves at the same time, being careful to touch only the inside surfaces of the gloves with the bare hands; (5) dispose of the gloves by placing inside out in the trash; (6) wash hands thoroughly. Other important points to consider are: do not touch the face or clothing with contaminated gloves; change gloves when heavily soiled or if they are torn; do not wash or reuse disposable gloves; and, in any operation with gloves and hands, work from clean to dirty to minimize potential contamination risks.

Food Shields and Utensils as Barriers against Contamination

Despite a lack of scientific data that food shields (formerly called sneeze guards) are effective for protecting food from airborne contaminants, most food businesses with a buffet, salad bar or display of saleable RTE food use these guards. Unfortunately, food shields probably cannot protect food from highly aerosolized particles such as viruses; although a vomiting event in a foodservice area is a rare event, all exposed food must be discarded (Todd et al., 2010a). Utensils adequate for dispensing foods include spatulas, tongs, scoops, spoons, ladles, single-use dispensers and thin papers for grasping and weighing deli meats and serving bakery items. Some of these utensils should also be used for mixing foods and handling potentially contaminated foods such as raw meat, so that the hands of food workers are less likely to become contaminated. When food operations adopt a policy that includes single-use items to avoid risks of contamination, these items must never be reused. These items also must be protected from contamination until their use; specifically, they must not come into contact with food or the skin or mouth of a person. Utensils that are not single use should be thoroughly washed and sanitized before reuse. In some operations utensils and papers tend to be used inconsistently or not at all. Outbreaks attributed to contaminated utensils are most likely contaminated by a food worker. Food employees also should wear hair restraints such as hats, hair coverings or nets, beard restraints and clothing that cover body hair, which are designed and worn to effectively keep their hair from contacting exposed food, food contact surfaces including clean equipment, utensils, linens and single-use items.

Protective work clothing means any clothing provided by the employer to protect the worker from hazards in the workplace or to prevent contamination of the workplace by materials the worker may bring into it on their personal clothing. Work clothes, such as overalls, can be sources of contamination of other persons, food contact surfaces and foods themselves. In general, protective clothing of food workers should not be worn while they are eating, drinking, smoking or visiting the toilet. Diapering a sick child at home while wearing a uniform has led to a foodborne disease outbreak in a healthcare institution. Yet, there are surprisingly few instances in food codes to request the proper location of toilets, the effectiveness of washrooms and that outer clothing should be removed before any toileting activity. However, it is preferable to install toilets that will flush automatically and have sink faucets and antiseptic dispensers designed to have a minimum of hand contact.

Management should insist that separate sinks are installed for food preparation, dishwashing and cleaning, and hand washing, and they are used properly. Protective clothing, such as uniforms and overalls, should not be capable of holding anything that could become foreign matter, as well as pens, repair tools, or knives, etc., as there is a chance these items could fall out and contaminate the food items, e.g., only have pockets on the inside, or preferably no pockets at all with access to pockets only in non-work clothes. Washrooms

with toilets and hand sinks should be some distance away from food processing and preparation areas but not so far as to discourage their use on a regular basis. Design the washroom facility, including installing hooks on which to hang the clothes, so that staff have to remove the outer layer of protective clothing before engaging in any toileting activity (McFoodies, 2012). Dirty uniforms, overalls and other clothing should be placed in a receptacle or movable container in order to deliver them to the laundry. If employees have to launder their own work clothes, there should be periodic checks to ensure this is done as frequently and properly as required. As previously indicated, laundering of highly infectious material (most likely in healthcare facilities but also in homes where there has been diarrhea) can cause aerosols and infect the user.

The 2009 FDA Food Code states in general that workplace contaminants means chemical or biological substances arising from workplace processes, and may include airborne contaminants or contaminants on surfaces, such as tables, benches, eating utensils, clothing or skin. The employer must ensure food is not stored or consumed in areas where the presence of these contaminants could result in a hazard to workers as a result of ingestion with food or beverages. Managers should observe facility personnel for clean outer clothing, effective hair restraints, prohibited jewelry and the condition or protection of fingernails, and if the employees regularly change their clothes in the establishment, lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.

In today's society where cell phones are commonplace, they should not be allowed in food processing and preparation areas as they are a distraction from the work at hand and can also fall into open containers of food; in addition, because of frequent handling, they can be contaminated with many types of microorganisms including pathogens. Make it a policy that no staff are allowed to take mobile phones into food processing areas.

Improving Compliance

Lack of compliance for hygienic practices is notorious in both the healthcare and food industries, particularly the washing and/or sanitizing of hands (Todd et al., 2010e). This can be illustrated by a study of food workers from 29 catering businesses that produced high-risk foods in Wales (Clayton and Griffiths, 2004). Hand hygiene practices were carried out adequately on only 31% of the required occasions and were not even attempted 55% of the time. Errors included touching potentially contaminated objects or surfaces including hair and face without subsequent hand washing, improper handling of potentially contaminated foods, and failure to adequately clean potentially contaminated food contact surfaces and also frequently used objects such as telephones, cupboards and shelves, food containers, equipment and door handles. Two main hand hygiene errors were identified: (1) a failure to use soap and (2) a failure to dry hands adequately. Infrequent cleaning of such surfaces coupled with a failure to wash hands may help explain the high bacterial counts noted on these same surfaces in other studies.

Other common challenges that make it hard to clean include issues that affect employee compliance with company and heath authority hygiene guidelines and regulations: (1) lack of facilities providing sufficient warm water and hand driers in an easily accessible location; (2) lack of employee motivation; (3) lack of education and training; and (4) lack of a managerial role model. One of the most effective tools for change is the culture of the organization to encourage food safety and hand hygiene through example and pertinent information.

Hand Hygiene Occasions

Hands should be clean and properly washed in food operations before or after certain actions. These include: (1) after touching bare human body parts other than clean hands and clean, exposed portions of wrists and arms; (2) after visiting the washroom for toileting or toilet cleaning; (3) after caring for or handling any kind of animal; (4) after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating or drinking; (5) after handling soiled equipment or utensils, e.g., after disassembly and cleaning of processing equipment; (6) before donning gloves for working with food; (7) during food production, preparation or service, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks, e.g., when handling both raw and RTE foods and (8) after engaging in other activities that contaminate the hands, as specified in hygiene guidelines and management policies.

There are many guidelines on how to wash and dry hands; these differ slightly in wording for approaches and times. The basic steps are outlined as follows: (1) remove watches, bangles, all jewelry, except a simple wedding band before any operation producing or preparing food; (2) rinse hands, wrists and arms (including prosthetic devices if appropriate) under clean, warm, running water, rubbing fingers and palms to remove any visible soil and food particles; (3) apply the recommended amount of antiseptic cleaning compound, typically 1 ml but more may be required after certain operations; automatic soap dispensers are preferred to bar soap, but these have to be monitored to maintain sufficient liquid soap or foam and to prevent their contamination though employee use; (4) rub hands together vigorously for 10 to 15 seconds while ensuring that soil is removed from the palms, between fingers and backs of hands and wrists; (5) remove visible soil from under the fingernails with a fingernail brush as recommended; (6) thoroughly rinse hands under clean, running water; (7) thoroughly dry hands, wrists and arms using single-use disposable towels, a continuous towel system that supplies a new towel at each use, a heated air, hand drying device or a pressurized air blast, as approved by the regulatory authority.

Employees should be careful not to recontaminate hands during the washing and drying operations by touching faucets, sinks and contact with toilets; automatic hand washers or use of paper towels to turn off faucets and open doors reduce this risk. In smaller facilities where the only employee hand-washing facility is in the public washroom (toilet), particular care must be taken to avoid recontamination. The whole hand hygiene operation should take about 40–60 seconds, depending on how much soil is originally present on the hands. In addition, double hand washing may be recommended for employees after toileting or after operations involving hands contaminated with much soil.

EXCLUSION OF INFECTED EMPLOYEES TO WORK IN SPECIFIC FOOD OPERATIONS

Policies for Food Worker Exclusions

Enteric organisms from fecal sources are excreted during an infection, whether the individual is symptomatic or not, but the infection exists over a limited time period (usually hours to weeks). Many of these enteric pathogens are of concern to food workers.

e.g. *Salmonella*, *Shigella*, HAV and NoV. These pathogens can contaminate the hands after defecation or from touching fecally-soiled clothing or surfaces. The use of toilet paper is no guarantee of preventing feces reaching uncontaminated hands, and finger contact is almost 100% certain for those individuals with diarrhea. Thorough hand hygiene following any defecation has to be ingrained as a lifelong habit. Changing diapers with loose stools, cleaning after episodes of vomiting or diarrhea by family members, washing dirty linens and contact with sick or healthy pets also are well-established risk factors. Fecal matter and vomitus can remain on clothing following home clean-ups and be transmitted to kitchen environments at work. There is no way for management to detect such a scenario and workers must take precautions before returning to work, e.g., change out of street clothing into work uniforms or overalls, thoroughly wash their hands and arms, and admit potential exposure to pathogens.

Policies do exist in many jurisdictions, however, for the exclusion of food workers infected with pathogens from working with food, but these are difficult to implement effectively. Whereas it may be possible to identify an individual showing symptoms of frank enteric disease like vomiting and diarrhea, it is much more difficult to determine if workers are excreting pathogens when they appear perfectly normal healthwise. Post-symptomatic workers may continue to excrete pathogens, but at lower rates, for days, weeks and occasionally years. Shedding duration can be measured only by a regular stool-testing regimen, and even so this approach often is ineffective, costly and not always recommended because of the intermittent pathogen excretion. Even with an apparently effective policy, an outbreak can occur; several hundred cases of salmonellosis occurred from airline meals in 1976 because the infected employee was not identified during regular inspection and testing of the establishment. The extent of asymptomatic food workers excreting pathogens can be estimated from a study in Turkey where 1.6% of 307,954 workers in military food-service operations were positive for enteric pathogens in stool specimens (Kir et al., 2006). However, the World Health Organization concluded that asymptomatic carriers of nontyphoidal *Salmonella*, *Shigella*, *V. cholerae* and enteric viruses pose only minimal risks as long as good hygiene is practiced (WHO, 1989).

Stool Testing

Stool testing and exclusion of workers has been an issue for many decades, and recommendations differ among jurisdictions, with no consistent approach for stool testing and worker exclusions. Typically, three negative stool specimens are required before an infected food employee can return to work. However, the clinically well food worker with formed stools should be allowed back at work without further examination of fecal specimens. Generally, pathogen-negative stool samples, either pre-employment or from an employee recovering from a diarrheal illness, are not necessary conditions of employment or return to work. Exceptions may be considered for typhoid and paratyphoid infections and infection caused by enterohemorrhagic *E. coli*, since these are severe diseases and infected individuals can excrete the pathogens for long periods after recovery. When *E. coli* O157:H7 infection is identified in a food worker, the worker should be excluded from work until bowel movements are normal and two negative fecal samples taken 48 hours apart have been obtained. Symptomless contacts of a person with HAV infection can continue food handling, but

workers who have symptoms of hepatitis, have been in an outbreak or have been associated with family members suffering from HAV infection, or have traveled to regions where HAV is endemic would be excluded from work until they have a medical release based on laboratory testing. Those infected with norovirus should be treated the same way as for HAV.

Unfortunately, from the above information it is impossible to determine when employees are free from a pathogen since excretion can occur sporadically for many weeks or months after apparent recovery. However, it is likely the pathogen levels in their stools become increasingly low over time and even if some fecal matter remains on fingers after defecation, any organisms can be removed through vigorous hand hygienic practices. The same position should apply for asymptomatic persons with levels in stools assumed to be lower than for those with frank enteric symptoms. Thus, the best policy is to exclude those who show signs of nausea, vomiting, abdominal cramps or diarrhea (concern should also be raised for sore throat, fever and jaundice though these may have non-enteric pathogen origins) until they recover. Treat every employee as if he or she is infected and excreting at low pathogen levels, but that proper hand washing and drying and other barriers to pathogen spread are taught and enforced. Employees should report gastrointestinal illness to their supervisors but this may not happen until the symptoms are obvious to co-workers.

If suffering from an illness involving jaundice, diarrhea, vomiting, fever, sore throat with fever, discharge from ear, eye and nose or visibly infected skin lesions (such as boils, cuts) a food worker should report to his or her supervisor. The supervisor should then use discretion as to whether or not the person should be subjected to certain restrictions or suspended from food processing, handling or serving duties. Medical advice may be necessary in making this decision (WHO, 2000).

Health department clearance for some symptoms may be required by law which may or may not expect three consecutive stool specimens to be negative. Also, employees returning from a region of the world with certain endemic enteric diseases like typhoid and dysentery should be asked to be cleared by the health department. When employees or patrons give indications of enteric illness, or there are community outbreaks, managers should be particularly vigilant about preventing spread of pathogens in the food production, preparation and serving environment. Since young children tend to excrete higher levels of pathogens than adults, employees with such children should also inform their managers and take special precautions to avoid any fecal transfer.

Lack of Health Benefits

Unfortunately, although more people are employed in the food industry (>15%) than in any other sector in the United States, benefits are very limited for these workers, often at the minimum wage level, and this means there is a risk of ill employees going to work. In the EU wages for food workers are generally higher than in the United States and sick leave is likely to be more prevalent. When people go to work infected and ill, they perform less efficiently and can also infect others, which can contribute to more employees who stay at home ill and also those who decide to come to work as newly infected persons (Todd et al., 2008a). Paid sick leave policies have been shown to reduce the rate of contagious infections in the workplace by isolating sick workers at home. Failure to take time off to regain one's health actually led to longer absences because health worsened, and as an illness spread

within the workplace additional workers were affected, raising the total employee absence time. For instance, in a 2012 report of the Food Chain Workers Alliance, entitled "The Hands That Feed Us: Challenges and Opportunities for Workers along the Food Chain" (Food Chain, 2012), 79% of food system workers do not have a single paid sick day, or do not know if they have paid sick days, and 58% lack health coverage. Consequently, 53% admitted to picking, processing, selling, cooking and serving food while sick for an average of at least 3 days per year. This issue of employees in the food industry being paid low wages and having few or no health benefits applies to all regions of the world, and is likely to be worse in developing countries. It will be interesting to see whether existing policies for paid sick leave will remain in place during the current economic downturn, especially in Europe. Thus, until sick leave policies are more universally accepted, the risk of a food employee transmitting pathogens at work is high.

CONCLUSION

Although hand hygiene is not a new concept for prevention of disease spread, it still remains the best strategy to reduce the opportunities for transfer of microorganisms to foods. Exclusion of employees colonized and excreting enteric pathogens is a generally failed policy to detect carriers and should only be applied to workers returning from countries with endemic diseases such as typhoid and cholera, or who have been exposed to enterohemorrhagic *E. coli*, such as on a farm, or exposed to ill persons. The asymptomatic carrier state is perhaps normal for many persons, and certainly those recovering from an enteric infection can excrete the causative pathogen for weeks and months. Also, about half the population harbors *Staphylococcus aureus* in the nasopharynx, and its presence should not be used to close an operation by health authorities because it is found in one or more workers (as has happened on many occasions, particularly in developing countries), or dismiss a carrier. Proper investigations of outbreaks can help to identify risk factors associated with food workers (and other sources) and aid in implementing appropriate prevention and control strategies (Todd et al., 2011).

To limit pathogen transfer, the use of appropriate physical barriers, e.g., building design, utensils, food shields, gloves, hair nets and an effective hand hygiene policy, is the best strategy food processing and foodservice managers can implement. Yet, employees continually forget to wash their hands or do so ineffectively, and foodborne outbreaks associated with lapses in hand hygiene in food operations, particularly foodservice facilities, occur right up to the present time. The key components affecting risk of pathogen transmission are hand hygiene compliance, hygiene efficiency and cross-contamination. Compliance reflects (1) the frequency of the cleansing process, (2) the willingness to adhere to the recommended procedures, (3) hygiene efficiency through the combined effects of washing, brushing, rinsing, drying, sanitizing, gloving, etc., (4) prevention of cross-contamination by having more hands-free operations, (5) handling less raw and more processed food, and (6) working on sanitized surfaces. The parts of the hands that are most likely to retain fecal or food contamination are the thumbs, palms, spaces between fingers and fingertips (including the fingernail area), and employees and employers need to focus on ensuring these are well cleaned before they start or resume work on RTE food.

Training and monitoring of activities alone are not sufficient. Monitoring can be accomplished by direct observation and recording of positive and negative behaviors or by some automated system of recording use of water, soaps or ABHRs. A major consideration is the ability to alter human behavior by peer pressure, such as positive deviance, or through rewards and penalties applied to both management and other employees. These issues lead into the critical impact of the cultural values of both society and workers' organizations. The climate of an institution is a key element in promoting positive change (Griffith et al., 2010). There are two components to this: the food safety culture of the organization, and the knowledge and practice of the person in charge (PIC) of the specific operations such as in a franchise. How management creates and supports the food safety culture within a business may be the most important factor for determining whether that business can avoid violations on inspection, foodborne illness of its patrons or costly recall of its products. The more confident the business is in the production and/or service of its food, the more likely it will implement proper hygienic measures and institute effective training of the staff, both managers and other employees.

The PIC of the workers on the line needs complete knowledge of food safety risks in the company's operations and why hand hygiene, including adequate washing, is necessary to avoid contamination of the food and its contact surfaces. He or she has to demonstrate making use of the different barriers, including washing hands frequently. The presence of a well-trained PIC provides a system for routine observation and feedback and for making hand hygiene easy and convenient with necessary supplies regularly stocked, putting reminders in the workplace, requesting better engineered facilities, avoiding overcrowding, understaffing and excessive workload, facilitating skin care for workers' hands, and implementing administrative sanctions and/or rewards. Collaboration and advice from local health departments and their inspectors should be encouraged, because these departments should be more involved in education than in regulation to effect change. Any change in operational practices is where vigilance should be heightened, and employees and their actions must be carefully monitored to determine whether new risks may arise.

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CHAPTER

29

Pest Management

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INTRODUCTION

Man is in direct competition with a variety of other species for food. These competitors not only consume the product but also contaminate the product with feces, exuviae or hairs, frass and microorganisms. They can also alter the physical properties of the product by increasing temperature and possibly moisture content, and pose health threats by acting as vectors of pathogens and parasites. The importance of implementing effective pest management strategies cannot be overemphasized as the discovery of live insect stages or contaminants such as insect fragments and exuviae, or rodent hairs and droppings, has severe financial implications. Such incidents usually lead to the recall of the entire distribution of a particular product and may result in expensive litigation procedures, but potentially the greater financial loss is the longer-term effect on consumer confidence in the product which may never be fully restored.

In food production facilities there is a constant threat of pest populations becoming established as food is always present and there are many locations and access points for pests to enter and find refuges. Insect food pests are cosmopolitan while food facilities are twice as likely to encounter rodent problems in comparison with domestic premises and are legally bound to practice high food safety standards (HGCA, 2002). Many procedures can be adopted to prevent pest access, to detect their presence on arrival and to control infestations when they occur, and these are discussed below.

PESTS OF FOOD PROCESSING AND PRODUCTION FACILITIES AND THE RISKS THEY IMPOSE

Any site where food is gathered, sorted, processed or stored is an attraction to wandering rodents, birds, insects or mites whose lives depend on the successful location of food sources. Farmers, crop storage and distribution specialists, food processors and retailers all need to take precautions to render their premises less vulnerable to exploitation by pests.

While problems from vertebrate pests can largely be addressed by exclusion strategies, the same is not true for insect and mite pests, although exclusion strategies are still an important ingredient of pest management. Incoming supplies are the primary source of these pests and many species can become established in the fabric of the building, feeding on food residues and wandering to and from harborages to locate new supplies.

Vertebrate Pests

Rats, mice, sparrows and pigeons are ubiquitous and major sources of contamination of food products in food processing facilities. They act as vectors of *Salmonella*, *Shigella* and *Leptospira* bacteria, various viruses, rickettsiae causing Q fever and other pathogens. Weil's disease caused by *Leptospirosis icterohaemorrhagiae* picked up by contact with rat excreta can be fatal, as can some cases of *Salmonella* food poisoning. Rodents also cause damage by the gnawing of wood, plastics, electric cabling and even metal water pipes, sometimes with catastrophic consequences. For birds, netting of openings and needle-matting of surfaces are

well established, effective strategies to prevent ingress, but problems may still occur where continual access for transport is needed or weathering of buildings provides openings in inaccessible areas of roofing where birds such as sparrows, starlings or pigeons can gain access.

Rodent-proofing is a more complex problem as in addition to the obvious exclusion of ground-level entry points, attention needs to be paid to the drainage system as well as roofing eaves as rodents will ascend drainpipes, either internally or externally, and gain access to lofts and then through the whole building via heating ducts or piping and along electrical conduit routes. Access of rats from sewerage systems is also not an uncommon occurrence so screens and other barriers should be in place and regularly maintained. The use of rodenticides for rat control requires the involvement of trained operators and even after careful observance of regulations is still a potential risk to non-target organisms (Eason et al., 2010). Resistance has developed to anticoagulants such as warfarin and now only second generation compounds are in widespread use, difenacoum and bromadiolone for use indoors and outdoors and the more toxic brodifacoum and flocoumafen for indoor use only under carefully controlled conditions. Formulation and mixture with an appropriate food is of critical importance as baits are readily rejected. All baiting stations should be checked weekly and replaced if necessary (HGCA, 2002).

Anticoagulants have always been less effective against mice because of avoidance following small intakes of bait, and since the loss of calciferol based on vitamin D_3 no really effective bait is available. Physical traps are used to complement anticoagulant baiting strategies along with single dose agents based on alphachloralose or zinc phosphide. In addition sodium cyanide and aluminum phosphide formulations are available for fumigation treatment of rat harborages and burrows away from occupied buildings. However, none of these complementary measures can guarantee adequate control and for each facility an effective exclusion and trapping strategy is therefore a necessity.

Externally, access by rodents to buildings is prevented by clearance of all shrubbery and disused machinery from the vicinity of the exterior walls and the deployment of traps at regular intervals around the property and both inside and outside potential points of entry into buildings. A typical layout of trap deployment for a food facility is presented in Figure 29.1.

Beetle Pests

Coleoptera is the largest order of insects and provides the majority of stored product pests with over 20 species of beetle or weevil of worldwide importance in international trade. Table 29.1 lists some that are commonly associated with food processing facilities, together with their food preferences and requirements for rapid development. Many species are of tropical origin that have arrived and become established in heated premises since the advent of international trade. Others, such as the biscuit beetle and granary weevil, famous for infesting sailors' biscuits and grain supplies in the days of sailing ships, are native to temperate regions. Excavations of archeological sites have found dead specimens of the biscuit beetle in leather artifacts dating back to Roman times and in the remains of food left in tombs in ancient Egypt.

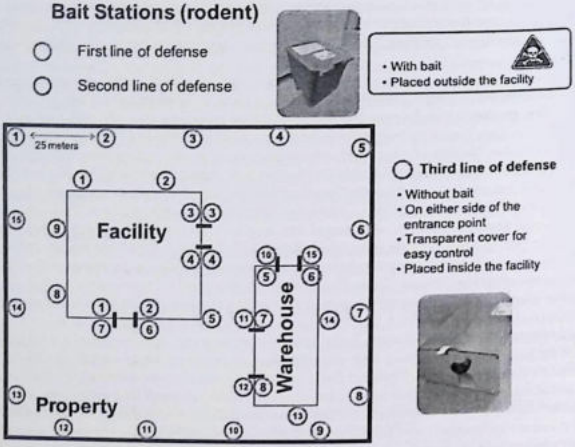

FIGURE 29.1 A typical layout of rodent traps for the protection of a food processing enterprise. *By permission of R. Stadler.*

Stored-product beetles may be divided into two categories, those developing externally on semiprocessed foods and among finely divided products, and those internal feeders developing within whole seeds such as cereal grains and legumes. The latter group includes bruchids, weevils (Curculionidae) and grain borers (Bostrichidae) which cause problems because of infested raw materials and rarely become endemic in the structure of the food production facility. They are, however, notoriously difficult to eradicate because they avoid detection and are protected from direct contact with control measures. The lesser grain borer and the granary and rice weevils occur as pests of rice and flour mills in this manner (Figure 29.2).

Those beetles feeding on semiprocessed materials or foods may again be divided into two groups, those with relatively short-lived adults (anobiids such as cigarette beetle, and dermestids such as Khapra beetle) and those whose adult stage may last a year or longer. In this latter group, including the *Tribolium* and *Cryptolestes* species which are serious flour mill pests, and the *Oryzaephilus* (and also *Tribolium*) species (Figure 29.3) occurring widely in breakfast cereal, pet food and confectionery manufacturers, both larval and adult stages actively feed on food products. It is this group that often establishes residual infestations in

TABLE 29.1 Developmental Requirements of Beetle and Moth Pests Often Found in Food Processing Facilities.

Species	Food Preferences	Developmental Range/Optimum, and Fastest Multiplication Rate
Cryptolestes ferrugineus (Stephens) Rust-red grain beetle	Grains, flour, meals, oilseeds, dried fruit and other dried vegetable materials	20–38°C, min r.h. c. 30%/32–35°C, 60-fold in 4 weeks
Cryptolestes turcicus (Grouvelle) Turkish grain beetle	Cereal products, notably wheat flour	c. 20–36°C, min r.h. 50%/28–33°C, c. 40-fold in 4 weeks
Gnatocerus cornutus (F.) Broad-horned flour beetle	Cereal products	15–35°C, min r.h. 30%/c. 30°C, c. 20-fold in 4 weeks
Lasioderma serricorne (F.) Cigarette or tobacco beetle	Cocoa, soybeans, tobacco, various cereals, spices, textiles and many other products	22–38°C, min r.h. 30%/32–35°C, 20-fold in 4 weeks
Oryzaephilus mercator (Fauvel) Merchant grain beetle	Oilseeds, dried fruit, nuts and cocoa beans	17–38°C, min 30% r.h./30–35°C, c. 30-fold in 4 weeks
Oryzaephilus surinamensis (L.) Saw-tooth grain beetle	Cereal grains, cereal products, dried fruits, nuts and some oilseeds	20–38°C, min r.h. c. 40%/31–34°C, 50-fold in 4 weeks
Rhyzopertha dominica (F.) Lesser grain borer	Cereal grains, flours, meals and macaroni	19–40°C, min r.h. 30%/32–35°C, 40-fold in 4 weeks
Sitophilus granarius (L.) Granary weevil	Cereal grains (exclusively internal grain feeder)	15–30°C, min r.h. c. 50%/25°C, 15-fold in 4 weeks
Sitophilus oryzae (L.) Rice weevil	Cereal grains (exclusively internal grain feeder)	15–34°C, min r.h. c. 40%/28–30°C, 30-fold in 4 weeks
Stegobium paniceum (L.) Biscuit or bread beetle	Cereal products and many other dried vegetable and animal products	17–32°C, min r.h. c. 60%/25–28°C, 7.5-fold in 4 weeks
Tribolium confusum J. du Val Confused flour beetle	Cereal products, copra, groundnuts, sesame and oilseeds	20–38°C, min r.h. 20%/30–32°C, 60-fold in 4 weeks
Tribolium castaneum (Herbst) Rust-red or red flour beetle	Cereal products, groundnuts, cacao, spices, dried figs and dates, copra, dried yam, palm kernels, nuts and oilseeds	22–40°C, min r.h. 20%/32–35°C, 70-fold in 4 weeks
Corcyra cephalonica (Stainton) Rice moth	Cereals, cereal products, dried fruit, seeds, cocoa and ground nuts	18–35°C, min r.h. 50%/30°C, 50-fold in 4 weeks
Ephestia cautella (Walker) Tropical warehouse moth, almond moth	Dried fruit, nuts, cereals and cereal products, cocoa beans, spices, copra, carobs, pulses and dried vegetables	17–36°C, min r.h. 25%/30–32°C, 60-fold in 4 weeks
Ephestia elutella (Hubner) Warehouse or tobacco moth	Grain, cocoa, dried vegetable products	10–30°C, min r.h. 20%/25°C, 20-fold in 4 weeks
Ephestia kuehniella Zeller The Mediterranean flour moth or mill moth	Cereals and cereal products	10–30°C, min r.h. 20%/25–28°C, 50-fold in 4 weeks
Plodia interpunctella (Hubner) Indian meal moth	Dried fruit and nuts, cereals and cereal products, cocoa, oilseeds, confectionery, citrus pulp, dried vegetables, pulses, seeds and carobs	18–36°C, min r.h. 20%/30–32°C, 50-fold in 4 weeks

Data from various sources, see Hall (2003).

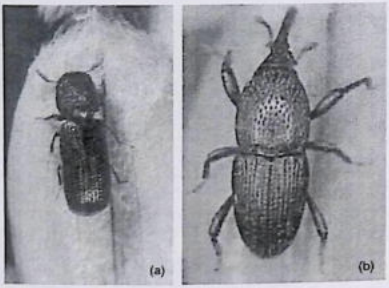

FIGURE 29.2 Two internally feeding grain beetles: A. Lesser grain borer *Rhyzopertha dominica*; B. Granary weevil *Sitophilus granarius*.

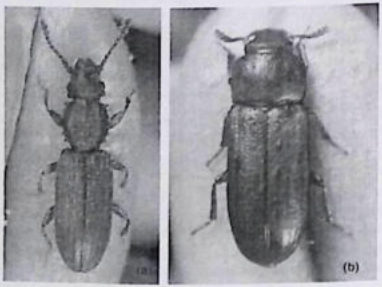

FIGURE 29.3 Two externally feeding grain beetles: A. Saw-toothed grain beetle *Oryzaephilus surinamensis*; B. Rust-red flour beetle *Tribolium castaneum*.

cracks, crevices and voids where food material escaping from processing machinery may accumulate. The long-lived adults seek out harborages from which they wander, often in a daily cycle, to scavenge for food and locate additional oviposition sites from which fresh infestations may start.

Despite their tropical origin and need of warm conditions for breeding, adults of many species of stored product beetle, both "internal" and "external" feeders, are highly cold tolerant and can readily overwinter in parts of the facility. Long-term infestation problems are revealed

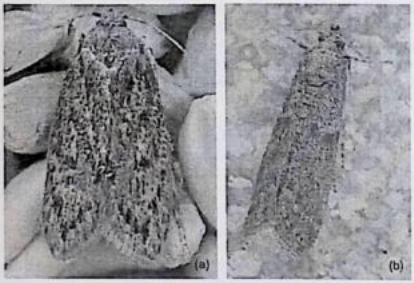

FIGURE 29.4 Two moth pests of stored products: A. Brown house moth *Hofmannophila pseudospretella*; B. Almond moth *Ephestia cautella*.

if the mealworm *Tenebrio molitor* L., at 12–17 mm in length the largest of all stored product beetles, *Gnatocerus* spp. flour beetles or spider beetles (Ptinidae) are present in the facility.

Moths

Most moth pests of food processing facilities belong to the family Pyralidae, although the brown house moth *Hofmannophila pseudospretella* (Stainton) (Figure 29.4A), and the white-shouldered house moth *Endrosis sarcitrella* (L.), are commonly encountered in damper, cooler situations such as mill basements and storage areas (Bell, 2003). Adult moths do not feed and damage is caused by the larval stage which features a heavily sclerotized head capsule with biting and chewing mouthparts while the rest of the elongated body is flexible, unpigmented and unsclerotized. In addition to the consumption and contamination of food, moth larvae produce silk from glands in the mouth which builds into webbing that can obstruct machinery and slow down production lines.

Oviposition in pyralid moths occurs from dusk onwards, but is inhibited by light (Bell, 1981). The egg stage lasts a maximum of 7 days at 25°C and there are five larval instars. The duration of the larval stage is influenced by temperature, food source, humidity and whether or not a larval overwintering diapause occurs at the fifth instar. On completing their development, in preparation for pupation or diapause, larvae spin a tough cocoon which may be double-layered. The pupal stage lasts about twice the duration of the egg stage at a particular temperature and adults are short lived, females laying most of their 200–300 eggs within 3 days.

The rice moth is a serious pest of mills in hot damp climates but can become established in heated premises anywhere in the world. The tropical warehouse or almond moth *Ephestia cautella* (Figure 29.4B) is the most frequently intercepted moth pest on food imports into the developed world and a common pest of food processing facilities. The Mediterranean flour

moth *E. kuehniella* is the principal moth pest of flour mills and bakeries in temperate regions of the world while the warehouse moth *E. elutella*, as its name suggests, is largely confined to warehouse storage areas where it overwinters as a diapausing larva, able to tolerate temperatures down to −10°C. The arrest is triggered by late summer day lengths of less than 14 hours (Strumpel, 1969). The Indianmeal moth *Plodia interpunctella*, perhaps the most versatile of all the pyralid species in occupying niches in the food industry, can also overwinter as a diapausing larva.

Details of the developmental limits and optima for each species are provided in Table 29.1, together with their food preferences.

Other Insects

Cockroaches, flies, ants and psocids can also cause problems in food processing facilities. The principal cockroaches belong to the genera *Periplaneta*, *Blatta* or *Blatella*. Eggs are produced in capsules, with up to 40 eggs per egg case and nymphs can mature to adults within 12 weeks. Cockroaches are disease vectors and, particularly *Blatella germanica* (L.), can cause allergenic problems, besides the obvious risks of contamination and spoilage of food (Ebeling, 1991). Most species are cryptic, hiding in refuges with access to food residues.

Many different flies are hygiene threats in industry, including house flies, blow flies, fruit flies and drain flies, each originating from different sources of hygiene failure. They can transmit many fecal and oral-borne pathogens. UV Light traps are widely employed to monitor and control flies in bakeries, restaurants and food processing plants and keep problems under control as long as adequate attention is paid to remove potential breeding sites (Taylor, 2003).

Ants have caused problems at most food production or processing premises at some time or other. Worker ants forage for food and carry it back to a central nest often at a considerable distance from the food source, leaving a chemical trail from that source. The result is that increasing numbers of workers appear in the facility, all following the same path (Beatson Campbell, 1991). Two species regularly causing problems in houses, hotels, restaurants, hospitals, warehouses and food production and processing facilities are the common black ant *Lasius niger* (L.) and the pharaoh's ant *Monomorium pharaonis* (L.). The latter can be controlled by insecticide baits based on juvenile hormone activity because, unlike the *Lasius* spp., there is usually only a single queen producing eggs in the nest.

Psocids are tiny, primitive insects feeding mainly on molds and decaying vegetable material in damp situations. They sometimes appear in huge numbers on food materials in commercial or domestic premises. The smallest opening in a food package can provide a point of entry for the minute nymphal stages. The commonest species is *Liposcelis bostrychophila* Badonnel, a rapid-moving, wingless, pale-colored insect about 1 mm long for which only females are known. Parthenogenetic multiplication can be rapid, but temperatures above 20°C and high humidity are needed for egg production (Turner, 1994).

Mites

Mites, more closely related to spiders than insects and extremely small, utilize microenvironments of moderate temperature and raised humidity. The most important family

associated with food storage problems is Acaridae, though the dried fruit mite *Carpoglyphus lactis* (L.) (Carpoglyphidae) and cosmopolitan food mite *Lepidoglyphus destructor* (Schrank) (Glycyphagidae) are also common pests. The life cycle includes a brief larval stage typically followed by three nymphal stages prior to the reproductive adult stage. Their rate of increase is unparalleled by any insect, with only 14 days being needed to complete development under optimal conditions and with a single female being able to produce 555–600 eggs (Cunnington, 1965; Boczek, 1991). Eggs are cold tolerant and in some species development can proceed down to 5°C, but in all species low humidities prevent development.

The flour mite *Acarus siro* L. is able to infest any food used by humans if the local environmental conditions are suitable. The mold mite *Tyrophagus putrescentiae* (Schrank) is perhaps the most cosmopolitan mite pest of stored products, occurring in any product with a high fat or protein content. The tiniest opening permits entry of mites into packaged products and, once inside, an unpleasant taint is produced in the substrate. Many mites are also strongly allergenic.

MINIMIZING PEST OCCURRENCE IN FOOD PREMISES

It can be seen from the optimum requirements of insect pest species that the ideal environment of food processing premises should be one of low temperature, low humidity and an absence of accessible food sources. Unfortunately none of these parameters can be maintained throughout a site and so there are always tensions in striving for the right balance between production needs and pest avoidance. Most food ingredients are vulnerable to pest attack, especially those with an equilibrium relative humidity above 65%, and the continual movement of commodities to and from trade premises poses a constant threat of importing pests. In nearly every country legislation demands the highest standards for any food product destined for human consumption, so the elimination of pest contamination of food is of paramount importance for the industry.

Effective control measures carried out at the source of raw ingredients provide a vital start to the chain that leads to the final processed product. Buildings need to be designed to avoid access points from outside and doors and windows need to be precision fitted and kept closed whenever possible. Recessing of external drainpipes prevents a ready access route to the eaves for rodents and wall surfaces should have a smooth finish both inside and outside. Internally, minimization of voids, ledges, crevices or dead spaces is an important aspect at the planning stage as these provide locations where insect pests can establish refuges. New machinery and facility construction should include pest preventive design as a priority. Rigorous, systematic cleaning of processing machinery and food production areas on a regular basis helps reduce risks of infestations becoming established. Timely and appropriate removal of accumulating waste and debris by vacuum cleaning, sweeping and washing is another vital aspect to be built into management practice. Streamlining product distribution to reduce residence time in store, and avoidance of storage alongside other less secure products, are other goals in the quest to avoid infestation problems. Care should also

be taken to avoid stacking products in corners or near to walls, which reduces access for cleaning and creates a harborage for pests.

Packaging can be an effective measure for reducing access of pests to food materials after processing but standard carton designs generally provide little protection against stored product insects. The spot weld glue patterns commonly used tend to leave channels through which smaller insect or mite stages can enter and does not provide a complete seal (Mullen and Mowery, 2000). Card, paper and cellophane wrappings are the least resistant to insect penetration, while polycarbonate, some polyesters, polyurethane and aluminum foil are much more resistant (Rao et al., 1972; Cline, 1978; Highland, 1984; Bowditch, 1997; Collins, 2003). All packaging is vulnerable to damage by rodents, and insects such as the lesser grain borer, biscuit beetle, cigarette beetle and larger larvae of pyralid moth species possess powerful biting mouthparts and are also able to penetrate most films. Any measures to improve packaging design by reducing the chance of an incomplete seal, and removing joins, folds and corners that are susceptible to mechanical damage or provide leverage for insect mouthparts, should be implemented. Over-wraps also improve resistance, particularly if applied as shrink-wraps fitting tightly around the package. A higher level of protection is provided by the "form-fill-seal" machines employed in modified atmosphere or vacuum packaging. A heat-molded base tray is filled with product and a flat lid is heat sealed across the top in the relevant atmosphere for the product.

All the above measures have economic implications and require there to be an adequate profit margin for the final product. Furthermore, although the presence of pests can be minimized, total elimination of pest incidence can never be guaranteed. There is therefore a need for measures to detect pests at an early stage before they locate and damage the product. Meanwhile research continues to refine methods of excluding and controlling pests (Riudavets et al., 2009; Moerman, 2010), but problems can only be avoided if vigilance is maintained and management procedures are optimized and rigorously applied.

PEST DETECTION STRATEGIES

A vital part of pest management programs is the early detection of pests. Many systems of trapping have been employed over the years, ranging from sticky papers and tapes, baited traps of various kind and thin lines of grease or food grade mineral oil around processing machinery or other vulnerable areas. The present focus is on the use of pheromones, the volatile chemicals released by the pest insects themselves that function as a means of communication between individuals (Burkholder and Ma, 1985; Campbell, 2007), and on food volatiles (Collins et al., 2007). Pheromones are particularly important for insect reproduction, both in long-range attraction of the opposite sex and short-range mate location.

The chemical structure of pheromones has been analyzed for a large number of species of concern in stored product protection (Burkholder and Ma, 1985; Phillips, 1997). A list of some of the materials that have been isolated and identified is given in Table 29.2. There are two basic types of pheromone involved in pest detection systems, sex pheromones and aggregation pheromones.

TABLE 29.2 Attractants Produced by Some Stored Product Beetles and Moths

Species	Attractant	Details
Lasioderma serricorne Cigarette beetle	Serricornin: (4,6-dimethyl-7-hydroxynonan-3-one)	Sex pheromone produced by females. Commercially available
Stegobium paniceum Biscuit beetle	Stegobinone: (2,3-dihydro-2,3,5-trimethyl-6(1-methyl-2-oxobutyl)-4H-pyran-4-one)	Sex pheromone produced by females. Commercially available
Rhyzopertha dominica Lesser grain borer	Dominicalure: (1-methylbutyl-(E)-2-methyl-2-pentenoate)	Aggregation pheromone produced by males. Commercially available
Cryptolestes ferrugineus Rust-red grain beetle	Ferrulactones I and II: [(E,E)-4-8-dimethyl-4,8-decadien-10-olide, and (3Z, 11S)-3-dodecen-11-olide, respectively]	Two-component aggregation pheromone produced by males. Commercially available
Cryptolestes turcicus Turkish grain beetle	(Z,Z)-5,8-tetradecadien-13-olide	Aggregation pheromone produced by males
Sitophilus granarius Granary weevil	Sitophilate: (1-ethylpropyl-2-methyl-3-hydroxy-pentanoate)	Aggregation pheromone produced by males. Commercially available
Sitophilus oryzae and *Sitophilus zeamais* Rice weevil and Maize weevil	Both species; Sitophinone: (5-hydroxy-4-methyl-3-heptanone, the 4S, 5R enantiomer)	Aggregation pheromone produced by males. Commercially available
Trogoderma granarium Khapra beetle	92:8 mixture of (Z)- and (E)-14-methyl-8-hexadecenal	Sex pheromone produced by females
Carpophilus hemipterus Dried fruit beetle	(2,4,6,8)E-3,5,7-trimethyl-2,4,6,8-decatetraene and related compounds	Aggregation pheromone produced by males. Commercial lure available
Carpophilus dimidiatus Corn sap beetle	(3,5,7,9)E-6,8-diethyl-4-methyl-3,5,7,9-dodecatetraene	Aggregation pheromone produced by males. Commercial lure available
Oryzaephilus mercator Merchant grain beetle	R enantiomers of Z-3-dodecen-11-olide and Z,Z-3,6-dodecadien-11-olide	Aggregation pheromone produced by males. Commercial lure available
Oryzaephilus surinamensis Saw-toothed grain beetle	R enantiomers of Z,Z-3,6-dodecadien-11-olide, Z,Z-3,6-dodecadienolide and Z,Z-5,8-tetradecadien-13-olide	Aggregation pheromone produced by males. Commercial lure available
Tenebrio molitor Yellow meal worm	4-methyl-1-nonanol	Sex pheromone produced by females
Gnatocerus cornutus Broad-horned flour beetle	(R)-acoradiene	Aggregation pheromone produced by males
Tribolium confusum, *Tribolium castaneum* Confused flour beetle, Rust-red flour beetle	Both species: 4R,8R-dimethyldecanal	Aggregation pheromone produced by males. Commercial lure available
Trogoderma spp. Warehouse beetles	(Z)-14-methyl-8-hexadecenal	Sex pheromone produced by females. Commercial lure available
Corcyra cephalonica Rice moth	Farnesal: (E,E-3,7,11-trimethyl-2,6,10-dodecatrienal)	Sex pheromone produced by males. Commercial lure available

(Continued)

TABLE 29.2 (Continued)

Species	Attractant	Details
Ephestia cautella Tropical warehouse or almond moth	Z-9-tetradecenyl-acetate	Sex pheromone produced by females. Commercial lure available
Ephestia elutella Warehouse moth	ZETA: (Z, E-9,12-tetradecadienyl-acetate), and ZETOH: (Z,E-9,12-tetradecadienol)	Sex pheromone produced by females. Commercial lure available
Ephestia kuehniella Mediterranean flour moth	ZETA: (Z, E-9,12-tetradecadienyl-acetate)	Sex pheromone produced by females. Commercial lure available
Plodia interpunctella Indianmeal moth	ZETOH: (Z, E-9,12-tetradecadienol), ZETA: (Z, E-9,12-tetradecadienyl-acetate), and Z, E-9,12-tetradecadienal	Sex pheromone produced by females. Commercial lure available

Sex Pheromones

Sex pheromones are usually emitted by females to attract males for mating. They have been reported from many moths and certain families of beetles including Anobiidae, Bruchidae and Dermestidae in which adults are relatively short-lived and feed very little or not at all (Burkholder and Ma, 1985).

Sex pheromone activity may be exclusive to a single species but commonly may be shared between several related species. Thus, the sex pheromone TDA (Z, E)-9,12-tetradecadienyl acetate (also known as ZETA), is active not only against *Plodia interpunctella* but also against at least four other of its pyralid relatives (Brady et al., 1971). Similarly, the anobiids *Stegobium paniceum* and *Anobium punctatum* share stegobinone (Kuwahara et al., 1978), and several *Trogoderma* spp. share (Z)-14-methyl-8-hexadecenal (Cross et al., 1976).

Aggregation Pheromones

Aggregation pheromones are usually produced by males and attract both sexes to suitable habitats and food sources where mating can then proceed. Beetles of the families Bostrichidae, Cucujidae, Curculionidae and Tenebrionidae which have adults that feed and are relatively long-lived substantially release pheromones of this type. As with the sex pheromones, aggregation pheromones may involve mixtures of materials and related species may share a common pheromone (Table 29.2). Aggregation pheromones have also been reported from mites (Kuwahara et al., 1982).

Food Volatiles

A wide range of volatiles and aromas emitted from food materials are attractive to stored product insects, notably those from groundnuts and carobs, and even plain water is effective in attracting moth species in dry conditions (Wakefield et al., 2006; Nansen et al., 2009). Food bait traps have been employed widely in food processing facilities to monitor for the

presence of beetle pests with varying degrees of success. The combined use of pheromones and food attractants offers the prospect of a monitoring system for a wide range of pest species.

Pheromones as Pest Management Tools for Detection and Monitoring of Pest Populations

Pheromones are powerful attractants because of the extreme sensitivity of insects to these cues, and enable infestations to be detected at very low levels when visual or other forms of inspection are unlikely to be successful. This information is a critical input for pest management programs and associated decision-support systems in the food industry, where contamination, not only by whole insects but by fragments of them, is a major public health issue. Discovery in a laboratory oil flotation test of rodent hairs, mite or insect fragments in a product sample is the retrospective discovery of a control failure, requiring urgent action to locate the source and revise pest management procedures.

Pheromones are often complex mixtures of related compounds and their stereo-isomers can evoke vastly different responses in the species concerned; correct identification, synthesis and blending of the components is essential. Efficient delivery mechanisms for pheromones are also crucial. They must be capable of being adjusted to produce the appropriate concentration level for the species concerned, releasing the pheromone at a uniform rate, and have a capacity consistent with the particular application and operational lifetime. Trap design is important for both walking and flying insects. The distribution of traps in the treatment area is also a key factor. A vital issue after detecting the presence of insects in a facility is the accurate location of the infestation origin and to this end, precision targeting of infestation sources by spatial analysis has proved useful (Campbell, 2007; Trematerra et al., 2007), enabling control measures to get under way before other signs are evident.

PEST CONTROL STRATEGIES

Chemical Control Methods

Until recently chemicals were the mainstay for pest control in the food and agricultural industry but there has been a steady move away from reliance on biocides as a succession of adverse side effects for one compound or another have come to light. Hence the more toxic substances have largely been replaced and the use of the remaining materials is being confined to application to surfaces or areas where subsequent contact with food or packaging is unlikely, thus avoiding the problem of chemical transfer to the food (Highland et al., 1984).

Insect Growth Regulators

In recent years the focus has been on developing compounds of highly specific action, based on the physiology of the pest. In this area chemicals that act by disrupting insect life cycles have been developed. Insect growth regulators have come into use for the protection of many stored products such as grain (Oberlander et al., 1997). Methoprene, fenoxycarb

and hydroprene are commercially available juvenile hormone agonists, which cause the terminal disruption of insect development but have little or no mammalian toxicity. Their use in admixture on grain or on surfaces such as fabrics can confer protection against pests for over a year.

A second group of insect growth regulators act by interfering with the molting hormone ecdysone with consequent prevention of normal metamorphosis and these are effective against Lepidoptera. A third group, effective against cockroaches, act by inhibiting the synthesis of chitin which also prevents normal molting of immature stages. Besides the very long life of the compounds, which can be an issue in international trade if residues of any added chemical are detected, another constraint for the use of insect growth regulators has been in integrated pest management programs where economically important bio-control agents may be adversely affected.

Insecticides and Repellents

The use of insecticidal sprays and dusts has been a routine measure for spot treatment of localized infestations and surface application to areas of high risk. Organophosphorus and pyrethroid compounds remain in use for this purpose though registrations on some compounds are lapsing in many countries, restricting the choice available. Much effort is being placed on the search for new insecticidal compounds of botanical origin and some such as azadirachtin from the neem tree have joined with pyrethrins as registered botanical insecticides. A more recent addition, the bacterial metabolite-based product, spinosad (Fang et al., 2002), is also available as a dust formulation. Dichlorvos space sprays have now been replaced by ULV or aerosol treatments of synergized pyrethrins or pyrethroids in food production facilities, sometimes in mixture with an insect growth regulator such as methoprene (Arthur, 2010), but are only effective against flying insects. The field of insect repellency is one still under investigation, a non-toxic, non-specific insect and mite repellent being the goal.

Fumigants

For many years fumigants have been relied upon for the whole site treatment option when infestation problems get out of control. Flour mills and chocolate factories would typically have an annual fumigation by a licensed company to have a fresh start. To be effective the fumigant had to be suitable for rapid and even distribution throughout the treatment area and in order to minimize production downtime it had to be effective against pests within 24 hours. The first fumigant in widespread use for treatment of structures, hydrogen cyanide, was replaced in the 1960s by methyl bromide, which, though less of an acute toxic risk to operators was still a highly toxic compound. It was extremely effective when used in a well-sealed structure, being an excellent penetrant of voids containing food residues and highly toxic to all pests, achieving control within 24 hours.

Methyl bromide, listed as an ozone depleting compound under the Montreal Protocol in 1992, was phased out from all but a few specialist uses in non-Article 5 (developed) countries in January 2005. Developing countries can continue using methyl bromide until 2015, beyond which their use also will be confined to a few quarantine-related circumstances (UNEP, 2006). The only other fumigant widely registered at the start of this century was phosphine, which is an excellent fumigant for commodities in store where the longer residence times permit

the long exposure periods (up to 3 weeks at 15°C) required for effective control of pests. Best results are obtained by using a double layer of polythene sheets for packaged materials and treatments may only be carried by registered pest control operators who apply the aluminum or magnesium phosphide gas releasing formulations and dispose of the residues remaining at the end of the treatment according to established procedures. Access to the building in which the fumigation is carried out must be restricted and gas monitoring is required during the 24-hour aeration period after unsheeting to ensure that local atmosphere threshold limit values are not exceeded before releasing the stock for handling.

Phosphine is, however, difficult to use in food processing premises because of its corrosive properties against electronic equipment and the long exposure times required, especially at temperatures below 25°C. Although an alternative fumigant, sulfuryl fluoride (trade name Profume), has been registered for use in empty flour mills starting in Switzerland in 2003, in the UK and Italy from 2004, and now in many European countries, Australia, the USA and Canada, concerns over its global warming potential and the significance of fluoride residues have delayed registrations for use on many food materials or in structures where raw or processed food is present. Its use also requires additional heating as insect eggs are tolerant and would otherwise require long exposure times for control (Bell, 2006). With increasing pressures for the safe and effective use of chemicals, any move away from heavy reliance on them is obviously desirable.

Physical Control Methods

There are opportunities and limitations for the use of physical control methods in structures. The use of modified atmosphere (MA) techniques for space treatments, for example, is restricted to specialist chambers because whereas buildings can be sealed sufficiently for fumigation, they cannot be sealed to the much higher standard required for MA applications. Scope for use of sonic, microwave or radiation technologies is also very limited. Nevertheless several physical methods are of value in the controlling of pest outbreaks.

Heat

For the food processing industry the downtime and production loss arising from whole site treatments to combat pest problems has restricted control options to those which act most rapidly and effectively. This was the principal reason for adopting methyl bromide as the mainstay for a reliable annual whole-site treatment strategy. Heating to 47°C or above results in rapid immobilization and death of insect and mite stages within a few hours. Heat is thus one of the few options offering a similar rate of action to chemical fumigation. The principal problem for heat disinfestation, though, is the planning of heating requirements and heat source deployment to obtain a uniform heat profile throughout the structure without causing high localized temperatures which would cause damage to structural or electronic components. The temperature of air from heaters needs to be limited to 65–70°C to avoid activating sprinklers or causing expansion and cracking; and air speeds should not exceed 5 m/s to avoid dust explosions. Structural heat treatment involves raising the building temperature to 50–55°C at a rate of 5°C per hour. Sufficient heaters to ensure that 50°C is reached within 6–8 hours are required. Spot heat treatments may also be carried out where a zone of a processing facility or an item of machinery is heated to above 50°C with a forced hot air stream.

Much progress has been made using a combination of heating strategies, often in conjunction with the use of inert dusts to treat areas difficult to heat such as voids and cracks, a procedure first tested in Canada and further developed in Europe (Dowdy and Fields, 2002; Bell et al., 2004). Residual infestations in deep-seated harborages in the basement or elsewhere remain a particular problem. It must be remembered that the target temperatures for control must be reached at the point where the insects reside in the structure, a process that may take 24 hours, and that the presence of protective material such as food residues can lower the temperature experienced by the insect (Bartlett et al., 2005).

Cold

The intense periods of winter cold have long been used by millers and warehouse keepers in Canada and the northern USA for a "freeze-out" of pests and there is seldom any need for additional control methods in the first few months after treatment. Cold can also be used as a spot treatment by the injection of liquid nitrogen into confined spaces such as wall voids. However, insulation in walls can affect cold distribution, leaving protected warm spots. Also, surfaces can be stained and warping of wooden structural components may occur.

Most insects succumb to exposure at temperatures below −10°C within a few days while below 10°C insect reproduction ceases and population levels of most pests slowly decline (Fields, 1992). The stage of development of the pest is a factor in its cold resistance: eggs are more sensitive, and adults or larvae, especially those in diapause, are the most cold tolerant. Nevertheless adults of most species can survive temperatures around 4°C for many months and so can readily overwinter in buildings in temperate climates. In consequence, cold exposure requires very long holding times to be effective and this is rarely achievable in the production areas of food processing facilities. Nevertheless, the use of designated cold storage areas for incoming ingredients is a widely practiced measure in many industries in spite of the requirement for high capital investment.

Impaction

Many situations in which agricultural products are mechanically conveyed during food processing offer the opportunity for control of insects by shock, abrasion and impaction. The principle was developed over 70 years ago for use in the flour milling industry and impaction machines such as the "Entoleter" became a routine fixture in facilities such as flour mills (Pagani et al., 2006). In the Entoleter, flour falls between two rapidly spinning discs. Centrifugal force pushes the flour to the edges of the discs where it impacts a row of steel pegs mounted on the rims, and is thrown against the outer steel casing before falling into the basal receiving hopper. The material passing through the Entoleter thus encounters two major impactions and this effectively controls all free living insect stages. Impaction machines can also kill a high percentage of insects such as weevils developing inside cereal kernels (Vincent et al., 2003; Beckett, 2010).

Inert Dusts

Inert dusts cover a wide range of materials including clays, sands, ashes, diatomaceous earths (DE, fossilized remains of diatoms consisting mainly of silica with small amounts of other minerals), silica aerogels and non-silica dusts, such as phosphate and lime. Inert dusts have a long history of use for grain protection (Ebeling, 1971). Their lethal action against

pests is caused by dehydration, the cuticular waxes being adsorbed by the desiccant upon prolonged contact. Abrasion of the cuticular joints in mobile stages may also be a contributory factor but recent formulations are being designed to minimize their abrasive properties to protect conveying machinery.

Inert dusts are registered in many countries for treatment of grain and pulses against insect pests and for use as sprays applied to the fabric of food premises to minimize residual infestation and migration of pests. They form a useful part of IPM strategies providing an alternative to chemical protectants for pest control (Dowdy and Fields, 2002). Some formulations are accepted as suitable for use on foods certified as "organic" in some countries. DEs are widely used as food and processing additives.

Irradiation

Irradiation from a cobalt-60 source has been used primarily as a bactericide for many years for treatment of some commodities, mainly spices, but also for dried and fresh fruit, potatoes, onions and poultry. It requires proximity to a commercial treatment source to be practical and consumer acceptance has limited its widespread use.

The methodologies for use of irradiation include exposure of a commodity by continuous flow through an irradiator or by batch treatment of cartons by pallet load, or indirect methods such as sterile male release for pest population management. A 10-MeV electron beam unit has also been in use for certain applications but the reduced safety concerns are outweighed by the very low penetrability of commodities, restricting the form in which they can be presented for treatment.

Sterile male release has given effective control of heavy field infestations of insects but apart from application in certain warehouse situations is not of relevance to the food industry where the avoidance of insect presence is the goal.

Biological Control Methods

Many organisms are known to attack, infect or parasitize stored product insects, some o which are listed in Table 29.3. The use of such organisms in food processing facilities is limited by the need to ensure that their presence does not itself lead to problems as discovery of any insect fragments in a finished product is unacceptable. Nevertheless opportunities exist for their deployment in receival facilities to deal with background pest levels in empty stores as an alternative to cold storage or fabric treatments with insecticides (Scholler et al., 1997). Pathogens are in use in conjunction with attractants to provide a control system for flying pests (Kellen and Hoffmann, 1987), and also as additives to bulk commodities such as cereals (Wakefield et al., 2010).

Use of Pheromones for Population Control

Pheromones can be used to provide the attraction agent for mass trapping to physically remove insects, by disrupting mating to prevent breeding, or by acting as an attracticide to a point where pesticides, pathogens or sterilizing agents are used as the control agent. The technique is used to reduce pest populations to manageable levels rather than eliminate them and is most suited to confined areas. It is most effective at relatively low starting population densities. Aggregation pheromones are more effective than sex pheromones

TABLE 29.3 Potential Biocontrol Agents and their Possible Target Food Pest Species

Parasite/Predator/Pathogen	Description	Host Species/Prey
Anisopteromalus calandrae (Howard)	Pteromalid wasp, endoparasite attacking larvae	*Lasioderma serricorne, Rhyzopertha dominica, Sitophilus* spp.
Choetospila elegans Westwood	Pteromalid wasp, endoparasite attacking larvae	*Lasioderma serricorne, Rhyzopertha dominica, Sitophilus* spp., *Trogoderma granarium*
Dinarchus dasycer (Walker)	Pteromalid wasp, endoparasite attacking larvae	*Stegobium paniceum*
Lariophagus distinguendus (Foerster)	Pteromalid wasp, endoparasite attacking larvae	*Lasioderma serricorne, Stegobium paniceum, Rhyzopertha dominica, Sitophilus granarius*
Pteromalus cerealellae Ashmead	Pteromalid wasp, endoparasite of larvae and pupae	*Lasioderma serricorne, Sitophilus* spp.
Zatropus incertus (Ashmead)	Pteromalid wasp, endoparasite attacking larvae	*Sitophilus oryzae*
Cephalonomia gallicola Ashmead	Bethylid wasp, ectoparasite attacking larvae	*Lasioderma serricorne, Stegobium paniceum*
Cephalonomia tarsalis Ashmead	Bethylid wasp, ectoparasite attacking larvae	*Oryzaephilus* spp.
Cephalonomia waterstoni Gahan	Bethylid wasp, ectoparasite attacking larvae	*Cryptolestes ferrugineus, C. turcicus*
Habrobracon brevicornis (Wesmael) nd *H. hebetor* Say	Ichneumonoid (Braconid) wasps, endoparasites attacking larvae	Pyralid moths
Venturia canescens (Gravenhorst)	Ichneumonid wasp, endoparasite attacking larvae	Pyralid moths
Trichogramma cacoeciae Marschal, *T. evanescens* Westwood and *T. pretiosum* (Riley)	Trichogrammatid wasps attacking eggs	Pyralid moths
Acarophenax tribolii Newstead and Duvall	Predatory mite attacking eggs and small larvae	Tenebrionid beetles
Cheyletus eruditus (Schrank)	Predatory mite attacking eggs and small larvae	Stored product beetles and moths other than internal grain feeders
Pyemotes tritici L.-Fossat & Montagne	Predatory mite attacking eggs and small larvae	Stored product beetles and moths other than internal grain feeders
Pyemotes ventricosus (Newport)	Predatory mite attacking eggs and small larvae	Most stored product beetles and moths
Xylocoris flavipes (Reuter)	Predatory bug	All free-living stages of stored product beetles and moths
Adelina spp., *Farinocystis tribolii*, *Mattesia diaspora*, *M. oryzaephili*, *Nosema* spp.	Pathenogenic schizogregarines	*Cryptolestes ferrugineus, Oryzaephilus* spp., *Tribolium* spp., *Plodia interpunctella*
Bacillus thuringiensis and *B. cereus*	Entomopathogenic bacteria	*Lasioderma serricorne*, Pyralid moth larvae
Polyhedrosis viruses	Larval pathogens	Pyralid moths
Beauveria bassiana (Balsamo) Vuillemin	Entomopathogenic fungus	*Sitophilus* spp., *Tribolium* spp., *Oryzaephilus* spp.

because both sexes are attracted to the traps. Nevertheless mass trapping has been successfully trialed with sex pheromones against moths in flour mills to reduce pest populations to a constant low level (Trematerra and Gentile, 2010). The pheromone trap is baited with an insecticide such as cypermethrin or another quick knockdown agent or arrestant to retain the attracted moth. Alternatively a pathogen source may be incorporated to disseminate disease through the pest population.

Another approach is to use sex pheromones to disrupt mating. It is achieved by flooding the environment with the sex pheromone of the target species so that mating behavior is disrupted by false-trail following and sensory fatigue so that mate location and reproduction is minimized. The dispensers need to release adequate amounts of pheromone over a prolonged period and treatments need to be applied before emergence of the target species over a wide area for successful results.

Integrated Pest Management (IPM)

IPM is a pest risk-management approach combining a selection of the methods described above in a way that addresses socioeconomic, health and environmental risks in a sustainable manner while maintaining an acceptable level of productivity. It is highly information based, integrating knowledge about the pests with knowledge about the facility to avoid pest problems and maintain high product quality. A book edited by Heaps (2006) reviews the present status of IPM for mills and processing facilities. For successful implementation, adequate training of industry staff on the tools employed is necessary and this is a problem in some countries where there are few opportunities for formal professional education (Bartosik, 2010). In many cases pest management is contracted out by companies to a registered pest control company with specialist trained staff, but for any management strategy to work the minimum requirement is that a weekly inspection of facilities, and particularly trapping and baiting locations, is carried out and coupled with a clearly laid-out line of action if evidence of pest presence is obtained.

EMERGING THREATS FOR THE SUCCESSFUL MAINTENANCE OF PEST MANAGEMENT

The big issue regarding the continued successful use of chemicals for control of stored product pests is the development of resistance. Pests have become resistant to insecticides, insects growth regulators, fumigants such as phosphine and even to some bacteria-based sprays. The problem is often compounded by cross-resistance to other groups of compound. Resistance to phosphine was first detected more than 30 years ago and more recently occurrences of strongly resistant strains have been reported from Australia (Nayak et al., 2010) in the rusty flat grain beetle *Cryptolestes ferrugineus*. To achieve control of this strain at 20°C a concentration of 720 ppm needs to be maintained for 24 days, a far greater dosage than needed to combat previously encountered high resistance levels in the lesser grain borer *Rhyzopertha dominica*, and other pests.

Adoption of alternative strategies that avoid chemical control tends to be costly and labor intensive. This places a burden on the manufacturer that cannot always be passed on to the

consumer and can result in lower standards of pest management than when chemicals were in wider use. A related effect that is often overlooked is that the reduced market for chemicals results in products being withdrawn from the market, particularly when an existing compound comes up for regulatory review on a prefixed timetable. Product registration is required in most countries for each chemical intended for use in pest control. Significant efforts have to be undertaken by commercial companies to conduct research, assemble and submit a registration package to obtain a label for legal use of a new compound or to extend the use of one that is under review. The registration process is very costly with lengthy delays and requires that the company developing the product has a high level of technically qualified personnel. Applications are often returned with requests for more data, increasing the expenditure. Where the company can only see a small market in a particular country or application, they are unlikely to proceed with registration. This can result in the disappearance of existing compounds from the market, reducing the options for pest control.

Although some problems remain, pest management standards in the food industry have never been higher and research is actively in progress to keep abreast of developments as new pests and new products and procedures come into being.

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CHAPTER

30

Safe Handling of Food in Homes and Food Services

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OUTLINE

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INTRODUCTION

Preparing food in the home or food service is frequently the last link in the food chain before food is consumed and in essence it entails catering/preparing and serving of food. Safe food handling at this point is critical in preventing foodborne illness and also in maintaining the food safety measures undertaken by other supply chain participants up to this point. This is one of the most complex links within the food supply continuum and presents

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challenges in managing food safety risks. This is related to many factors such as diversity of foods prepared within a facility or at a food event; the multi-ingredient or component nature of the food handled; extremes in volume of foods handled and size of the operations; wide ranges of food worker education and communication levels and high employment turnover; and overriding socioeconomic factors enabling safe food handling practices worldwide.

The principles of safe food handling in the home and food service are not dissimilar to the basic principles in other sectors that are presented in Chapters 33–36. The technologies employed, elements of food safety assurance and food safety management in accompanying chapters are also relevant. The food safety hazards are common also although their incidences can vary in this sector. Differences at this end of the food chain are related to the nature of the food preparation practices, the potential for hazard exposure associated with those practices and the opportunity for the persistence and growth of microbial pathogens if there is poor control of food safety, particularly when there are no further controls for their elimination or reduction before consumption. While the principles of safe food handling are similar, a more flexible approach in their implementation is often necessary, tailoring food safety management to accord with local culture, economics and available infrastructure, particularly in the domestic and the informal food services sectors. In this chapter emphasis is placed on specific aspects of safe food handling in food services and the home and some of the challenges in managing food safety programs are highlighted. It is assumed the basic principles of food safety management, foodborne hazards and their control in other chapters are read in conjunction with this chapter.

Food handling in the home may simply be serving food procured outside the home or the preparation of meals from raw, partially or fully ready-to-eat food. Food services for the purpose of this chapter include the preparation of any food or meal prepared outside the home and may be either temporary or permanent, ambulatory or on a fixed site. Some examples include food preparation in vendor stalls or vehicles in streets or markets, bars and restaurants, cafeterias and canteens (e.g. in schools, workplaces, shopping centers), care facilities (e.g. child daycare and aged care centers, hospitals, institutions), catering operations, transport (boats, trains and planes) and many others. Foods available in food services such as street venders and market stalls may have been prepared in homes and small cottage industries. In poor communities, people may rely on food prepared by ambulatory vendors and in markets as they do not have the facilities for preparation at their dwelling place. In contrast, in developed countries, the increasing trend is to eat food prepared outside the home and to buy food from markets in association with busy lifestyles, income growth, health and environmental consciousness (Price, 1997; USDA, 2009). Almost one-half of every dollar spent on food in the USA is believed to be spent on food from restaurants (Jones and Angulo, 2006). Food prepared in these sectors can be for one or a few persons in a single sitting or it may be catering with thousands of meals, stored and served at a later time, resembling industrial-scale food manufacture.

EVIDENCE OF FOODBORNE ILLNESS AND CONSEQUENCES

Food safety risk managers can obtain valuable information from foodborne illness surveillance on priority hazards and their health impact, the most vulnerable populations, the foods attributed and locations where they were consumed and prepared, and factors that

may have contributed to the food being hazardous. Surveillance is not universally available and most is derived from developed countries. Most data are based on outbreaks and do not include the many sporadic cases that occur. If high numbers of consumers are exposed at a common time or place there is a greater chance an outbreak will be recognized. Often locations or setting of outbreaks that are reported are places where food was consumed and not necessarily where it was prepared. Notwithstanding some of these biases, such data provide valuable insights and guidance in food safety management.

Food services and the home are frequently cited as the location for foodborne illness outbreaks. In 2007 in the USA, 40% of 503 confirmed outbreaks were reported as located in restaurants and delicatessens and 16% in private homes (CDC, 2010). In the UK in 2006, among 66 outbreaks, the setting was restaurants for 58% and homes and private locations for 18% (EFSA, 2009). In Australia in 2008, restaurants were reported as the location of 43% of confirmed and suspected outbreaks (OzFoodNet, 2009).

The health risk associated with the consumption of contaminated food depends on the level of the hazard and severity of the associated health consequences. The susceptibility of the individual consumer is an important risk factor for foodborne illness where those with a developing, declining or impaired immune status such as the very young, the elderly and the ill are most vulnerable and may experience the most severe health consequences. For example, among 17,468 laboratory-confirmed cases of enteric infection in the USA in 2009, the reported incidence was highest among children aged less than 4 years and the percentage of persons hospitalized and the case fatality rate were highest among persons aged more than 50 years (MMWR, 2010).

The number of vulnerable persons is increasing as the proportion of aged persons in the population is increasing, advancing medical intervention is extending life expectancy of the health-impaired and immune-deficient persons, and while young children remain at high risk of exposure particularly in areas of poor sanitation and hygiene. All this means safe food handling for vulnerable persons is increasingly recognized as a priority public health activity worldwide. Food consumed by vulnerable persons living in the community may be prepared domestically or purchased from the informal food sector or may be provided by a delivery service from a community food service facility. Vulnerable people may also be gathered in special care facilities (e.g. hospitals, child daycare and aged care centers) where they may be exposed to food prepared in food service operations. Authorities have taken action to recommend the avoidance of certain foods for vulnerable populations in institutions; however, adherence to these guidelines has been reported to require improvement (Dalton et al., 2010; Nelson et al., 2008).

While the public health cost of illness resulting from a food safety failure in this sector is similar to that in others, the cost to an individual business can be greater. A medium or small operator may no longer be viable following loss of a license, adverse publicity, litigation and legal costs, and loss of customers following an incident or recall. There is an increasing trend for public disclosure of regulatory hygiene inspection ratings of restaurants and similar outlets on official websites or by placing a notice on the outside of the premises. Adverse results can be quickly disseminated via the media and internet social networking. The intention of these programs, also known as "scores on doors" or "name and shame," is to allow consumers to make informed choices based on hygiene inspections about the places in which they choose to eat and from which they purchase food. It is anticipated that businesses will be encouraged to improve hygiene standards as negative publicity is damaging for trade.

At national and international levels, reports of foodborne illness are damaging for trade and tourism. Food services directly interface with travelers who are frequently compelled to eat their food while in transit or at their destination and are unable to prepare their own food. An incident of illness related to business or recreational travel has a particularly lasting impact if it is associated with loss of time and earnings or if it is incapacitating. From a public health perspective infected travelers present a specific concern as they are a potential means for the spread of exotic diseases around the world. For example, cholera and typhoid are diseases that are endemic in regions of poor sanitation and hygiene. In developed regions these diseases occur mainly in travelers returning from endemic areas. New or rare strains of biological agents can be introduced into a country via travelers as, for example, *Salmonella Enteritidis* is not endemic in Australia and of the cases of infection that occur most are among travelers from overseas (OzFoodNet, 2009).

FOOD SAFETY HAZARDS

Food safety hazards of concern may be biological, physical or chemical. In developed countries outbreaks of the following microorganisms and their toxins are most commonly reported: predominantly enteric viruses, a non-typhoidal *Salmonella enterica*, and *Campylobacter* spp., followed by staphylococcal enterotoxins, *Clostridium perfringens*, pathogenic *Escherichia coli* (particularly enterohemorrhagic pathotypes), *Bacillus cereus*, *Vibrio parahaemolyticus* and marine toxins (CDC, 2010; EFSA, 2009). Others include *Shigella* spp., other pathogenic *Vibrio* spp., and *Brucella* spp. These microorganisms may be included also in sporadic incidents where routes of transmission are not determined. Parasitic infections include *Giardia lamblia*, *Cryptosporidium* and *Cyclospora* sp. In regions of poor sanitation and hygiene and in certain endemic regions Hepatitis A virus *S. Typhi* and pathogenic *E. coli*, mycotoxigenic fungi and a broader range of parasites may be more important. Other hazards vary depending on the local features such as human and zoonotic disease epidemiology and the presence of toxic animals and plants. Physical hazards (stones, metal, plastic, insects, bone and seeds, etc.) have a greater chance of being undetected in food sold at markets and street stalls compared with packaged food screened by manufacturers. Physical hazards introduced during food handling (Band-Aids, finger-nails, broken glass, etc.) can pass unnoticed at this final stage of the food chain. They can be introduced during food preparation or by consumers when using self-service facilities.

Agricultural and veterinary chemicals, non-approved food additives and accidental contamination with chemicals used for cleaning and sanitization are important, particularly where there is limited control of or regulatory compliance with food safety in primary production and manufacturing and in implementation of safe operating procedures. Allergens are a particular concern in this sector as much of the food is unpackaged and unlabeled making it more difficult to inform the consumer of the entire ingredient list.

FOOD SAFETY RISK FACTORS

In outbreaks, foods attributed are often multi-ingredient dishes and overall most food commodity groups are included as a main component or as an ingredient. There are several

food handling factors repeatedly reported following outbreak investigations. In the UK in 2006, among 66 outbreaks were included inappropriate food storage (14%), infected food handler (6%), cross-contamination (33%) and inadequate heat treatment (18%) of food (EFSA, 2009). An assessment of the foodborne illness risk factors in institutional foodservice, restaurants and retail food stores was undertaken in the USA in 2000 and 2004 with recurring risk factors identified, namely: improper holding time and temperature, poor personal hygiene and contaminated equipment (USFDA, 2004). The frequency of failure of compliance in these areas in different foodservice operations is shown in Table 30.1.

FOOD SAFETY MANAGEMENT

Most governments are moving progressively to require all food businesses, including food service operations, to be registered and to have a food safety program or plan in place.

A proactive and preventive approach is preferred and the hazard analysis critical control point (HACCP) system has been chosen by many authorities as the basis for such food safety programs although other approaches may be taken (CAC, 1969). HACCP is described in Chapter 31 and includes a series of defined steps based on scientific evidence; however, it may not be practical to apply HACCP in its entirety in this sector, for example in small and less developed businesses. To overcome this, a food safety program that is based on core HACCP principles may be more appropriate where hazards are identified and controls for their management and corrective actions are put in place, provided the approach remains based on sound knowledge of food safety (Carvalheiro and Rocha, 2008). Flexibility allowing procedures to be in proportion to the health risk, size and type of business, and capability, with emphasis on relevance and future improvement, is more important than detail and

TABLE 30.1 Foodborne Illness Risk Factors and Rates (Percent) at which Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types Were out of Compliance in the USA in 2003. Data taken from (USFDA, 2004)

	Institutional Food Service			Restaurants		Retail		
Risk Factor	**Hospitals**	**Nursing Homes**	**Elementary Schools**	**Full Service**	**Fast Food**	**Deli**	**Meat and Poultry**	**Seafood**
Improper holding/time and temperature	40.3	30.7	30.8	63.8	41.7	64.4	29.8	42.2
Contaminated equipment/protection from contamination	18.9	20.4	22.2	37.3	21.9	23.4	24.4	20.0
Poor personal hygiene	17.5	20.2	16.3	42.7	31.2	23.5	21.4	16.8
Other/chemical	13.4	18.1	13.5	30.6	28.3	21.9	16.3	17.5
Inadequate cooking	6.3	5.0	4.5	25.8	9.1	9.2	–*	–
Food from unsafe sources	0.5	3.2	3.0	13.0	2.3	5.0	5.0	12.7

*Low levels of non-compliance.

TABLE 30.2 The World Health Organization's Five Keys to Safer Food (WHO, 2006)

Keep clean
Separate raw and cooked
Cook thoroughly
Keep food at safe temperatures
Use safe water and raw materials

complexity. The challenges of universal implementation of HACCP have been recognized internationally. More detailed information is available in "Guidance to governments on the application of HACCP in small/less developed food businesses" (FAO/WHO, 2005).

Food services vary in operational organization, e.g. food may be prepared in individual units or in a centralized facility serving satellite units; food may be prepared on site or brought in partially (for assembly) or wholly prefabricated from suppliers to economize on skills, labor and equipment. Similarly food consumed in the home may be prepared there or purchased from a food vendor or food service. Food safety risk management generally lies with the owner/primary care giver and/or the person(s) responsible for the food service operation. By purchasing pre-prepared food the safety management is passed on partially; however, the food service manager is responsible for ensuring incoming products are procured from a safe and reliable source and food distributed to branch units remains safe.

Safe food handling in the home and the general community can also be based on the application of HACCP principles. Food handlers in these settings acquire their food safety knowledge through educational messages provided by their relatives and community contacts, schools, community centers, authorities and the media. These messages should be based on the identification of the major local food safety hazards together with practical and culturally appropriate safe food handling practices for their control. The *Five Keys to Safer Food* is a simple global health message developed by the World Health Organization (WHO) that is based on scientific evidence and is for use in education of all types of food handlers, including ordinary consumers. The message and training materials for adoption to different audiences are available online at http://www.who.int/foodsafety/consumer/5keys/en/. The Five Keys to Safer Food are shown in Table 30.2.

APPLICATION OF HACCP PRINCIPLES TO FOOD SERVICE AND THE HOME

The Codex Alimentarius Commission provides a sequential approach for the application of the seven HACCP principles and this approach is considered in relation to preparation of food in food services and the home (CAC, 1969).

Food service operations can range from large multinational corporations to very small and less developed businesses. The personnel similarly range from large multidisciplinary workforces to a single individual. While in the former the resources and capability

to develop food safety programs may be available in-house or can be commissioned, for the latter this will most likely be lacking. For those lacking the expertise or resources expert advice and assistance in establishing an effective food safety plan may be obtained from industry and trade organizations, from regulatory authorities and hygiene inspectors, from consultants and from extension services provided by some educational institutions. Information for self-help can be obtained from published literature and from model HACCP guides and similar resources developed for various commodities and business types that can be applied following adaption to a particular business. Regulatory authorities may provide manuals, tables, forms and checklists to guide and assist in development of food safety programs that meet their requirements. The WHO (http://www.who.int/foodsafety/en/) and the Food and Agriculture Organization (FAO) (http://www.fao.org/ag/agn/agns/) provide resource material including guides to food safety risk analysis and its components of risk assessment, management and communication with guidance for developing countries and less formal food sectors such as street vended foods. Risk assessments for specific food safety hazards both biological and chemical and specific products are also available. The Codex Alimentarius Commission provides a wide range of Codes, Guidelines and Standards for general principles of food hygiene, for specific commodities and specific food handling locations. These are available in hard copy or can be downloaded from their website at http://www.codexalimentarius.net/web/index_en.jsp (cited August 2010).

PREREQUISITE PROGRAMS

A successful food safety program depends on basic hygienic and sanitary operating conditions, known as "prerequisite" programs (CAC, 1969). In undeveloped communities there may be limited understanding of basic hygiene and a lack of infrastructure available to enable basic hygiene prerequisites to be implemented (Vollaard et al., 2004). HACCP-based programs may have to be staged to allow implementation of basic hygiene first, or if the food services in question are the only source of accessible food and nutrition for the community they need to occur concurrently to maintain the food supply. In its simplest application, prerequisite requirements are not identified as separate from managing critical control points. For example, in the WHO Five Keys that can be applied in the community and with small food services such as street foods, these basic hygiene requirements are included in "keep clean" and "use safe water and raw materials" along with control points (Table 30.2). Education and training are included in prerequisite programs; however, because of their importance they are discussed under a separate heading in this chapter.

Design, Layout and Facilities

There are some unique aspects in the application of prerequisite programs in food services and homes compared with other parts of the food chain. The location, design and layout of some food services are examples as they can be temporary or permanent, mobile, ambulatory or fixed, and they may have very limited space for food preparation. Space for storage

of food and for storing cleaning agents, etc. can also be limited, increasing the opportunity for cross-contamination. Those in vendor vehicles and stalls in streets and markets may lack access to services such as power, potable water, sewerage and waste removal. Affordable vehicles or stalls designed with food safety taken into account could be made or provided for rental on a community basis. The provision of designated sites for stalls and vendors with access to shared facilities and materials and conducive to the preparation of safe food also help to overcome this. Such venues provide a convenient location for authorities to communicate with and to provide education and training for the food handlers. There has been considerable study of food services and vendors of this type and the Codex Alimentarius Commission provides specific guides such as the "Revised regional guidelines for the design of control measures for street-vended foods in Africa" (CAC, 1999) as does WHO and FAO from their websites. Many local authorities provide safe food handling guidelines specifically for food services and individuals preparing food when traveling, for charities and community groups, at markets and temporary events, and in home-based businesses.

Control of Incoming Materials

Prerequisite programs include managing the quality of incoming raw materials and ensuring they are from approved suppliers and are safe and fit for the intended purpose. Food services and homes are frequently cited as the setting for illness outbreaks; however, the contamination may occur earlier in the food chain and this location is the place of consumption (Jacob and Powell, 2009). The quality of the incoming ingredients or foods is important particularly if the food is consumed with no further processing and if it is intended for high risk individuals. There have been some notable examples of contaminated raw ingredients used in food services and homes. Salmonellosis outbreaks attributed to egg and egg-related dishes prepared in food services and homes have been associated repeatedly with the purchase of cracked and dirty shell eggs and eggs not produced under approved quality assurance schemes together with inadequately cooked or uncooked eggs and egg-based dishes (Slinko et al., 2009). Pathogenic *Vibrio* spp. are a food safety risk in shellfish, particularly in oysters, that are popular in food services where they are served raw. The health risk has been closely related to pre-harvest management and post-harvest handling leading to regulatory controls (DePaola et al., 2010). Raw oysters should only be accepted from approved sites and with identification labels.

The intentional or unintentional addition of unapproved food additives or chemicals in food occurs particularly in regions where good hygiene practices and enforcement of controls are limited. The addition of melamine to powdered milk used in infant formula resulted in a nationwide outbreak of serious illness in children (FAO/WHO, 2009). Uncooked chicken pieces accidentally contaminated with ammonia during a refrigerant leak in a warehouse then prepared for a school lunch resulted in 157 persons becoming ill (Dworkin et al., 2004).

Ice, while not a food, is often used to keep food chilled. Both the ice and the water from melted ice can come into direct contact with prepared food or food to be eaten raw. Ice should be made from potable water or if this is not available at least it should be from a reliable and known source.

Personal Hygiene

The variety of food services and residential dwellings presents various opportunities for food to be exposed to the environment and pests, contact surfaces, other foods, food workers and the general public. In a review of 816 foodborne outbreaks where food workers were involved, Todd et al. (2007) reported bare hand contact was the most frequently reported risk factor followed by failure to properly wash hands, inadequate cleaning of processing or preparation equipment or utensils, cross-contamination of ready-to-eat foods by contaminated raw ingredients and (for bacterial pathogens where growth is required) temperature abuse.

Food handling in this sector remains largely manual; food is chopped, sliced, portioned, plated or assembled and embellished, sometimes repeatedly, increasing the risk of exposure to the environment, surfaces and food handlers. Food is consumed after direct contact with serving dishes and implements, plates and cutlery that are cleaned for reuse or may be intended for single use. Heat and chemicals are commonly used to ensure that the number of microorganisms on utensils and surfaces have been reduced to a level that does not compromise the safety of the food that comes in contact or cause infectious diseases. Automated washing machines are highly effective as they allow the use of high water temperatures and strong cleaning agents. Minimizing food residue, followed by manual washing and sanitizing, is also effective. In food services and homes with minimal facilities, washing with soap and clean water and drying in the sun are practical alternatives although not optimal solutions.

Food prepared in this sector is exposed to food handlers during preparation and serving and to the general public during self-service, retail purchase and in the home. Other diners can be a source of infection if infected when handling common utensils or in contact with food as can occur in self-service and smorgasbord-style operations. This is recognized in the spread of norovirus infection where vomit from an ill person can spread infection to other diners via aerosols (Boxman et al., 2009). Personal hygiene and sanitary operating conditions are important in minimizing opportunities for contamination especially when at this point food receives no further processing to eliminate contaminants. Education and training in personal hygiene, in encouraging infected workers to report illnesses, and in the provision of facilities to enable good personal hygiene is necessary and has to be ongoing especially where the workers have a high turnover and limited motivation to comply.

In these settings food can be exposed at any point through the food flow to handler's hands or excretions from lesions, sneezes and vomit, the exception being where operations are automated or enclosed. Infections reported in association with infected food handlers in food service and homes include typhoid, shigellosis, streptococcal, hepatitis A, norovirus and protozoan (*Toxoplasma*, *Cryptosporidium* and *Giardia*) infections, and staphylococcal intoxications. Food workers have been symptomatic or asymptomatic shedders of pathogens; they may have been exposed to infected family members or contacts; and have subsequently used improper personal hygiene practices (Todd et al., 2007). The pathogen source is not always obvious. In a salmonellosis outbreak linked to delicatessen foods the infection was believed to be transmitted via the food handlers who had contact with chickens carrying *Salmonella* at home (Hedican et al., 2010). It is not always possible to determine whether

BOX 30.1

ARGUMENTS FOR AND AGAINST THE USE OF GLOVES BY FOOD HANDLERS (TODD ET AL., 2010)

Arguments for Glove Use:	Arguments Against Glove Use:
Gloves protect the worker from foods/ingredients that can cause damage to their skin	Gloves can reduce operational dexterity and increase the risk of injury for workers
Gloves protect the food from direct hand contact	Higher levels of food contamination are possible in the event of glove failure
Glove use is more easily observed to verify hygiene compliance versus hand washing	Small numbers of gloves have pinhole leaks that are not possible to detect before use
Gloves can be used to cover worker skin damage or infections	Gloves can be worn for longer than they should be
	Gloves give a false sense of security as a substitute for good hand hygiene practices
	Gloves increase the risk of hand irritation

the food worker is also a victim having eaten some of the contaminated food while at work, whether infected by a co-worker or if they were the cause (Todd et al., 2007).

Failure to wash hands properly or lack of hand-washing supplies and facilities are frequently contributing factors in outbreaks (Todd et al., 2007). Norovirus infections are commonly linked to infected food handlers and this has been conclusively demonstrated by detection of an outbreak virus strain on the hands of the food worker preparing the implicated food (Boxman et al., 2009). Use of clean tongs, cutlery or gloves prevents bare hand contact with food. Gloves offer a barrier to hand contact and are commonly used as a hygiene measure in food service. Glove use is debated and some of the arguments for and against identified by Todd et al. (2010) are shown in Box 30.1.

While gloves can reduce the opportunity for contamination of food from bare hands they can also be a source of contamination if inappropriately used (Todd et al., 2010). Disposable gloves are used when handling ready-to-eat foods and reusable gloves may be used when handling raw food that will receive a microbiological kill step before serving, e.g. raw meats. Gloves should be clean and sanitized if reused and color coded to allow ease of detection if torn and fragmented during use. Hands should be washed before gloving and loss of integrity of the gloves should be ensured such as by limiting use of jewelry, maintaining short fingernails and avoiding punctures from sharp objects in foods or the work environment. Where gloves are used strategies will be needed to encourage food workers to comply with glove use, and management must ensure the glove supply is continuous and conveniently located (Todd et al., 2007).

Maintenance and Sanitation

Equipment used in food preparation and assembly (e.g. slicers, shredders, mixers, conveyors) have multiple parts and crevices where food residue can accumulate allowing bacteria to harbor and grow. Total disassembly of equipment, cleaning and sanitizing, or heat disinfection of the entire apparatus to reach inaccessible parts may be required for hygiene maintenance. An outbreak of salmonellosis attributed to lettuce served at a fast food chain was traced to the shredder used in its preparation (Stafford et al., 2002). The same serotype of *Salmonella* as the patients' was detected in the shredder where it had remained due to poor maintenance. The transfer of *L. monocytogenes* from meat slicers to roasted meats and fermented sausages during slicing has been demonstrated experimentally (Lin et al., 2006). *L. monocytogenes* was subsequently shown to grow on the sliced and packaged uncured roast turkey meat during storage at 4°C.

In food services there are often multiple food types prepared and handled simultaneously and the area and facilities available for food handling or storage can be minimal. Activity and demand in these operations can escalate during peak service periods such as meal times. These scenarios can provide opportunities for cross-contamination if they are not controlled with preplanning and effective prerequisite programs. The ready manner in which cross-contamination can occur has been demonstrated experimentally with *Campylobacter* spp. on raw chicken transferred to ready-to-eat salads by using the same cutting boards and knives and by unwashed hands (Van Asselt et al., 2008). Luber (2009) studied the internal contamination of eggs and external contamination of poultry with *Salmonella* and *Campylobacter*, respectively, and the associated risks. The study concluded cross-contamination from the use of the same cutting board for chicken meat and salad without cleaning in between or spreading of pathogens via the kitchen environment seemed to be of greater importance than the risk associated with undercooking of poultry meat or eggs.

In large facilities, a single direction for the flow of food from raw materials to final product, designated equipment, tools and storage/chilling units for raw and cooked foods, and restricted movement of food workers between raw and cooked food preparation areas can be engineered to prevent the opportunity for cross-contamination. In small operations this may not be possible and practical interventions may have to be devised. Examples include hand washing between handling raw and cooked foods, designated and identified equipment and utensils for use exclusively with raw or cooked foods, and protected storage of ready-to-eat and cooked food above raw food in stores or refrigerators. Products used in the preparation of allergen-free meals have to be stored and kept separate at all times.

Food residues remaining on poorly cleaned and sanitized equipment, surfaces and fixtures provide a reservoir for bacteria that can transfer to food during processing repeatedly over time. *Listeria monocytogenes*, an environmental bacterium relatively resistant to environmental conditions, is able to grow at refrigeration temperatures and has been found in many food processing environments, cold stores and refrigerators in food services and homes (FAO/WHO, 2004). The bacterium can colonize seals and surfaces in cold storage and refrigeration units, containers and pallets. Minimizing the presence of *L. monocytogenes* in equipment and premises with hygiene maintenance and standard operating procedures is essential. The numbers of *L. monocytogenes* in food can be further controlled by minimizing the time during which growth could occur; this could include labeling ready-to-eat food

with the date of preparation, and determining the date by which the food can be safety consumed using predictive models.

HAZARD ANALYSIS

Product Flow

In retail and food services, products may range from a single product line (hamburger, pizza, satay, shellfish, fruit) to a diversity of products varied at regular intervals (e.g. meals in restaurants, cafeterias, institutions, transport caterers). The product may be prepared to a strictly controlled formula (e.g. fast food chains and other food service franchises) or may change opportunistically. There may be a single product and process (e.g. ice cream) or various food components and processes combined in a final complex food product (e.g. plated meal service, catering operation and restaurant). Ideally a food safety plan should be established for each product line. However, where there are multiple food lines, undertaking this for each food item would take considerable resources and is not necessary. It is more efficient to prepare plans for broadly grouped products. This is most often based on common food preparation processes and the flow of a food through the operation from raw material receipt to consumption. For example, a catering operation may prepare menu items with recipes differing in major ingredients (e.g. meat, chicken, seafood) although with common processing (e.g. cooking, holding or serving). In this example, common controls of adequate cooking and cooling would place them in the same group even though the hazards identified and the critical limits may differ.

The basis for grouping foods will vary with the type of business. Some typical process steps and examples along the product path or flow through food services or in homes for cooked food are shown in the columns in Table 30.3. These examples are not exclusive as other variations and process technologies (see Part II of this book) may be employed. The groups are formed based on common steps of cooking and further differentiated based on whether the food is held after cooking and, if so, the storage temperatures, the option of reheating and the need for final holding and holding temperature.

Another example is an approach proposed by the USA government for food services and retail establishments based on the number of times the food passes through the temperature zone where bacterial growth may occur during the flow of food through the operation (USFDA, 2006). The temperature zone referred to as the "temperature danger zone" is defined as 5°C (41°F) to 57°C (135°F). Other food flows may occur although the number of passages through the temperature danger zone is the key to the three categories of preparation processes.

Process 1: Food preparation with no cook step (no cook step to destroy pathogens).
Example flow: Receive – Store – Prepare – Hold – Serve
Process 2: Preparation for same day service (passes through the temperature danger zone once).
Example flow: Receive – Store – Prepare – Cook – Hold – Serve
Process 3: Complex food preparation (passes through the temperature danger zone two to three times always).
Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve

TABLE 30.3 Examples of Common Processing Steps and the Flow of Food from Receipt to Consumer (Top to Bottom of Table) during Preparation in Food Service, Retail and the Home and Food Groupings

	Food Groups			
Process Steps	Fresh – Serve	Cook – Serve	Cook – Chill (short/ extended shelf-life)	Cook – Freeze
Receive	+[a]	+	+	+
Store	+	+	+	+
Prepare	+	+	+	+
Cook[c]	–[b]	+	+	+
Cool	–	–	+	+
Assemble, fill (aseptic or non-aseptic),[c] seal, label	–	+/–	+	+
Chill	+/–	–	+	+
Freeze	+/–	–	+	+
Store/distribute	–	–	+	+
Reheat	–	–	+	+
Hot hold	–	+/–	+/–	+/–
Serve/sell	+	+	+	+
Examples	Raw oysters, sashimi, green salads, cut fruits, sliced cooked meats, cheese, meat (to be cooked by customer)	Fried chicken, hamburgers, cooked eggs, hot vegetables, stir-fries, noodle dishes	Pre-cooked meals, meats, sauces, soups, entrées, desserts, pizzas	

[a] *+ Process included.*
[b] *– Process not included.*
[c] *– The product may be cooked at this step or pasteurized in packs after filling.*

Intended Use

Food items prepared for vulnerable persons should be given special attention due to their increased susceptibility to food safety hazards. Special flow diagrams for their foods may be required as additional controls and the design of a special formula or menu may be needed to minimize the risk. Foods prepared for consumers with intolerance to allergens also require individual plans to ensure freedom from contamination with the specific allergen.

Potential Hazards

The hazards that can reasonably be expected to occur in foods and be present in the food handling environment or in other inputs during food handling in this sector are as varied as the types of food involved and may be biological, physical or chemical. Evidence for some

hazards commonly reported in foodborne illness outbreaks attributed to food prepared and consumed in these settings have been described above (see "Food Safety Hazards").

The efficacy, feasibility, sustainability and cost effectiveness of controlling identified hazards are important considerations especially for many small and less developed businesses at this point of the food chain. If control cannot be ensured menus should be redesigned, products or processes reformulated or foods restricted or prohibited from use. An important consideration is the intended use of the product particularly if catering for high risk groups. There have been frequent outbreak scenarios linking specific pathogens, at-risk groups and settings in this sector that have resulted in authorities developing specific regulations or guidelines to ensure safety. Neonates are susceptible to *Cronobacter sakazakii*, an environmental bacterium that may be present in powdered infant formula. If formula is reconstituted and held at temperatures allowing survival of the bacterium and for enough time to allow growth it may present a hazard for neonates and infants (FAO/WHO, 2006). This scenario could occur in hospital settings preparing formula for nursery inpatients and stringent microbiological criteria are used for these powders. A higher probability of infection with *E. coli* O157 following exposure to lower pathogen concentrations is known to occur in children and the elderly, and food services, schools, aged care and daycare facilities have been the location of outbreaks (Desmarchelier and Fegan, 2003). Foods high risk for O157 STEC should be avoided for these vulnerable groups. The elderly, immune-suppressed and pregnant women are at highest risk of listeriosis and education programs and guidelines for vulnerable persons recommending avoidance of high risks food are widely recommended or enforced by authorities (Dalton et al., 2010).

Some bacterial hazards are more frequently associated with food handling practices in this sector. For example, spore-forming bacteria (*Clostridium* spp. and *Bacillus* spp.) and toxin-producing bacteria (*Staphylococcus aureus*, *Bacillus* spp. and *C. botulinum*) that generally have to grow in food before it becomes hazardous. Suitable conditions can occur in food supporting growth with poor control of cooking, cooling and holding temperatures and lack of control of the duration the food is held at those temperatures. The extensive direct handling of foods can result in the introduction of pathogens such as norovirus, hepatitis A virus, protozoans, *S. Typhi* and *Shigella* spp., if poor personal hygiene is practiced among food workers as already discussed. This is a concern when no further treatment is applied that would result in their inactivation. Pathogenic *Vibrio* spp. and parasites in foods such as fruit and vegetables and seafood obtained from an unsafe source and served raw will similarly not be inactivated before consumption.

Just as foods can be grouped according to common processes to overcome the complexity in food services and homes, hazards that can be controlled with similar approaches may be considered collectively. Although this is not exclusive some examples are shown in Table 30.4.

Critical Control Points and Limits

Establishing and implementing control measures and critical limits in this sector is simplified if few product lines and processes are involved or if foods and hazards are grouped as described above. Food safety metrics, as described in Chapters 1, 31 and 33, can be applied although formal application will depend on the size of the operation. Some food safety controls and their critical limits may be proscribed by regulations enforced by local,

TABLE 30.4 Groups of Hazards that are of Concern in Food Services and the Home and Examples of Common Approaches for their Control. These Controls are Examples and not Meant to be Exclusive

	Approaches to Minimize or Eliminate the Hazards	
Hazard Group	**Technologies for:**	**GHP**
Non-spore forming bacteria (e.g. *Campylobacter*, *Salmonella*, *E. coli* and *Vibrio* spp.)	Inactivation or removal Controlling growth	Safe raw materials Maintain personal and equipment hygiene Avoid cross-contamination
Spore-forming bacteria (e.g. *Clostridium* and *Bacillus* spp.) and toxin-producing organisms (*S. aureus*, *Clostridium* and *Bacillus* spp.)	Controlling growth to prevent outgrowth bacterial spores and toxin production	Maintain personal and equipment hygiene Avoid cross-contamination
Fecal–oral route of transmission (enteric viruses, *S. Typhi*, *Shigella* spp., parasites)		Safe raw materials Personal hygiene Avoid cross-contamination
Physical and chemical hazards		Safe raw materials Safe chemical storage Maintain equipment hygiene and safety
Allergens		Safe raw materials Maintain equipment hygiene Avoid cross-contamination Personnel with consumer contact trained to provide consumer advice

regional or national governments. These can include specific controls, criteria and critical limits in the management of food safety practices applied at steps such as receipt, storage, processing, display, packaging, transportation and for recalls. There may also be regulations applying to the safety requirements for specific commodity groups (e.g. dairy, eggs, meat, fruit and vegetables, seafood, etc.). The person managing the food safety programs should be aware of local, regional or national regulatory requirements and must incorporate them in the food safety program.

The risk factors commonly identified in association with foodborne illness outbreaks in food services and home settings provide evidence for the most common failures in managing food safety. This information provides an indication of important food safety controls to be emphasized and re-enforced. The following lack of controls is commonly reported in different countries, the first two are most common (EFSA, 2009; USFDA, 2004).

- Inadequate heat treatment of food.
- Inappropriate storage of food, i.e. improper holding time and temperature (cold holding of potentially hazardous food and inadequate date marking of ready-to-eat food).
- Failure in control of general hygiene measures such as poor personal hygiene.
- Inadequate cleaning and sanitization of equipment leading to food contamination.
- Failure to keep raw and cooked food separated to avoid cross-contamination.

Some examples and highlights for this sector are discussed here. Cooking or alternate processing to inactivate or remove biological hazards and effective chilling and freezing to control growth of biological hazards (see Part I and II) have been presented in detail in earlier sections of this publication and should be consulted as they are not repeated.

A variety of foods prepared in food services and homes have been implicated in outbreaks where inadequate cooking was reported. *E. coli* O157 and *S. Enteritidis* are examples of particular concern as there is a higher probability of infection for at-risk groups from low numbers of these bacteria present after they have survived the cooking process (Vought and Tatini, 1998). Undercooked ground beef burgers (Desmarchelier and Fegan, 2003) and egg-based dishes have been implicated (Marcus et al., 2007) in outbreaks of infections from these bacteria, respectively. It is important that the required temperature is reached at all points in the food and for the time determined to render it safe. Determining these critical limits should be based on sound scientific evidence and cooking processes controlled. Some heating processes may be overlooked as, for example, an outbreak of campylobacteriosis was linked to garlic bread. Following laboratory investigation it was revealed the internal temperature reached 19–22°C and this was inadequate to kill the bacterium in the contaminated butter (Zhao et al., 2000).

The preparation of food before cooking can impact on the effectiveness of the cooking process. Outbreaks of salmonellosis and campylobacteriosis occur following consumption of inadequately cooked chicken (Bryan and Doyle, 1995). Frozen food such as large whole poultry carcasses and pieces of meat should be completely thawed in advance in a refrigerator or by microwaving under control. Where this is not possible due to limited facilities, thawing under potable running water under controlled conditions (e.g. at a temperature of 21°C for not more than 4 hours) can be substituted (CAC, 1999). This does not apply to smaller portions of manufactured frozen ready-to-cook products that should be cooked according to the manufacturer's cooking instructions on the package label. Improper thawing of whole frozen chickens can occur when trying to reduce time to meet unexpected demand for additional food during peak service hours or when consumer sales have been underestimated.

Food preparation in this sector takes place in advance of serving in most types of food services. It also occurs in homes with busy and time poor occupants or when food is prepared in homes for special events or for vendors. Ingredients, meal components or whole meals can be held hot, chilled or frozen until required for assembly, reheating and/or serving. As this involves food being exposed to temperature danger zones, often more than once, critical control points should be identified.

Managing the critical temperatures–time limits in these zones requires an understanding of microbial behavior as well as the dynamics of heat transfer in foods and the relationship with the structure and volume of food containers. Critical limits are chosen for individual products to meet the required performance objectives (see Chapters 31 and 33). Inexperienced food handlers may not have the level of knowledge to determine these parameters. These may be stated in food regulations that specify temperatures for hot and cold holding of ready-to-eat food, and that define the maximum duration of holding before refrigeration, before reheating or before the food should be served. Foodborne illness in the community has often been associated with events (e.g. celebrations, functions, picnics) where larger than usual quantities of food are prepared and temperature and time management is lacking by persons ignorant of

hazards associated with scaling up domestic food practices (McLaughlin et al., 2006). Persons commencing cottage industries and preparation of home-based food production need to become acquainted with basic food hygiene and safety before commencing business.

The accurate way to monitor cooking and cooling is to measure the internal temperature of each product and record the duration. The practicality of temperature and time monitoring, verification and recording for every food item will vary with the size of the operation, the volume and range of food prepared. Fast food operations may cook hundreds of a particular item, e.g. hamburgers at peak times. In this situation it may be more practical to verify that the process and the equipment are consistently capable of achieving the required cooking performance and undertake less frequent but regular testing and record keeping. Implementation of controls, the use of thermometers and recording equipment, verification and monitoring can be impractical in many poor regions and in many homes. While it is an aspirational goal, some level of safety assurance may be achieved more practically in the interim by exploring local and culturally relevant practices that can be substituted. For example, recommending food or water comes to a "rolling boil" for sufficient time may be an interim compromise for cooking in areas of poor sanitation and hygiene and with minimal facilities. Identification of changes in a food's texture and taste after processes such as cooking and acidification may offer a degree of protection. Women in traditional societies after many years of experience may be able to judge when acidification is adequate by taste. Promotions of food safety for eggs and *S. Enteritidis* recommend eggs should be cooked until the yolk and white are no longer runny. However, temperature and color change in red meat and crustaceans may not reliably indicate sufficient heat has been reached to inactivate vegetative bacteria.

Producing food in this sector is dependent on multiple activities where dangerous temperature zones occur and can be cumulative, e.g. storing, thawing (raw or cooked), preparing, portioning, assembling, holding (hot or cold), reheating, displaying, packaging, transporting, etc. While having food pass through this danger zone may be unavoidable the duration in that zone can be strictly minimized so that bacterial growth is insufficient for the food to become hazardous. Bacteria may be present because they have survived cooking or other processing, they may have been introduced post-processing or the food may be unprocessed and served raw. Some important considerations include date marking and control of cold storage duration to control psychrotrophs; managing batch sizes, unit volumes and container design to enhance heat and cold transfer; and ensuring the capability and monitoring of hot or cold holding equipment (e.g. display cabinets, bain-maries, trolleys, transport modules and vehicles to meet requirements). These should be considered for both regular production volumes and take into account peak production times or unexpected events. When an operation is stretched beyond its anticipated production errors can occur as the food safety plan was not designed to accommodate these increases.

Both vegetative bacteria and those from spore-formers following vegetative cell formation, and toxin-producing bacteria, can often grow quickly in foods common in food services during cooling or reheating and have no other hurdles to inhibit growth. Errors at this stage are not reversible by cooking to eliminate bacteria as some toxins, such as staphylococcal or *B. cereus* toxins, if formed, may be heat resistant.

Inadequate cooling has often been associated with outbreaks of foodborne illness in food services and homes where the food attributed had been cooked (McLaughlin et al., 2006;

Shapiro et al., 1999) or contaminated post-cooking (Todd et al., 2007), was raw or contained raw ingredients (Mannes et al., 2010). Mannes et al. (2010) reported a salmonellosis outbreak involving 319 cases, almost a 100% attack rate, which provides an example of the extent of contamination that can occur and the consequences for public health when contaminants are present in raw ingredients and poor hygienic practices and inadequate refrigeration occur. The attributed food vehicle was raw egg mayonnaise included in chicken and pork rolls prepared in a bakery. *S. Typhimurium* isolates matching the case isolates were detected in the raw egg mayonnaise, ham, pork, chicken, pate and shell eggs, and from swabs of the preparation bench, tongs, meat slicer, floor drain and display tray, and in environmental samples taken at the source premises. A refrigeration storage breakdown and inadequate refrigeration in the display unit were observed. The count of *S. Typhimurium* in the raw egg mayonnaise sample was in excess of 1.1×10^7 colony-forming units/mL and suggested significant growth of contaminants in the raw eggs occurred in the raw egg mayonnaise during either the faulty refrigerated storage and/or after the rolls were held in a display unit with poor temperature control.

Fruits and vegetables have been linked increasingly to cases of foodborne illness in food services and home settings (Lynch et al., 2009). These foods are frequently eaten raw either alone or in salads. Viruses and parasites introduced at primary production or during food handling will not grow during storage but can persist and cause infections (CDC, 2010). Evidence is growing of the ability of bacterial pathogens (e.g. *E. coli* O157 and *L. monocytogenes*) to persist and grow in produce under certain conditions (Lynch et al., 2009). *E. coli* O157 will grow on cut or damaged surfaces of salad leaves at a more rapid rate than on intact leaf surfaces (Khalil and Frank, 2010) and growth may occur under conditions of temperature abuse during storage (Delaquis et al., 2007). Such conditions can occur in this sector.

In the home and in underdeveloped businesses, those preparing food will not determine critical control points formally. They will practice control measures they have learnt from family and community contacts, from recipes and from messages provided by the media and authorities. Public education messages can be based on sound scientific information, for example in the WHO Five Keys to Food Safety "Cook thoroughly" and "Keep food at safe temperatures" capture the important controls discussed (Table 30.2). Authorities and education groups provide numerous fact sheets on food safety controls such as cooking correctly and temperature control. Some messages are for specific consumer groups at high risk (ill, elderly, babies, pregnant women) or they may be targeted at a specific food and/or hazard (special care foods, hamburgers and *E. coli* O157, eggs and *S. Enteritidis*). Messages may be disseminated at a particular time of year when authorities know failures in food safety occur and re-enforcement is required (cooking turkey at Christmas or Thanksgiving, cooking barbecues, summer eating, emergency events).

Manufacturers may define safety control points for users of their products through the provision of instructions on labels or package inserts. Some common examples include advice on storage, e.g. refrigeration, refrigeration temperature and storage duration required for perishable or shelf-stable product after opening; on preparation, such as whether or not to wash ready-to-eat packaged fresh leafy produce, or ingredient use; on cooking or reheating, including times and temperatures and ways to measure temperature; and cooking or reheating methods such as required microwave operating capacity and use.

Illness outbreaks have been associated with manufactured foods for which consumers were required to apply critical lethality steps before consumption. Examples include

BOX 30.2

SOME EXAMPLES OF CONSUMER MISINTERPRETATIONS AND EXPECTATIONS

Consumer expectations:

- Manufactured food is safe regardless of instructions for further pathogen lethality treatments
- Methods on labels are validated for use in consumer's food preparation setting

A manufactured ready-to-cook product appearance that may cause user misinterpretation the product is fully cooked:

- Batters and crumbs that are set and have a cooked color
- Char-grill marks
- Browned pie crusts
- Plastic trays can be associated with microwave reheating rather than cooking

Instructions that can confuse lethality level of heat treatment required:

- Both microwave and cooking instructions can be confusing as microwaves are commonly used for reheating
- Consumers may have limited knowledge of microwave wattage
- Consumers are not able to calibrate temperature measuring devices

Washing fresh and fresh-cut produce in water removes all pathogens.

contaminated ready-to-cook foods such as frozen chicken entrées, breaded products (NACMCF, 2006) and pies (MacDougall et al., 2004). Such products may have been manufactured with partial cooking then chilled or frozen and may appear to the consumer to be fully cooked. The products were then reheated inadequately and consumed.

Such outbreaks have emphasized that manufacturers need to ensure the safety status of their products, how the consumer will handle their product, how accurately their package labels and instructions can be interpreted, and provide guidance on how to apply validated controls (NACMCF, 2006). Further considerations in developing cooking instructions to ensure lethality to pathogenic bacteria may include product composition, geometry, temperature before cooking and proper monitoring using thermometers. Some examples of consumer expectations and some misinterpretations when handling minimally processed and processed foods that need to be considered by manufacturers and suppliers are provided in Box 30.2.

Monitoring and Corrective Action

Managers and supervisors should have sufficient knowledge of food hygiene and safety principles and practices to be able to monitor the food safety measures and to make decisions when deviations occur and for the corrective action to be taken. Employees should be informed of their role in this process and on how to document and communicate the outcomes to management. In a small business this responsibility may lie with a single individual who should be appropriately trained and available to make decisions when the business

is operating. In very small or underdeveloped businesses, street vendors, etc., the relevant authority may have to take this responsibility through regular inspection and guidance on corrective actions and solutions when necessary.

It is apparent in the salmonellosis outbreak investigation of Marmes et al. (2010) described above that failures occurred in the quality of the raw eggs, general hygiene and when storing the raw egg mayonnaise both during the refrigerated storage prior to preparation of the pork and chicken rolls and after in the display cabinet. The use of pasteurized egg, good hygienic practices, corrective action taken to discard the product after faulty refrigerated storage and monitoring display holding temperatures would all have helped to prevent the high numbers of *Salmonella*.

Validation and Verification

Validation of the effectiveness of a food safety program, verification that is operating in accordance and auditing are described in Chapters 44 and 51. The implementation of these activities and auditing of the programs should ideally be prioritized in accordance with the food safety risk of the business. For example, the risk would be significant in large institutions catering for vulnerable persons compared with a small vendor of a low risk food to low risk individuals. It is reasonable to expect that as a minimum requirement all food services should document their food safety plan, keep records relating to the procedures outlined in the plan including action taken in the event of a deviation, and review the procedures if any changes take place in the food produced or the processes used.

In some small and less developed businesses in underdeveloped regions this may be best undertaken less formally by local authorities. Large-scale commercial food service or other community facilities (e.g. schools, daycare centers, hospitals and institutional care establishments) may retain food samples for at least until the end of its shelf-life so as to be available for future possible analysis in the event of an investigation into the product's safety or quality.

EDUCATION AND TRAINING

A successful food safety program requires development of a food safety culture among management and staff. Food services present challenges as often there is a high turnover of staff and their education level can range from highly qualified chefs and food technologists to minimally educated and illiterate workers. Non-professional food work in the food service industry is attractive to poorly skilled and itinerant workers and they often receive minimal wages. These workers may include newly arrived immigrants with limited language ability and different cultural backgrounds or they may be students or others undertaking casual work. Given their employment status and the fact they may have other aspirations for their long-term life plans they may not be motivated to make a commitment to food safety and quality in the short term (Choudhury et al., 2011).

Success in establishing a sustainable food safety culture depends on commitment, leadership and support from management in making food safety a foundation value integrated with other business functions. Seaman and Eaves (2010) conducted a study among food industry managers in London, England, and found while most managers were aware

of their responsibilities in training they often did not provide adequate support for practices or evaluation of their effectiveness. Poor motivation has been associated with lack of consequences for non-compliance (Niode et al., 2011).

Continuous training, education and supportive supervision are required. These should be culturally appropriate and tailored to account for language capability, literacy and education levels. Dalton et al. (2010) conducted a national case–control study of listeriosis in Australia and recommended prevention messages should be disseminated in multiple languages as they identified a lack of uptake of education messages in English among women from families where English was a second language.

The messages should be positive although the consequence of non-compliance should also be clear. Multiple approaches should be provided internally, via authorities or by consultants and some examples include demonstrations, use of multimedia communications and high profile community individuals (Powell et al., 2009). Novel approaches can be sought. Chapman et al. (2010) evaluated the use of regular topical information sheets placed in highly visible areas that had successful outcomes. Training may have to begin with basic hygiene and practical demonstrations before HACCP principles and could be provided by authorities before or at the time of business registration and licensing for less developed businesses. For domestic food handlers and food handlers in general, the WHO Keys provide basic food safety messages. Additional messages are required for at-risk groups on safe food choices and food handling. These can be provided through multiple channels such as community and industry groups, schools, public media and social networking.

When compliance is poor, understanding behaviors and barriers to adoption should be explored and alternate approaches that address overcoming the barriers developed. Niode et al. (2011) found from interviewing managers of Asian and Mexican restaurants in northern California that training would be improved if based on foods common to their cuisine and appropriate visual aids were used for employees. Barriers to be addressed in implementing food safety messages among restaurant workers have included time constraints, inconvenience, inadequate training and inadequate resources (Howells et al., 2008). Nesbitt et al. (2009) identified factors to be addressed among domestic food handlers in Canada and included demographic characteristics. They found increasing total annual household income, male sex and elderly status were associated with increases in certain high risk food behaviors.

CONCLUSIONS

Preparing food in food services and the home is the last step before food is consumed. Food production in this sector is increasing in developed countries, and in poor communities the population may be dependent on food prepared by others as their sole source of nutrition. Ensuring food safety in this sector is a critical link in the food chain continuum; however, it is also faced with specific challenges. Evidence from foodborne illness surveillance, the identification of risk factors and at-risk groups, and from understanding impediments, behaviors and cultural beliefs that influence the uptake of food safety practices are some of the activities that are helping to improve food safety in this sector.

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CHAPTER

31

Hazard Analysis and Critical Control Point System (HACCP)

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OUTLINE

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INTRODUCTION

HACCP stands for the hazard analysis and critical control point system. Today it is known more by its acronym than its full name. HACCP as defined by the Codex Alimentarius Commission is a system that *identifies, evaluates and controls hazards which are*

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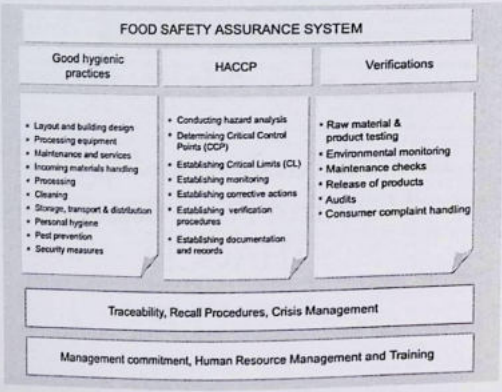


FIGURE 31.1 Overview of the food safety assurance system in the food industry.

significant for food safety. Worldwide, it is considered as the reference method for food safety assurance. However, as pointed out in Chapter 1, to be effective in ensuring food safety, HACCP has to be implemented in conjunction with a number of other programs, some of which are part of the "prerequisites programs." Examples of these are cleaning and sanitation, pest management, hygienic design, etc.; they are often grouped under the term *good hygienic practice*. Some other activities also related to food safety management, such as consumer complaint handling, environmental and pathogen monitoring, chemical contaminants monitoring and audits, are verifications which are also required in the HACCP system but are often implemented separately (Figure 31.1). It is nevertheless important that the design of these activities and programs and their outcome be carried out in coordination with the HACCP system, i.e. these different programs have to be geared into each other as the wheels of the same machinery (Figure 31.2).

Originally, the HACCP system was introduced to ensure the microbiological safety of food products. Later on, its use was extended to all types of foodborne hazards, including chemical hazards, allergens and physical hazards. The HACCP approach can also be used for auxiliary systems such as the water system.

There have been many debates and articles on the challenges in the application of the system, in particular in small and less developed businesses. Even in large food operations, the application of the system has not been without difficulties, partly because of misperception of the system and partly because of the lack of understanding and/or commitment of

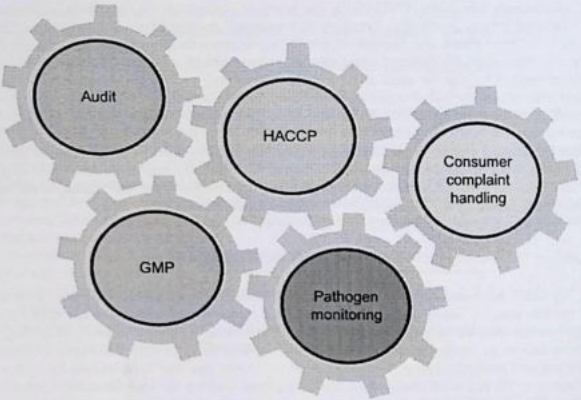


FIGURE 31.2 The figure illustrates the importance of an integrated approach to food safety management and the interaction between the different elements of the food safety assurance system.

necessary resources. The successful application of HACCP requires considerable expertise, time investment and multidisciplinary collaboration.

Considering the importance of food safety for consumers' health and for businesses, such an investment is fully justified, as without food safety there will be no business.

HISTORICAL BACKGROUND

HACCP was originally designed by the Pillsbury Company, together with the National Aeronautics and Space Administration (NASA) and the US Army Laboratories at Natick. They developed the HACCP system to ensure the safety of food for astronauts. For many years after its conception, the system was promoted by international organizations such as the World Health Organization and applied on a voluntary basis in certain food industries (Motarjemi et al., 1996). In 1993, the Codex Alimentarius Commission recognized the HACCP system as a powerful tool to improve food safety and established the Codex guidelines for the Application of the HACCP system. This has had major implications for the widespread implementation of the HACCP system. Another event in the history of food safety provided a major impetus for the promotion of HACCP. In 1995, with the establishment of the World Trade Organization and the coming into force of the Agreement on Sanitary and

Phytosanitary Measures (WTO/SPS), the work of Codex, i.e. its standards, guidelines and recommendations (including the Codex document on the Hazard Analysis and Critical Control Point system and Guidelines for its application) became the international reference or the "yardstick" for national requirements in food safety. This implied that WTO member states needed to take the work of the Codex Alimentarius into consideration and align their national legislation with the provisions of the Codex Alimentarius Commission, unless they could provide scientific evidence that the Codex Standards did not provide adequate health protection for their population. This meant that *de facto* the application of the HACCP system became an international requirement for food safety assurance. Today, the principles of HACCP are integrated in the national legislation of many countries as well as in the ISO 22000 standards, i.e. the standards defining the requirements for the management of food safety developed by the International Standard Organization (ISO, 2005).

THE NEED FOR HACCP

Up until the introduction of the HACCP system, the food safety assurance system was a reactive one, i.e. based on the implementation of directives referred to as "codes of practice" which were developed based on experience, combined with end-product testing. Such codes had to be fairly general in order to be applicable in diverse situations of food production and food processing. Therefore, they could not and did not consider hazards which where specific to a food product, i.e. its ingredients and/or the specific conditions of operation. As with globalization and changes in society, the nature and origin of raw material were becoming more and more diverse, the technology used in food production and processing more complex, and the traditional approach became increasingly inadequate for preventing and controlling hazards in foods. Also, with increased industrialization, mass production and distribution of food, the risk of large-scale foodborne disease outbreaks as has been experienced in recent years became greater. Many foodborne pathogens proved to be particularly virulent, in particular with the vulnerable group of the population, and led to severe or chronic health problems, if not death. It had become clear that end-product testing, until that time used as the main quality control method, proved to be inadequate for providing assurance, since a large number of samples would need to be tested to have a certain degree of assurance of safety; in practice, adequate end-product testing to obtain reliable information was economically not feasible, and often the results would be received after the product had been marketed and/or eaten.

Thus there was a clear need for a more effective system of food safety assurance, where hazards and risks with a given product would be identified and measures necessary for controlling these hazards would be prospectively determined and deployed. It is against this background that the HACCP system was introduced to complement the traditional approach to enhance food safety assurance. With time, it was also experienced that HACCP would be best applied if it were combined with the application of general codes of hygiene and not as a stand-alone system. In other words, the general codes of hygiene would be used as a first line of defense to have a general hygienic condition of food production, processing or any other operations (transport, distribution, preparation, etc.). HACCP would be applied as a second line of defense to have a tailor-made system of food safety assurance

for the product under consideration, and end-product testing would be carried out as a last line of defense for confirmation that the preventive measures are effective (Motarjemi et al., 1996).

In summary, the benefits of the HACCP system lie in the fact that HACCP:

1. Is a proactive approach to food safety management; this means it allows conceivable and reasonably expected hazards to be identified, even when failures have not previously been experienced. It is particularly useful for new operations.
2. Is flexible, i.e. necessary control measures can be adapted to changes in operations, such as change in equipment design, in processing procedures and technological development.
3. Helps to target resources to the most critical part of the food operations.
4. Is applicable to the entire food chain, from the raw material to the end product, i.e. growing, harvesting, processing/manufacturing, transport and distribution, preparation and consumption.
5. Overcomes many of the limitations of the traditional approaches to food safety control, generally based on:
   a. snap-shot inspection, which is a rather ineffective approach in foreseeing potential problems;
   b. end-product testing, which would entail high costs for analysis and which would lead to identifying problems without understanding their cause

PRINCIPLES OF THE HACCP SYSTEM

As stipulated in the Codex guidelines on HACCP, the HACCP system is comprised of seven principles. These are as follows:

Principle 1: Conducting a hazard analysis.
Principle 2: Determining the critical control points (CCPs).
Principle 3: Establishing critical limits.
Principle 4: Establishing a system to monitor control of the CCP.
Principle 5: Establishing the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
Principle 6: Establishing procedures for verification to confirm that the HACCP system is working effectively.
Principle 7: Establishing documentation concerning all procedures and records appropriate to these principles and their application.

To ensure the most effective outcome, the application of the HACCP system is carried out following a number of steps. The Codex Guidelines outline 12 steps for conducting an HACCP study and establishing an HACCP plan. To this should be added the training of different operators, implementation of the plan as well as a number of prerequisite activities.

With regard to the HACCP application, the importance of validating the elements of the HACCP system needs to be highlighted. This means that at every step in the development of the HACCP study, it is important to ensure that decisions are valid, i.e. that they are established based on a scientific and technical basis. In particular, the control measures

must be effective and achieve the expected outcome (e.g. regulatory or industry limit, performance or food safety objectives). As such, validation is the assurance in the food safety assurance system. As the Codex Guidelines for HACCP are not explicit on the subject of validation, separate guidelines on the validation of control measures have been established by the Codex Alimentarius (Codex, 2008).

APPLICATION OF HACCP

Prerequisites to the Application of HACCP

The term *prerequisite* refers to all the measures and activities which need to be in place in order to support the application of the HACCP system. Very often, this term is used for technical programs that need to be in place, such as cleaning and sanitation or generally good hygienic practices. However, for the purpose of this text, the term is used in a broader sense in order to highlight the fact that certain conditions, other than technical measures, also need to be fulfilled before HACCP can be successfully implemented (Motarjemi et al., 2009):

1. Management commitment. The use of the HACCP system is very resource – and time – intensive. At times, it involves huge costs or investment as its application may underpin the need for new equipment, change in the process of production and/or quality of product, or change in the supplier of raw material. As mentioned before, a successful implementation requires high-level and multidisciplinary expertise as well as time investment. Therefore, the understanding of the management on the need and benefits of the HACCP system and its implications in terms of financial and human resources is essential and is a *conditio sine qua non* for the successful application of HACCP, short of which HACCP studies become only a paper exercise.
2. General principles of hygiene. As mentioned above, before applying the HACCP system, a certain number of programs and activities, generally considered as part of good hygienic practice, have to be implemented to ensure that products are manufactured, processed or handled in the minimum conditions of hygiene and good practices and that the generally known risks are as far as possible prevented. Failing which the number of risks to control through the HACCP will be large and the system will be difficult and costly to manage. Depending on the type of business and the stage of the food chain, these predefined rules, procedures and practices are referred to as good agriculture practice, good animal husbandry, good manufacturing practice, good transportation practice, etc.

   In practice, such codes refer to generic control measures that apply to a given sector of the food chain, regardless of its specific conditions (e.g. environment, ingredients, product formulation, production and processing). However, it is to be noted that a control measure recommended in a code, thus implemented as part of prerequisite program, can still be identified as control measure in an HACCP plan.

   The International Standardization Organization has elaborated a standard for the management of food safety in organizations, referred to as ISO 20005. This standard distinguishes between the terms "prerequisites" and "operational prerequisites"

BOX 31.1

DEFINITIONS OF PREREQUISITES ACCORDING TO ISO 22 000 STANDARDS (ISO 2005)

ISO 22000 defines the term "prerequisite" as follows:

Prerequisite program

Basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain that is suitable for the production, handling and provision of safe end products and safe food for human consumption.

Operational prerequisite program (operational PRP)

These are identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards in, and/or the contamination or proliferation of food safety hazards in the product(s) or in, the processing environment.

(Box 31.1). The latter refers to control measures identified in the HACCP studies for controlling a hazard; without the step in the food operation being considered as critical for safety.

3. Scientific research. Scientific and technical data and know-how are fundamental to any proactive and science-based food safety assurance system, such as HACCP. The type of scientific research that is needed entails:
   a. Toxicological and epidemiological research. HACCP being a risk-based system, such toxicological and epidemiological data are needed in order to evaluate the health significance of the different compounds, the degree of risk they present and their sources. In principle, such guidance should be provided by public health authorities.
   b. Epidemiology of microorganisms. Epidemiological data can provide guidance on the type of food that is the vector of a pathogen, on risk factors, health consequences and on various information (e.g. record of previous outbreaks) necessary for hazard analysis.
   c. Ecology of microorganisms. Understanding the ecology of microorganisms is essential for evaluating the potential source, likelihood of contamination, survival or growth of a pathogen in an environment, food or during processing.
   d. Mechanism of formation of contaminants. Certain contaminants are formed during processing or manufacturing, be it in the industrial setting or in the home. Understanding the mechanism of formation of such contaminants is essential for devising control measures, e.g. designing the process to minimize their formation.
4. Validated analytical methods. Validated analytical methods will be needed to manage hazards in foods, be it for verification purposes or as control measures for certain types of hazards (e.g. chemical contaminants).

5. Data on the level of occurrence. The first principle of HACCP on hazard analysis calls for an evaluation of the risk, including the likelihood of occurrence. Data on the occurrence of hazards in food is thus fundamental for a first evaluation and hazard analysis (see also above).
6. Determination of acceptable level. A control measure is defined as "Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level." This brings in the concept of "acceptable level." To be able to manage foodborne hazards, in particular when the occurrence of the agent cannot be fully prevented, there is a need to know to what level the hazard in question must be controlled and to decide on a limit of acceptability for the hazard in question. The determination of this level, preferably by regulatory authorities, or short of this by industry associations, is very important both for the industry and for consumers. Such limits, over and above providing guidance for managing the hazard in question in the context of HACCP or any other equivalent food safety assurance system, ensure a consistent approach to food safety through the food supply chain and on the global market.

For a number of chemical hazards, such limits have been established and regulatory standards at national or international level (Codex) are available. In recent years, a similar concept has emerged for microbial agents. In principle, it is recognized that no case of foodborne illness is acceptable and ideally there should be "zero" incidents of foodborne illness. However, as for the presence of naturally occurring or environmental contaminants, realistically this is not possible since many pathogens make part of our environment and/or the microbial flora of food animals. Generally, with the presently available resources or technologies, their eradication is not feasible. Therefore, authorities are considering setting a maximum level of microbial contamination of food at the time of consumption, referred to as *food safety objective*.[1] This would ensure that the incidence of foodborne illness will be maintained within a certain accepted or tolerated level. This accepted/tolerated level of illness is referred to as the appropriate level of protection (ALOP). Food safety objectives can also be translated into performance objectives,[2] i.e. the maximum level of contamination at an early stage of the food chain, or performance criteria defining the performance of an operation in terms of growth or reduction of microorganisms. Such food safety objectives, or in the case of chemical hazards, regulatory limits, need to be decided beforehand, preferably by the regulatory authorities. In other words, regulatory norms and standards provide guidance to industry as to what level they should control the hazards in the food and how stringent should be their control measures. Such information will be necessary for their validation of their process when designing the HACCP plan.

[1] Food safety objective (FSO) is the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).
[2] The maximum frequency and/or concentration of a (microbial) hazard in a food at a specified step in the food chain before the time of consumption that still provides or contributes to the achievement of an FSO or ALOP, as applicable.

It must be remembered that against all the preconceived ideas that regulatory requirements are an unnecessary burden for the food industry, they are extremely important for the food industry in designing their food safety plan, provided that they are based on science and take into account other factors such as feasibility and costs for industry and consumers (Motarjemi and Mortimore, 2005). It is also to be noted that regulatory standards, or norms, are values which delineate between acceptable or unacceptable presence of a given contaminant or foodborne pathogen. Even though they may not always be based on a strict risk assessment, they are viewed as the safety standard by the regulatory authorities who have decided on the limits, by the consumers, and by society at large. Exceeding this limit should be considered as a violation of the safety standards of the society.

Guidance for the Application of HACCP System

Depending on the type of operations and regions of the world, there are different approaches to HACCP. For the purpose of this text, the part of work where step-by-step analysis of hazards and control measures are carried out is referred to as an HACCP study, whereas the outcome of the study where the critical control points and the measures taken at those steps of the food operation are outlined is referred to as an HACCP plan.[3] Sometimes, due to the complexity of the production, it is easier to develop different HACCP plans for different parts of the production. In such cases, it is important to ensure that a proper link between the different HACCP plans exists. It is equally important that an HACCP study also covers rework.

Application of HACCP principles is preceded by a number of activities. These preliminary steps of HACCP application set the conditions for an accurate and valid HACCP study. For instance, the validity of hazard analysis relies on the expertise of the team, the precision with which various aspects of the product are described, e.g. the raw ingredients and their source, the supplier assurance system (e.g. availability of a supplier audit report), manufacturing steps and conditions, description of packaging and other auxiliary products, intended use of product, regulatory requirement, potential use or abuse by target consumers

Step 1 – Assembling the team. Food safety is a multidisciplinary system. To design the safety of a product and foresee its safe production, there is a need for a team of experts of different background and experience. The type of expertise depends on the product and conditions of treatment or handling, and on the scope of the HACCP study, i.e. whether it covers chemical agents, microbial agents, allergens, the full food chain or part of the chain. Therefore, it should be decided on a case-by-case basis. Examples of experts who could be considered are: microbiologist, chemist, toxicologist, nutritionist, operator, veterinarian/agronomist, food technologist/food processing engineer and regulatory expert.

The importance of teamwork and of the expertise of the team cannot be emphasized enough as it is the available expertise in the team that will be the determining factor for

[3]A document prepared in accordance with the principles of HACCP to ensure control over hazards that are significant for food safety in a segment of the food chain.

the quality and accuracy of the HACCP study. What is certain is that HACCP is not a one-person job as often experienced. Usually, a team leader referred to as a "coordinator" is assigned for the team. The coordinator has the responsibility to drive the development and maintenance of the HACCP study in collaboration with the team members. The team will also decide on the scope of the HACCP study. As alluded to above, this consists in deciding which types of hazards (microbiological, chemical, physical) and which part of the food chain the study will cover. It is possible to start with one hazard (e.g. *Salmonella*) or one type of hazards (e.g. microbiological) and to extend to other types of hazards at a later stage.

Step 2 – Description of the product. A full description of the product should be drawn up, including conditions for raw material storage, transport and distribution, and preparation by the end-users. The more in-depth such a description is done, the smaller the risk of overlooking a factor that can influence the presence of a hazard. Examples of information that could be included are:

- What is the product?
- What is its formulation and composition (raw materials and ingredients, physicochemical parameters potentially influencing safety (e.g. pH, a_w)?
- What is the nature of the product, e.g. fresh, canned, dried, vacuum-packaged?
- How is the product manufactured/processed?
- What is the packaging?
- What type of storage, transport and distribution are required?
- What is the shelf-life of the product?
- Are there any other special considerations that need to be addressed, for instance a previous record of safety of the product (see "Hazard Analysis," below)?

A frequent shortcoming is that these descriptions are not detailed enough to allow an in-depth hazard analysis. In absence of such information, important hazards may be missed during hazard analysis. Not infrequently, HACCP plans are developed without fully considering the supplier's food safety assurance, and subsequently hazards that may be present in the raw material are overlooked.

Similarly, steps following manufacturing, i.e. hazards which may occur during transport, distribution, and most importantly during preparation by consumers, are frequently omitted during certain HACCP studies. For certain types of products, factors such as the conditions for storage of the product during distribution or for the target customer/consumer, or the potential mishandling of the product may be crucial for designing safety, including the necessity for providing information on the safe use of the product.

Step 3 – Identification of intended use. Information on the intended use should be based on the expected use of the product by the end-user or consumer, including the country where the product will be sold. Examples of information that need to be considered are:

- What is the intended use (home retail, foodservice, further manufacturing)?
- What preparation procedures are required by the consumer/customer?
- What is the potential for mishandling?
- Who are the target consumers (age, health status)?

The above information is important to ensure that the safety of the product is designed according to the requirements or needs of the target customer or consumers. For instance, if

the product is to be sold in another country or to specific consumer groups, e.g. children, the limits applicable for the country in question or target consumers must be taken into account. The identified use will also determine which kind of information and instruction would be required on the package, as for certain products additional control measures may be at the customer or consumer end (e.g. cold storage, labeling for allergens, age of consumption or condition of consumption). As it will be explained elsewhere in the book, it is important that any assumption on the intended use of a product, e.g. age, hygienic condition of preparation and consumption, consumer practice, be validated (i.e. a reality check). For instance, in an outbreak associated with cookie dough, implicating some 70 persons in the United States in 2009, it was found that some US consumers had the practice of tasting the raw cookie dough. After the outbreak, the instruction on the package had to be revised.

Step 4 – Construct the flow diagram. The flow diagram should cover all the major steps[4] in the operation and the conditions for these, particularly steps likely to influence safety. It should, as far as possible, cover the entire food chain, including storage, warehousing, distribution and product handling downstream.

The flow diagram must reflect the real process of production, processing and manufacturing, or handling of the food product. Lack of accuracy may seriously jeopardize the quality of the HACCP study and the validity of decisions. All technical data such as temperature, time, pH, etc. should, as far as possible, be noted on the flow diagram. This can enhance visibility and understanding of the conditions of operations. It will allow an overview of the operations and identification of any possible risks associated with product design or operation.

It is also important to consider how the circulation of water and air and employee traffic can impact on the safety of the product, and, for this purpose, the flow diagram of water, air and people (or zoning plan) should also be taken into account. In this context, all building or reconstruction activities should also be considered as they may lead to the contamination of the factory environment with foodborne pathogens.

Step 5 – On-site confirmation of the flow diagram. This step in the development of the HACCP plan is intended to verify that the flow diagram reflects the real process and that no important consideration has been omitted. Very often, this step is neglected; however, a scrupulous on-site verification of the flow diagram, together with the examination of hygienic conditions by the entire HACCP team will be a strong basis for hazard analysis. To this end, it is important to check the correctness of information or whether information was overlooked. This should be checked during the period of operation and cleaning, but also during idle hours. Talking to operators working on line can also help in disclosing significant details. The on-site verification of the flow diagram is also an occasion for the members of the team to fully understand the role of the different operations units and the way the equipment works, as this insight is important for the evaluation of risks associated with operations.

[4]A point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption. The term "step" here refers to the steps in production, manufacturing, and processing operation and not to the step in the development of the HACCP plan.

Step 6 – Hazard analysis. Hazard analysis is defined as the process of collecting and interpreting information on hazards and conditions leading to their presence to decide which are significant for food safety, and should be addressed in the HACCP plan. In practice, this consists in listing all potential hazards associated with each step of operations (from raw material to final use), and in evaluating their significance, i.e. taking into account their likelihood of occurrence and their health consequences.

For this purpose, it is imperatively important to examine the past record of safety of the product in question. This should include:

- Outbreaks, contamination or other types of adverse events (including cases of fraud) associated with the product or agent in question;
- Risk factors, e.g. level of hazard, status of the host, nature of the organism; and
- Underlying factors, i.e. errors and their root cause leading to the incident.

There have been numerous outbreaks or contamination incidents, including cases of fraud that could have been prevented if the previous record of safety of the product were examined.

Note that a hazard is defined as "a biological, chemical, or physical agent in, or condition of food, with the potential to cause an adverse health effect." The term "condition" also includes aspects related to the properties of food. Examples are its consistency and form, which may cause choking, and the nutritional composition of the food, such as infant formula, or pet food, where excess or lack of a nutrient may endanger health. The property is also very much linked to intended use of a product as some products may not be appropriate for a specific target group.

Thus, at first all potential hazards associated with the various steps will be identified; this also includes hazardous conditions of food. At each step, control measures needed to control the hazards are also determined. More than one control measure may be required to control a hazard. In deciding on the control measures, it is fundamental to understand the factors and parameters that characterize the control measures and to have full understanding of the feature of the hazards (e.g. ecology and epidemiology of microorganisms).

Very often hazards are described in general terms, e.g. "microbiological hazard" instead of specifying *Salmonella*, *S. aureus* or hepatitis A virus. Although such an approach may in some cases be practical, it is often misleading, and in regard to microbiological hazards, it may even be dangerous. The reason is that microorganisms differ in their behavior, ecology and control measures. For instance, the ecology and control measure for *S. aureus* are much different than that for *Salmonella* or viruses. Thus, unless organisms share similar ecology and epidemiology, as far as possible they should be considered specifically. Similarly, chemical contaminants, or physical hazards, should be defined individually so that valid safety limits and methods of detection or testing can be identified.

A key question in the hazard analysis is whether a hazard presents a significant risk and qualifies as a *significant hazard*. In the plethora of hazards that may theoretically be associated with a raw material or an operation, it is often difficult to decide which hazards present a real safety threat and warrant a strict control under the HACCP plan. It is clear that the risk of hazard depends on many factors, among others on the source of the raw material, i.e. quality assurance of the supplier, the hygienic and other prerequisite conditions of operations allowing contamination, survival or growth of an agent, whether during the process

TABLE 31.1 The Different Types of Data that may be Needed for Hazard Analysis

Hazards	Examples of Data
Microorgansims	Health consequences, infectious dose of the agent, epidemiological information on the prevalence of the agent in the country/raw material, thermal resistance, survival, growth characteristics Food composition and food characteristics Target consumers and their health conditions Status of Good Hygienic Practice (GHP) and other prerequisites
Mycotoxins	Legislation and safety standards Climatic conditions, droughts, insect attacks and stress factors Surveys, alerts, historical records and monitoring data Agriculture practice (harvest, transport and storage) Target consumers (infants, adults, pets)
Agrochemicals	Legislation and enforcement Agriculture practices Infections in animals or disease of plants Surveys, alerts, historical records and/or monitoring data Target consumers
Allergens	Nature of raw material Evaluation of cross-contact at the supplier or during transport Evaluation of cross-contact on the factory premises Food safety management system at the supplier Verification data/historical record Target consumers
Physical hazards	Size, shape and nature of the hazard Quality assurance at the supplier Good manufacturing/hygienic practices on the premises Target consumers and possible handling upon use

there are other steps that would remove or control the hazards to safe levels, and/or the intended use of the product and the consumer itself. For instance, opportunistic pathogens like *Cronobacter sakazakii* are a threat mainly to newborns but not to healthy adults. Thus, it can be a significant hazard in an HACCP study of infant formula and not for adult food. It is for this reason that during the hazard analysis, over and above being able to identify the potential hazards, the conditions in which food or its ingredients are produced and processed should ideally be considered from farm to fork; as far as possible, it should be ensured that good hygienic practices are implemented throughout the food chain.

At the hazard analysis step, each hazard is to be evaluated for its degree of risk and is classified as significant or not significant. Risk is defined as a function of the probability of an adverse health effect and the severity of that effect, consequential to (a) hazard(s) in food. So, in the context of HACCP and ensuring safety of products, for evaluating risks, two types of information need to be considered: (1) likelihood of occurrence of the hazard in the food and (2) the health consequences. Table 31.1 provides examples of data that will need to be considered for the analysis of different types of hazards.

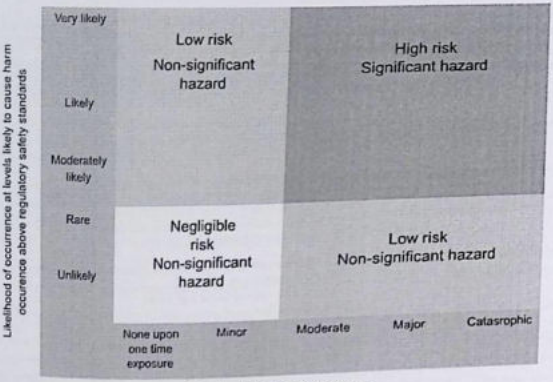


FIGURE 31.3 The evaluation of risk according to the likelihood of occurrence of the hazardous agent and the severity of health consequences. Hazards identified as high risk must be controlled at a CCP.

Hazards which are likely to occur in the raw material or during operation and present a health concern for the consumer are qualified as significant hazards and would need to be controlled through critical control points, as explained below. However, for the hazards which are viewed as non-significant on the grounds that the conditions of production, processing and/or handling will make any risk unlikely or remote, monitoring activities, referred to as *verification*, are carried out. The objective of these monitoring activities is to confirm that existing control measures are effective and that the risk of the hazard, as presumed, remains low at all times.

The evaluation of risks does not always provide a black or white answer. Even when hazards are evaluated as non-significant, there may be different degrees of residual risk (Figure 31.3). Thus, depending on the degree of risk, a different frequency of monitoring may be considered. For instance, for bolognaise sauce, where tomato is considered as a raw material, should the operator use fresh tomato from a supplier with unknown conditions of production, then *Salmonella* should be considered as a significant hazard, cooking of the sauce as the control measure and the step of cooking a critical control point (CCP), i.e. the hazard will be controlled through the HACCP plan. However, if the tomatoes are sourced with a supplier which is audited and if there is confirmation that they are produced under good agriculture practice and a good food safety assurance system, then the risk can be considered as low and the hazard as non-significant. Nevertheless, the supplier should

be periodically audited and the tomatoes also periodically tested for *Salmonella* as a way to verify the hazard analysis. Clearly, if canned tomatoes are used, the canning process will remove the agent, and the risk of *Salmonella* can be considered as practicably negligible; in this case there will be no need for testing, i.e. the frequency of testing can be nil.

Step 7 – Determine the critical control points (CCPs). In general, the critical control point refers to the step in the operations at which control is essential to eliminate, reduce or maintain a hazard at an acceptable level; in other words, a step at which, if the hazard in question is not controlled, the product is likely to be unsafe. From the above we can understand that we are referring here to significant hazards. A CCP can be different steps in the operation, from raw materials to a location, process, procedure or practice, including product formulation.

The designation of a step as a CCP usually has many implications over and above the need to set up a very strict monitoring procedure. It can also imply that all the records need to be reviewed, verified and signed before the product is released. This may sometimes delay the release of the product, particularly if the monitoring is based on testing. Also, if the critical limits at the CCP have been violated and the product has accidentally reached the market, consideration must be given to product recall.

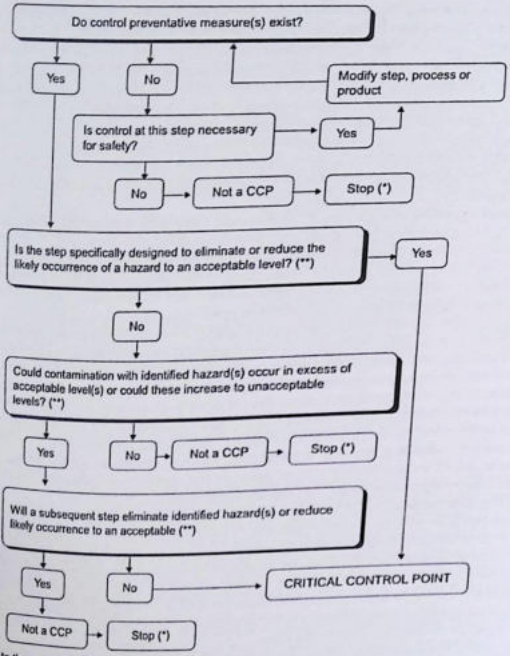
A condition for a step to be considered as a CCP is the fact that it should be possible to effectively monitor the step. Also, if a hazard is identified as significant, and no possible control measure exists, then the product or process must be modified. This principle of modification is often overlooked in practice and not infrequently, for business reasons, food establishments try to cope with a risky condition rather than to modify the process. For instance, it has occurred that a raw material is considered as a high risk because there is a doubt on the quality assurance of the supplier. Yet, instead of changing the supplier, testing of raw material is used as a means for controlling foodborne pathogens, while as mentioned before, testing for microbial agents cannot be an effective control measure and should be seen as a verification of the supplier quality assurance. In such a case, the supplier should be changed.

The determination of a CCP can be facilitated by the application of a decision tree, which supports a logical reasoning approach. Figure 31.4 provides an example of a decision tree, but other decision trees can also be used.

A lack of understanding or an inconsistent use of terms often leads to confusion. Not infrequently, the term "significant hazard" is confused with CCP, e.g. aflatoxin is referred to as CCP, or a control measure is taken for a CCP while a CCP refers to the "step" in the operation and control measure is the activity carried out at the step to prevent a food safet hazard exceeding an acceptable level.

Step 8 – Establishing critical limits. Critical limits[5] are basically limits of acceptability unacceptability of control parameters. Therefore, they should always refer to the monit ing parameters. Depending on the type of hazards and control measures, the nature of cri cal limits may be different. For microorganisms or hazards where testing is not a reliable method of control and physicochemical methods are used for controlling the hazard, critical limits refer to the process parameters. They are values such as pH, a_w, temperature, time (or flow rate), salinity, level of chlorine, overpressure, etc. For hazards where testing can be

[5] A critical limit is a criterion which separates acceptability from unacceptability.



(*) Proceed to the next identified hazard in the described process.

(**) Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan

FIGURE 31.4 Example of a decision tree according to Codex Alimentarius Commission (CAC 2003).

used as a reliable method for control, then values such as maximum residue limits (for agrochemicals) or maximum levels (for contaminants) can be adopted.

As several parameters may be important for controlling a step (e.g. for heat treatment, both time and temperature are determining factors), more than one critical limit may be needed. Therefore, the parameters necessary to monitor a step must be carefully identified. In HACCP, critical limits are associated with the CCPs. However, even if the HACCP study does not result in specific CCPs, limits for control parameters could be defined to ensure that control measures are applied in a correct manner.

Sometimes, when the control measure takes place in homes or in foodservice establishments where tools for physical measurements do not exist, it is possible to use indirect measures such as color or texture as monitoring parameters. For instance, as a critical limit in the home environment, it could be recommended that eggs should be cooked until they become firm, or meat should be grilled until it is no longer red. Such a recommendation could be considered when formulating the instruction on the package. In food operations, visual methods of monitoring can also be used as a means to ensure that certain measures have taken place, e.g. a production line has been cleaned between two products according to the established procedure to prevent cross-contamination of allergens.

Step 9 – Establishing a monitoring system for each CCP. In the context of HACCP as defined by the Codex Alimentarius, monitoring is the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control. Note that the monitoring which is carried out at a CCP, be it measurement or observation, is relative to the critical limits. Monitoring can be a physical measurement, visual inspection or chemical analysis.

The frequency of monitoring should be set so as to detect loss of control at the CCP and enable the necessary adjustments to control the process and prevent violation of the critical limits. Where possible, process adjustment should be made when monitoring results indicate a trend toward loss of control at a CCP. From the above, it is essential that very rigorous monitoring procedures must be established at the CCP.

Even when a step is not considered as a CCP, this should not be interpreted as that step not being important nor should it preclude monitoring of the control measure(s). Only the stringency and significance of the monitoring are different. To differentiate these two types of monitoring, for the purpose of this text we will refer to CCP monitoring versus verification monitoring. As mentioned above, the frequency of monitoring as verification can be adjusted according to the level of risk (Figure 31.3). Whether the monitoring is carried out at a CCP to ensure control, or as means for verification, it is important to have a consolidated and validated monitoring plan, indicating the type of monitoring, the frequency and time of execution, the method, the person responsible and actions in case of non-compliance.

A common failure in establishing a monitoring procedure for a CCP is omitting one or several key control parameters. For instance, not infrequently it is observed that, at the pasteurization step, which is often a CCP, only the temperature is monitored. The duration of the heat treatment, or the flow rate of the product, which is a determining factor for the duration of heat treatment, is not monitored. For water disinfection, only residual chlorine is considered and other factors such as contact time, pH of water and turbidity, which impact on the chlorination efficiency, are not considered.

It has also been experienced that some important steps in the operation have not been considered as CCPs on the grounds that they cannot be monitored "continuously" or a physical measurement method is not available. It is certainly much better to measure control parameters in an objective manner, e.g. with a temperature recorder. However, a lack of such methods for monitoring should not be a reason for not considering a step in the process as a CCP. If control at that step is important and visual observation can be effective in detecting deviations from acceptability, then the step can be considered as a CCP. The concept of continuity is also misunderstood. Monitoring a CCP should be carried out with specific and predetermined frequency. This may be every second, hour, day or defined moments as applicable. However, this has to be set in such a way that if a deviation is observed and critical or operational limits are violated, the corrective actions can be implemented in a timely manner before the product is released.

Step 10 – Establishing corrective actions. When applying the HACCP system, specific corrective actions[6] must be developed at each CCP in order to deal with deviations when monitoring shows loss of control. The actions must ensure that the CCP(s) has/have been brought under control so that only safe products reach the consumer. Strictly, this also includes possible disposition of the affected product. However, this decision should be made on a case-by-case basis. It is frequently observed that corrective actions are not well defined. There are times when they are mentioned as "see the QA manager or production manager." While it is a good practice that in times of problems the operator consult his superior, it is nevertheless important to document the specific corrective actions that have to be carried out to restore control, including ensuring that no unsafe product is released.

Corrective action should also prevent recurrence of the mishap leading to loss of control; therefore the cause of any deviation should be thoroughly investigated and the root cause of the problem determined (see Chapter 40).

Step 11 – Establishing procedures for verification. Verification refers to the application of methods, procedures, tests and other evaluations, in addition to CCP monitoring, to determine compliance with the HACCP plan. In practice, verification activities are carried out to verify the effectiveness of the HACCP plan and if it is implemented correctly, in other words, to check if what is planned is done and if the HACCP is well maintained and working as expected.

As such, verifications may include a variety of activities and collection of data to confirm that the HACCP plan is valid as well as well implemented. It can include:

1. Raw material testing and/or supplier's audit for verifying supplier's quality assurance.
2. Environmental monitoring for verifying the efficiency of cleaning and sanitation.
3. Calibration of equipment, in particular those used for monitoring of CCPs.
4. Audit of operations for confirming the adequate implementation of prerequisite programs and of the HACCP system.
5. Review of the records and of monitoring data confirming that the process parameters are kept under control and within established limits.
6. End-product testing for verifying the adequate implementation and efficiency of the system.

[6]Corrective actions are defined as the actions to be taken when the results of monitoring at the CCP indicate a loss of control.

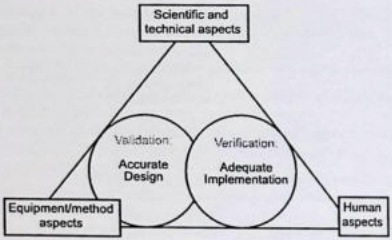


FIGURE 31.5 In validating a decision, three aspects, i.e. training and competence of employee, suitability and performance of the equipment and method, and scientific and technical data, need to be considered.

7. Verifying the consumer complaints to ensure the adequate implementation and efficacy of the food safety assurance system.
8. Verifying the training of employees involved in the implementation of prerequisite activities and of the HACCP system.

It should be noted that verification should not be ceased on the grounds that the results are negative; the results of monitoring are needed to be able to confirm that the food safety assurance system is implemented and effective at all times.

Principle 6 of HACCP also includes the concept of validation. The subject deserves some attention as validation is the assurance in the food safety assurance system. Without validation, the HACCP study has no scientific basis. According to the Codex Alimentarius Commission, validation is obtaining evidence that the elements of the HACCP plan are effective. This can be further explained as the demonstration that decisions made during the HACCP study have a scientific and/or technical basis and/or are based on accepted practices.

In validating the elements of an HACCP study, at each step it is important to consider three aspects: (1) the scientific and technical data, (2) the equipment used, i.e. if it is suitable for the intended use, and (3) the personnel who have to implement a decision (Figure 31.5). It is clear that designing a scientifically valid HACCP is of little value without the equipment used being suitable or the personnel competent to implement the decision. Validation is often confused with verification. To make a distinction between these two activities, validation is carried during the product design and the development of the HACCP plan to ensure that the plan is designed correctly, while verification is carried out as part of the implementation of the HACCP plan to ensure conformity with the plan (Figure 31.6).

While validation and verification activities are separate activities, the results of verification are of importance for (re-)validating the HACCP study as illustrated in Figure 31.7. If the results of verification show a problem, the first question that should be asked is was the HACCP plan implemented as planned? If a gap is noticed in the implementation, this needs

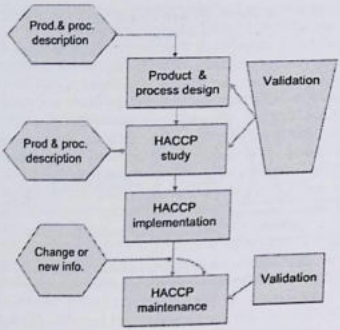


FIGURE 31.6 The process of validation and maintenance.

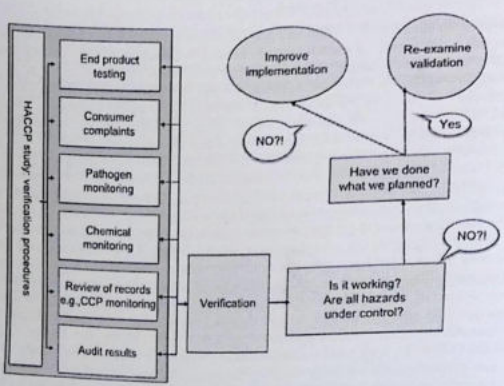


FIGURE 31.7 How verification can be used for the evaluation of HACCP implementation and efficacy.

to be corrected. However, if the investigation shows that in spite of the implementation of the HACCP system as planned, there is still an unsatisfactory situation, then the validation of the HACCP study should be questioned.

Depending on the elements that need to be validated, the exercise can be based on:

- Review of scientific literature and evaluation/extrapolation of information;
- Verification of conformance with regulatory requirements;
- Past records of verification data, surveys, or other types of historical information.
- Experimental trials, e.g. challenge tests.

Thus validation does not necessarily entail extensive and expensive studies and can be just verification of conformance with the regulatory requirements or extrapolation from studies already conducted.

Often the question is raised as to what needs to be validated. In principle, all the steps in the decision-making process need to be validated, from the hazards analysis, critical limits, monitoring parameters to corrective actions and verification procedure (Scott, 2005) (Table 31.2). The following example illustrates the importance of validating all measures: in an outbreak of *S. aureus* in Japan in the year 2000, the factory manager repasteurized a milk product which contained *S. aureus* toxin. Thus, the company applied a corrective action that was not valid, as the S. aureus toxin is heat stable. Similarly, errors can happen in the monitoring procedure if, for instance, the thermocouple used for monitoring is not set at a correct point in the food product, or the analytical method and sampling procedure for testing for a chemical are not valid. With regard to control of microorganisms, it is important to ensure that the intervention considered will ensure the performance objective or performance criterion.[7] For instance, in a canning process, the sterilization process should ensure a performance objective of <1 spore/10^{12} g C. *botulium* or a process criterion of 12 D reduction. This translates into process parameters of 2.45 min/121°C; or the process parameters of cold storage (i.e. shelf-life of a product at a given temperature) of a smoked product should ensure that there is no growth of psychrotrophic bacteria such as *Listeria monocytogenes* to above the food safety objective (e.g. 100 *Listeria*/g). Further examples of validation are provided in the Codex Guidelines for Validation of Food Safety Control (CAC 2008). While the validation of processing steps for killing and/or prevention of growth are often evident to food operations, the validation measures at the supplier, transport or consumer level are not always evident. For instance, for allergen management, to ensure correct information on the package, it is essential to verify the validation at the supplier level of their allergen control plan and of their allergen declaration. Similarly, it is important to validate the information provided to customers and consumers, i.e. that the control measure which is recommended at the consumer level, such as time and temperature of the storage of the product, is valid, and that the information is clearly communicated. For the latter, a focus group could be organized to evaluate the clarity of information. Again, in line with the principle of modification of product design where control measures are not feasible (see Q1 in Figure 31.4), if a survey

[7]Performance criterion (PC). The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

TABLE 31.2 Examples of Activities that Need to be Validated, as Applicable

Principles	Validation
Conducting a hazard analysis	Ensuring: – Appropriate expertise is used in identifying potential hazards. For instance, public health guidance or regulatory requirements are checked, scientific literature is searched, experts are consulted and previous records of contamination or outbreaks are examined. – Identified control measures are effective in achieving the food safety or performance objectives, the design of equipment is adequate to achieve these criteria and personnel are qualified for the purpose. Where hazards are considered as non-significant, ensuring that: – Prerequisite programs, including suppliers' practices, processing of food, or other conditions (e.g. regulatory measures, epidemiological situation of the country) are adequate to control the hazards to safe levels.
Determining the critical control points (CCP)	Ensuring that assumptions leading to identifications of CCPs are valid (see above), personnel are properly trained in identifying CCPs and understand the significance of a CCP.
Establishing critical limits	As applicable, ensuring that critical limits are: – Consistent with the performance or product criteria needed to meet food safety or performance objectives. – In accordance with the regulatory requirements of the country where products are marketed and/or the specifications of customers if these are stricter.
Establishing a system to monitor the CCP	Ensuring that: – All parameters needed to monitor control measures are selected correctly. – Equipment or methods used for monitoring (e.g. limit of detection or quantitation, sampling method, etc.) are appropriate, valid, calibrated and functioning correctly. – Personnel are competent, trustworthy and adequately trained in the use of equipment or the methods of monitoring (i.e. validate their training). – Personnel know what to do in case of deviation.
Establishing corrective actions	Ensuring that: – Measures foreseen for correcting a deviation are effective. – Staff are adequately trained in implementing corrective actions in case of deviation. – Traceability is working effectively.
Establishing procedures for verification	Ensuring that: – Limits (including specifications) set for product or environmental testing are valid and comply with regulatory requirements and product or process specifications. – Methods for testing and procedures are valid and carried out by competent personnel. – All verification procedures are valid; data are adequately reviewed by competent personnel and acted upon.
Establishing documentation	Ensuring that documentation and records: – Meet the regulatory and/or customer requirements. – Demonstrate the hazard analysis and HACCP plan, and include data on validation, results of CCP monitoring and verifications, as well as corrective actions in case of deviation. – Include root cause analysis in case of non-compliance (near miss or incidents). – Allow for an efficient and speedy traceability and trace-back.

of consumer/customer practice and knowledge shows that the implementation of a foreseen control measure is not feasible at the consumer and customer level, the design of the product should be modified and/or the product in question should be considered unsuitable for the customer and should not be sold.

Validation should usually take place during the design of the product or during the HACCP study, i.e. before the implementation of the HACCP study. However, if there is a change or when new information comes forth, the need for revalidation must be considered.

Step 12 – Establishing documentation and record keeping. Documentation and record keeping often give the perception that HACCP is a paper exercise. Whereas these play a pivotal role in food safety as they are an important and effective means of communication, they allow communication with other colleagues on how food safety is planned and implemented and on the information that was considered in the decision-making process. Documentation can play an important role in maintaining the HACCP plan, reviewing and if necessary revising decisions.

Documentation also provides law enforcers, auditors and customers with evidence and information on the (1) hazards analysis conducted, i.e. what hazards are considered and controlled, (2) the hazards which are considered significant and are controlled by a CCP step, and (3) evidence that the food safety assurance system has been continuously under control.

Documents are also important in case an incident needs to be investigated. They provide evidence that all appropriate actions have been taken or provide guidance on the possible source of a problem.

Examples of documentation and records that should be collected and reviewed are:

- Procedures and requirements regarding GHP (e.g. pest management plan and records, personnel health and hygiene requirements and records, etc.).
- HACCP study, including hazard analysis, determination of control measures, process parameters and critical limits, and the HACCP plan as well as the validation data.
- Product formulation (specifications) and manufacturing process.
- Specification to suppliers or any other information to stakeholders in the food chain, e.g. to transporters and distributors for further handling of food.
- Reports of audits of suppliers, transporters, distributors.
- Records of CCP monitoring and the procedures used, as well as corrective actions taken in case of deviations.
- Verification activities (see above) as well as validation data or studies.
- Records of investigation and follow-up of non-compliance and/or corrective actions.
- Records of training of personnel, the nature and scope of their training as compared to their responsibility.
- Periodical review of the HACCP study and the HACCP plan.

Tables 31.3 and 31.4 provide examples of templates that can be used to document the key decisions of the HACCP study and the HACCP plan.

Implementation of the HACCP Plan and its Maintenance

The implementation of the HACCP plan at a production site starts with the training of personnel, including all personnel involved in one or several activities of the HACCP

TABLE 31.3 Example of Template for Documenting the HACCP Study

Steps	Hazards	Control Measures	CCP Yes /No	Limits	Monitoring	Corrective Actions	Verification

TABLE 31.4 Example of Template to Record the HACCP Plan

CCPs	Hazards	Control Measures	Limits	Monitoring	Corrective Actions	Verification

system and/or the prerequisite activities (WHO, 1995; Williams et al., 2003). In doing so, the managers and employees should be informed of their tasks and responsibilities, the importance and significance of their measures, the need for informing the HACCP team or the coordinator of the team of any change or deviation from the plan or the prerequisites (e.g. non-compliance observed during audits, verification data showing unsatisfactory results, or change in the process or supplier). It is to be remembered that non-compliance with the prerequisites has a bearing on the hazard analysis done during the HACCP study and its outcome, i.e. the HACCP plan. A major outbreak of salmonellosis in Germany, affecting some 1000 children, resulted from a sudden change of the supplier. Incidents related to undeclared allergens are also frequently associated with a change of supplier without taking the necessary measures to examine the impact of the change on the operations and the product. Thus, any of the above conditions should trigger a re-examination of the HACCP study.

Also, those responsible for implementing the HACCP should fully understand the importance of compliance of CCPs and the need for thorough investigation of any non-compliance at these steps. The root cause of such near misses, up to the responsibility of management, needs to be established.

Further to the implementation of prerequisites and of the HACCP system, the HACCP plan should be maintained (Figure 31.6). This means a periodical review of the HACCP study to "verify" that the HACCP has indeed been maintained and continues to be valid in the light of the latest internal or external developments. It is to be emphasized that the periodical review is a verification of maintenance of the HACCP system and an update of the records. The maintenance of the HACCP plan itself should be done on a continual basis. Thus, contrary to the general practice, HACCP is not a one-time exercise. Also, the maintenance of HACCP does not necessarily lead to increased control but can also be beneficial, as certain changes in the environment of production or improvements in the prerequisites can result in the need for lesser control through the HACCP plan, as for instance if the raw material is changed to a product which has lesser risk of certain contaminants.

Over and above verification data, two types of information and changes should trigger a re-examination of the HACCP study and plan, and its validation.

1. Changes related to internal operations. Examples are:
   a. Change of the supplier, their practices or where the raw material is sourced
   b. Change in recipe, product formulation or packaging (including labeling)
   c. Change in the process line, equipment and material
   d. Change in personnel
   e. Change in food production environment, in particular in case of temporary maintenance work, which can lead to the exposure of the factory environment to foodborne pathogens
   f. Change in transport or distribution channel
   g. Change in target consumer and intended use and/or conditions of use (a product is intended for a younger age that previously considered)
2. Changes, external to the operations, i.e. related to the environment where the product is produced, processed or sold. Examples of these changes are:
   a. Emergence of new pathogens or chemical contaminants
   b. Changes in regulatory requirements where the product is sold
   c. Changes in technology, analytical capabilities, monitoring tools
   d. Changes in the demography and/or consumers' practices or perception
   e. Environmental contamination or social factors
   f. Report of incidents, outbreaks or errors in other operations in the world or new data on food contamination previously not known

Figure 31.8 illustrates the entire cycle of an HACCP application, from hazard analysis based on the examination of the status of prerequisite programs, to the implementation of the HACCP plan and its maintenance.

HACCP IN SMALL BUSINESSES OR LESS DEVELOPED BUSINESS

Worldwide, it is recognized that the HACCP system may be difficult to implement in small or less developed businesses due to lack of resources. An approach that some governments have taken to address this problem is to assist these businesses by carrying a generic HACCP study for a category of a product, and based on the outcome of the study, to develop an HACCP-based code of practice. Such an approach combines the requirements provided in a code as well as specific measures required for a specific product category of products.

ASSESSMENT OF HACCP

Whether as regulators, auditors or managers in a company, professionals may be brought in to evaluate the HACCP plan of a company (WHO, 1998; Motarjemi, 2000). Since HACCP requires a multidisciplinary expertise, one cannot rely on the assessment of auditors to ensure adequacy and validity of the HACCP study. However, auditors can check the understanding of the principles of HACCP and the vigilance with which these are implemented, validated

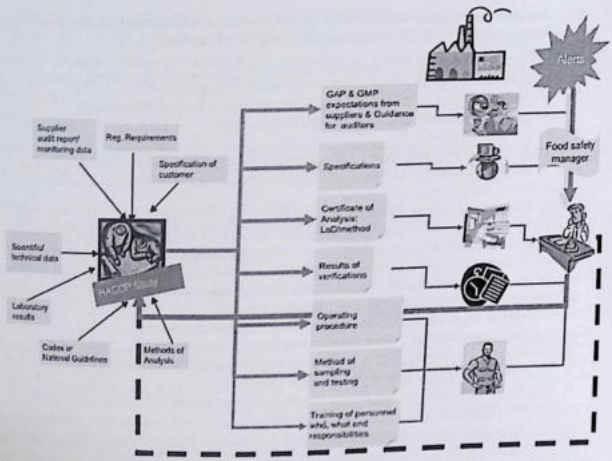


FIGURE 31.8 The process of developing an HACCP study, taking into account various information including the prerequisite situation, to implementation and maintenance.

and maintained. Auditors and inspectors are cautioned against the indiscriminate use of a checklist. While a checklist provides some benefits and ensures completeness of the assessment, it should not evolve into a tick-box approach, replacing critical evaluation. Like the development of the HACCP plan, its assessment requires a certain degree of expertise, as often audits are carried out to function as an aide-mémoire. Guidance on the regulatory assessment of HACCP as well as on internal audit is provided in Chapter 38, as well as elsewhere. (WHO, 1998; Motarjemi, 2000).

CONCLUSION

The application of the HACCP system is not a stand-alone system, but it should be seen as an element of food safety management. It complements basic good hygienic practices in food safety assurance by targeting product-specific hazards and devising control measures necessary for managing risks relevant to the product and conditions of operations.

However, it is not a magic wand and it is not a panacea for all problems. It can be a powerful tool for the management of food safety only if it is correctly understood and applied and if there is adequate commitment by the management for providing necessary resources and expertise (Motarjemi and Kaferstein, 1999). It should not be seen as a measure for regulatory authorities and/or implemented to satisfy the requirement of authorities; otherwise it becomes a bureaucratic exercise, with a massive amount of paperwork without much added value. It has to be used in the context of true commitment to food safety.

Finally, for more in-depth reading and understanding of the HACCP system, the reader is referred to a number of good books which have been written in this area; among these is Wallace et al. (2011) *Food Safety for the 21st Century: Managing HACCP and Food Safety throughout the Global Supply Chain*.

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CHAPTER

32

HACCP Misconceptions

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INTRODUCTION

For over two decades, HACCP has been promoted internationally, particularly in industrialized countries, as a method to enhance food safety assurance systems in the food industry. Nevertheless, in spite of the advance of HACCP as a core method for food safety management, large-scale foodborne diseases outbreaks, food contamination incidents or food recalls of major importance have continued to occur.

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Often the question has been raised as to why, despite the application of HACCP system, such incidents continue to happen? There are a number of explanations for this paradox. An in-depth review of these is given elsewhere (Motarjemi and Käferstein, 1999). Here we limit ourselves to stress only two points: (1) without any doubt, without the HACCP system, we would have experienced many more incidents and (2) considering the quantity of industrially produced food on the market, the number of incidents is relatively low.

As for any preventive measures, one cannot collect statistics and trends for events which have not occurred. Also, HACCP is not a panacea for all problems and the application of HACCP, no matter how rigorously implemented, cannot prevent all kind of incidents. Some of the major incidents, which have marked the history of food safety, could not have been prevented, with even the strictest application of the system. This is particularly the case where the problems are due to the malevolence of some individuals such as the incident of melamine with pet food in the USA in 2007, or the emergence of a new hazard or finding a new source for it, previously unknown, e.g. semicarbazide in baby food in 2003.

Having said this, when the health of consumers is at stake, any incident is one too many and all efforts should be put in place to prevent food safety incidents. What is particularly unacceptable is where by negligence an incident is repeated. This is where HACCP application should be of help, provided that it is properly understood, applied and the resource and infrastructures necessary for it are put in place, particularly so as to review and update the system in response to new knowledge. To this end, management of a company must be committed to providing the necessary resources, i.e. qualified human resources is a *conditio sine qua non* and is perhaps the most important Achilles' heel in the implementation of HACCP. Figure 32.1 shows a root cause analysis of the frequent shortcomings in the HACCP application.

This chapter highlights misconceptions and common errors in the implementation of HACCP, which have repeatedly been observed and which led to failures in the application of the system and have thus undermined the potential of the system to prevent incidents.

Some of the information presented here is mentioned in the previous chapter on Hazard Analysis and Critical Control Point System (HACCP) (Chapter 31). Nevertheless, some salient parts in relation to failures in the implementation of HACCP are highlighted here. Readers who are already conversant with the HACCP system, but would like to further improve the application of HACCP, may wish to focus on the guidance given in this chapter.

MISCONCEPTIONS

HACCP should not be Seen as a Measure for Authorities or Certification Bodies

Sometimes, HACCP is implemented mainly with the objective of satisfying the requirement of authorities, or is seen as a task that is mandatory, without the management of the business really seeing its value, understanding its principles and truly endorsing its implications.

HACCP can be helpful only if it is carried out with the specific objective of managing food safety in an effective manner, i.e. taking the right decision, ensuring that the decisions are actually effective and correctly implemented. In particular, it can help managers to identify those steps in the process that should receive the highest degree of attention and

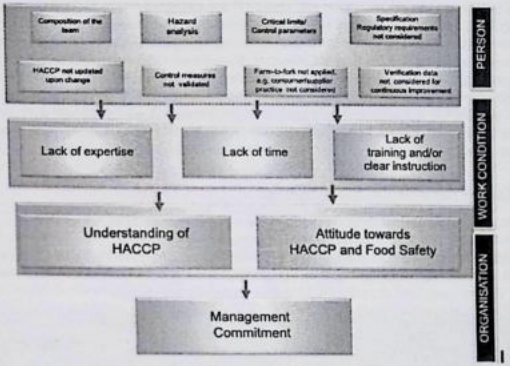

FIGURE 32.1 Root cause analysis of frequent shortcomings in the application of the HACCP system.

surveillance. When HACCP is applied only with the objective to meet the satisfaction of authorities, it will lead to a massive amount of paperwork without much added value. In this case, it has very little chance to become a meaningful exercise and there is a real risk that it will be seen as a burden by all personnel.

HACCP should not be Reduced to Simply Paperwork

Although the HACCP study includes desktop activities, HACCP is not a paper exercise. The proper application of HACCP implies scientific and technical expertise, monitoring of critical control point (CCP) parameters, verification of good manufacturing practice (GMP) on the factory floor, reviewing verification data (e.g. results of raw material monitoring, monitoring consumer complaints and calibration of key equipment), training of people, etc. HACCP should also not be equated with filling forms. In many cases, a number of forms have been created to facilitate the systematic approach and thinking process. However, this should not replace the critical thinking and scientific and technical expertise required to carry out a HACCP study – it is the quality of content that is important, not the form itself.

HACCP is not One Man's Job

As mentioned above, one of the biggest added values of HACCP is the promotion of multidisciplinary teamwork. To carry out a proper HACCP study, it is fundamental to

draw on the right and adequate expertise. The importance of a multidisciplinary team is particularly high when safety is considered at the product and process development. It is at this stage that many potential hazards have to be considered and managing the safety of the product needs to be thought through. As an example, microbiologists and veterinarians usually have not been educated and trained in equipment and process line design, nor in process measurement, control and monitoring. They will therefore never be able to do a useful HACCP exercise on their own. The involvement of somebody with an adequate engineering background is in most cases essential, as is the inclusion of personnel with appropriate operations and food safety knowledge.

HACCP is not a Stand-Alone System

A major misunderstanding or error in the application of HACCP is that it is viewed as a separate system. HACCP should be seen as an approach to food safety assurance; its application draws on an array of measures such as GMP, audits, monitoring, traceability, etc. (Figure 32.2). Therefore, it is essential that as part of a HACCP study, the state of

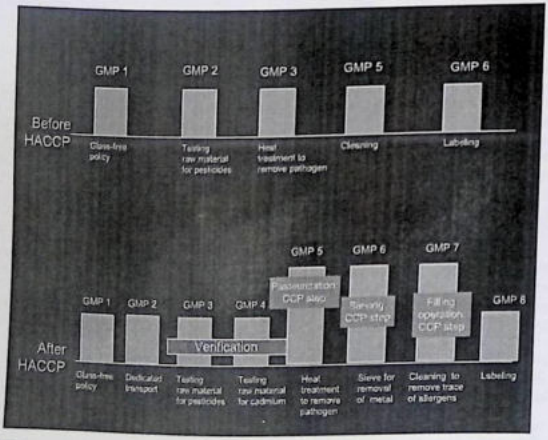

FIGURE 32.2 Schematic illustration to explain the relationship between GMP, CCP and verification activities. The figure shows that HACCP helps all necessary control measures often considered as part of GMP. It also gives weight to the control measures that are particularly important in terms of food safety.

these different measures be carefully considered. For instance, during the hazard analysis, the decision on the likelihood of the presence of a given pathogen in the ingredient will depend on its source. Knowledge about the origin of the raw material and conditions of production, previous record of safety, all audit and monitoring data of the supplier are essential for deciding on the significance of a pathogen. These require having traceability of the ingredient and information on the epidemiological situation of the country where the raw material is produced or on processing conditions of the supplier, should the ingredient be a semi-processed product. Similarly, the likelihood of recontamination of the food product is related to the cleaning procedures and the state of application of the good hygienic practices.

HACCP is not a One-off Exercise

Many see HACCP as a one-time exercise, and once the study is carried out, it is rarely reviewed or updated. First, HACCP is a tool for decision-making. As such, it should be flexible and should be part of the everyday thinking process. As the situation evolves, decisions may also need to be changed. For instance, a step in the process may temporarily need to be considered as a critical control point (CCP) until there is enough assurance that the risks are adequately under control. Or, the frequency of the verification of a supplier's products could be modified as the supplier confidence increases

Second, maintenance of a HACCP plan is as important as its development and implementation. Each time a factor related to food production, e.g. supplier, an ingredient, the process, the equipment, target consumer, etc. is changed, the consequence of this change on the hazard analysis needs to be considered and if necessary the HACCP plan needs to be changed.

Similarly, when new information becomes available, for instance when authorities communicate an alert about a new hazard or when verification data (e.g. pathogen monitoring, consumer complaints, raw material monitoring, audit reports of suppliers, industry information, etc.) indicate a new threat, such information should prompt the HACCP team to revisit their study and evaluate the adequacy of their measures. For instance, if verification data (e.g. audit report of the supplier) or raw material monitoring indicate that the supplier's food safety assurance is inadequate, this may necessitate a change of supplier or increased frequency of verification of the supplier's products.

Documentation and Record Keeping are not Bureaucratic Work

Documentation and records play a pivotal role in food safety as they are an important and effective means of communication. They allow communication with other colleagues or provide evidence to customers or regulatory authorities on how food safety is planned and implemented and on what the bases for decisions are. Documentation can play an important role in maintaining the HACCP plan, i.e. reviewing and if necessary revising decisions, providing evidence that appropriate measures have been taken in times of problems.

However, the value of the documentation lies in the quality and quantity of information that it contains. If the information is superficial or not adequate, the documentation becomes more a bureaucratic work than a tool for communication.

In case of incidents, HACCP records provide evidence that the appropriate actions have been taken and facilitate the investigation of the causes of problems.

HACCP does not Work if there is no CCP during the Food Chain from Farm to Fork

A fundamental principle of HACCP is to identify significant hazards and control measure(s) that are essential to eliminate or reduce the hazards to acceptable levels. Where such a control measure(s) is not in place, it is important to modify the production process and/or its conditions (e.g. labeling or providing information on the storage conditions or instruction of use). In many instances (particularly in the case of raw foods), significant hazards are identified, but there is no CCP during the food chain at which point the reduction of the hazard to an acceptable level can be achieved and no modification is, or can be, made to the food chain. For example, the CCP for hamburgers is at the preparation step, there is no real CCP at the slaughterhouse or meat plant level. Unless the meat is irradiated, cooking of hamburgers by consumers must become a CCP and consumers should be imperatively and adequately informed about their role. In these cases, if it is not acceptable to have a CCP at consumer level, the application of HACCP *per se* will not make food safe.

HACCP is not only Qualitative

There is a general misconception that the decisions taken within HACCP studies are qualitative. However, during the hazard analysis, the likelihood (possible, probable or likely) of contamination with a chemical contaminant, survival or growth of an organism or production of toxin and the magnitude of these events can also be estimated. Moreover, the efficiency of control measures has to be determined, i.e. how effectively a processing step can eliminate or reduce a pathogen to an acceptable level (evaluated in terms of log reduction), or what the extent of microbial growth will be during the shelf-life of a product under given conditions.

These concepts are generally addressed under the principle of validation of the control measures (CAC, 2008) and should not be mistaken for the concept of microbial risk assessment. The latter, recommended in the framework of Codex Alimentarius as one of the three elements of "risk analysis," is a governmental activity with the aim of integrating scientific facts into the decision-making process.

COMMON ERRORS OR SHORTCOMINGS IN THE APPLICATION OF HACCP

There are also a number of systematic weaknesses in the application of HACCP. The root cause of many major or international incidents can be attributed to these errors or shortcomings. Table 32.1 shows a variety of well-known food safety incidents and outbreaks and considers the likely errors and shortcomings in the application of HACCP and food safety management systems.

TABLE 32.1 Some Examples of Food Safety Incidents and Presumed Weaknesses in the Application of HACCP that Led to the Incident

Year	Place	Incident	Likely HACCP/FSMS Weakness	See Common Errors and Shortcomings Section Number
1993	Germany	*Salmonella* in paprika chips	Maintenance of the HACCP plan. i.e. Change in supplier and shortcomings in the control of the raw material	2, 13
1994	USA	*Salmonella* in ice cream	Shortcomings in the scope of the HACCP and application of perquisite programs (i.e. lack of dedicated transport, and poor GHP)	2, 7
1996	UK	*Salmonella*, cheddar cheese	Weakness in the validation of control measures, no corrective action, lack of understanding of HACCP principles	12, 11
2000	Japan	*S. aureus* with milk products	Weakness in the hazard analysis, lack of knowledge regarding risk, lack of temperature control for raw milk during power failure, non-valid corrective actions, inadequate communication during incident	1, 6, 7, 11, 12, 13
2002	Europe	Recall of honey due to Chloramphenicol	Weakness in the hazard analysis and verification of suppliers	1, 6
2002	Norway	*S. aureus* in ice cream	Poor implementation of prerequisite programmes (e.g. failure in the maintenance of the dispensing machine, cleaning and disinfection of the system, and the pasteurization of ice-cream mix). Poor verification and validation of control measures at the customer. Weakness in the scope of the HACCP	6, 12
2002	Denmark	Recall of spoiled baby food poorly sterilized	CCP was not monitored correctly Corrective actions were not valid (products released in spite of CCP violation)	9, 11
2003	Germany	Thiamine and Infant formula	Error in the validation of the composition and weakness in the verification of the product composition before its release	12
2005	International	Isopropylthioxantone (ITX) from ink of packaging	Weakness in the hazard analysis and verification	1, 6, 12
2006	International	Benzene and softdrinks	Weakness in the hazard analysis, verification and maintenance of the HACCP plan	1, 6, 12

(*Continued*)

TABLE 32.1 (Continued)

Year	Place	Incident	Likely HACCP/FSMS Weakness	See Common Errors and Shortcomings Section Number
2006	USA	*Salmonella* and chicken pie	Weakness in the control measures (communication with consumers on the microwave heating of products)	2, 6, 12
2006	UK	*Salmonella* in chocolate	Weaknesses in prerequisite programs, lack of knowledge and technical expertise, poor communication.	1, 5, 6, 7, 11
2007	Europe	Sunflower oil contaminated with mineral oil ex-Ukraine	Weakness in hazard analysis, maintenance of HACCP plan and verification (monitoring suppliers)	1, 6, 12, 13
2007	USA	*Salmonella* in peanut butter	Substantial weaknesses in prerequisite programs	6, 12
2009	USA	*Salmonella* in peanut butter	Substantial weaknesses in prerequisite programs, inadequate segregation between raw and roasted peanuts.	5, 7
2008	China	Melamine in infant formula[a]	Weakness in the hazard analysis, maintenance of the HACCP and failure in verification, inadequate raw material safety control; lack of knowledge of consequences of adulteration (although as a criminal offence it is possible that those involved may have gone ahead anyway)	1, 2, 6, 13
2008	USA	*E.coli* O157 in cookie dough	Weakness in the hazard analysis of the raw material and consumer practices and validation of control measures (safety instructions to consumers)	2, 6, 12
2011	Germany, France	Enteroaggregative *E. coli* O104:H4 and fenugreek	Weakness in prerequisite programs and verification of suppliers	1, 2, 12

[a]*Note this was the second well-known incident with melamine, the first occurred in 2007 in the United States as result of contaminated wheat gluten imported from China.*

1. **Expertise.** The success of a HACCP study and resulting plan depends on the expertise employed. A HACCP study is a task requiring both scientific and technical expertise (agronomy, veterinary science, food safety microbiology and chemistry, engineering and technology, consumer knowledge) and operational information and experience. When there is no access to such experts on site, the HACCP study can be reviewed by relevant experts.
2. **Past record of safety.** Analysis of foodborne disease outbreaks and incidents, even certain cases of fraud which *a priori* may seem unpredictable, are often repetition of previous events and in most cases preventable if they were better examined and taken into

account in HACCP studies. Therefore during a hazard analysis, data on the past record of the safety of the product, including any incident, case report of illness or outbreaks, epidemiological data on the event and its root causes need to be considered.

3. **Farm to fork approach.** Although the importance of an integrated approach to food safety and consideration of all steps from farm to fork has been stressed time and again in recent years, nevertheless, frequently HACCP plans are developed without fully considering this principle. For instance, HACCP plans are developed without fully considering the supplier food safety assurance, and subsequently, hazards that may be present in the raw material are overlooked.

   Similarly, those steps following manufacturing are frequently omitted during HACCP studies, for example hazards that may occur during transport, distribution and most importantly during preparation by consumers. For certain types of products, factors such as the conditions for storage of the product during distribution, target customer/consumer or the potential mishandling of the product may be crucial for designing safety, including the necessity for providing information on the safe use of the product. Shortcomings in the application of this point have been the source of numerous reported incidents: salmonellosis and chicken pie in 2006, *E. coli* infection and cookie dough 2008.

   The implication of this principle is that as far as feasible, one should investigate and understand:

   a. The source, origin, conditions of production of raw materials and ingredients;
   b. Conditions of transport and distribution; and
   c. Handling, storage and preparation practices by consumers and customers.

   This insight is essential for determining what control measures (including labeling and handling instructions) need to be considered outside the factory, e.g. at the supplier, transport, distribution and consumer/customer levels. Based on these, we should then define and communicate the:

   a. requirements to suppliers;
   b. expectations to transporters and distributors; and provide
   c. validated instructions for safe preparation and handling of products to caterers and consumers.

4. **Flow diagram.** Very often, flow diagrams used for the HACCP study do not reflect the real processing and manufacturing conditions of the product. Lack of accuracy and detail may seriously jeopardize the quality of the HACCP study and the validity of decisions.
5. **Product description.** Validity of hazard analysis relies on the precision with which various aspects of the product are described, e.g. the raw ingredients and their source, the supplier assurance system (e.g. availability of an audit report), manufacturing steps and conditions, description of packaging and other auxiliary products, potential use or abuse by target consumers. Too often these descriptions are not detailed enough to allow an in-depth hazard analysis. In absence of such information, important hazards may be missed during hazard analysis.
6. **Consideration of circulation of air and water and employee traffic.** When conducting the HACCP study, the flow diagram is often limited to the product. It is important also to consider how the circulation of water and air and employee traffic (or zoning) can impact on the safety of the product. In this context, all building or reconstruction activities should also be considered as they may often lead to increased contamination

of the environment with pathogens, as well as foreign materials. For these reasons it is useful also to consider site layout diagrams and to spend time observing the operation in practice.

7. **Hazard analysis.** Hazard analysis is a process of describing and evaluating potential hazards. Very often hazards are described in general terms, e.g. "microbiological hazard" instead of specifying *Salmonella*, *S. aureus*, hepatitis A virus, etc. Although such an approach may in some cases be practical, it is often misleading and in regard to microbiological hazards, it may even be dangerous. The reason is that microorganisms differ in their behavior, ecology and control measures. For instance, the ecology and thus control measure for *S. aureus* is much different than that for *Salmonella* or viruses. Thus, unless organisms share similar ecology and epidemiology, as far as possible they should be considered specifically. Similarly, chemical contaminants should be clearly defined so that valid safety limits and methods of testing can be identified.

   Similarly, control measures must also be defined and detailed as much as possible. For instance, instead of stating good hygiene practice (GHP), it should specify washing, disinfecting and drying hands or hand hygiene.

   The hazard analysis must include an evaluation of likelihood of occurrence and severity of effect of each hazard identified. This allows the identification of the significant hazards (see also point 8 below), which must be controlled for the food to be safe. Companies who do not take the time to do a thorough evaluation often struggle with establishment of the correct CCPs for the process concerned and their accompanying control and monitoring procedures.

   As mentioned before, hazard analysis must also be carried out taking into consideration the status and effectiveness of prerequisite activities, e.g. GMP, supplier quality assurance (review of the supplier audit report, ensuring that the audit has addressed the concern considered in the hazard analysis).

   The hazard analysis should also take into consideration relevant historical information, such as the previous safety record of a product or its ingredients or previous food safety incidents involving similar products and processes.

8. **CCPs or just good manufacturing practices.** One of the major difficulties in HACCP is the differentiation or understanding of what is at a certain production step a GMP and what is a CCP. Sometimes, operators have reported that a step, which is considered as a GMP, cannot be a CCP.

   To explain this, we need to go back to the time before HACCP. Food safety in the food processing and manufacturing industry was ensured through a number of measures referred to as good manufacturing practices (GMP). Some processing operations, today referred to as control measures, such as heat treatment (e.g. pasteurization), were then considered a good manufacturing practice. Thus, what in the past was referred to as *GMP* in HACCP terminology may today be referred to as *control measures*.

   In the context of HACCP, some of these control measures (or GMP), which play a significant role in controlling a specific hazard, received higher weight and the step at which the control measure is applied is thus now considered a CCP (Figure 32.3). In other words, a hazard analysis can actually permit to identify which good manufacturing practices are of direct relevance to food safety and if there is any additional measure which should be considered as part of GMP or with today's terminology prerequisites

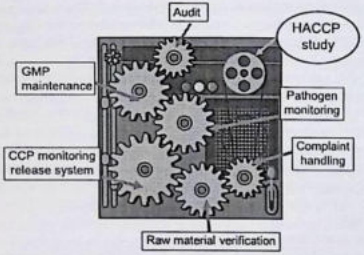

FIGURE 32.3 Schematic illustration to explain that different measures implemented as part of food safety assurance system are interrelated and need to be considered as part of the HACCP study.

programs. Therefore the question of CCP or GMP is a wrong question as both are interrelated. With the HACCP system we can strengthen the GMP to cover food safety concerns and also identify those GMP practices that are of importance for a close surveillance. This thinking process has been the basis for developing HACCP-based codes of practices for the small and developing businesses.

Part of this confusion comes from mistaking the term CCP for control measures (see below).

9. **Meaning of terms: significant hazards, CCPs and monitoring.** Lack of understanding or inconsistent use of terms often leads to confusion. Frequently, the term significant hazard is confused with CCP (e.g. aflatoxin is referred to as a CCP) or a control measure is taken for a CCP. This confusion also contributes to misconceptions mentioned above in relation to GMP versus control measure or CCP.

   To be crystal clear: a CCP is a step in the food operation whereas a control measure is an intervention specifically designed to prevent, reduce or eliminate the hazard. To differentiate these two concepts, a CCP is usually a step in the flow diagram of the food production, while for the control measure this is not always the case. For instance, CIP of an installation is a *control measure* to eliminate the risk of contamination of food, but does not enter in the process of food production itself and is thus not a step or CCP. This does not preclude the fact that the processing step at which the CIP is applied can be a control measure and that the CIP is mentioned as a comment on the flow diagram.

   It has also been experienced that some important steps in the operation have not been considered as CCPs on the grounds that they cannot be monitored "continuously" or a physical measurement method is not available. It is certainly much better to measure control parameters in an objective manner, e.g. using a temperature recorder. However, a lack of such methods for monitoring should not be a reason for not considering a step in the process as CCP. If control at that step is important and that visual/off-line control can be effective in detecting deviations from acceptability, then the step can be considered as

CCP. The concept of continuity is also misunderstood. The recording of a parameter leading to a line between two measurements is often mistaken for the concept of continuity. Monitoring a CCP should be carried out with specific and predetermined frequency. This may be every second, hour, day or defined moments as applicable. However, this has to be set such that if a deviation is observed and critical limits are violated, the corrective actions can be implemented in a timely manner before the product is released.

10. **Significance of CCPs.** As stated above, CCPs are steps in the food production that *must* be under control to produce a safe product. For each CCP critical limits are established to define the parameters that must be achieved to ensure safety. As such these limits define the acceptability or unacceptability of a product or a process. For food safety, CCPs and their associated critical limits are the most important steps and aspects of the operation. *Where a critical control point is violated, the product must be considered as potentially unsafe.*

    Therefore it is extremely important that:

    a. These steps are identified and controlled correctly, i.e. all parameters need to be controlled and identified and that the critical limits are validated, including consideration of any regulatory requirement.
    b. Monitoring of CCPs provides assurance that the control measures(s) are correctly implemented and are within the defined critical limits. Therefore:
        - The monitoring of CCPs must be carried out under the responsibility of trusted and well-trained operators.
        - Responsibility and the consequences of failures of CCPs must be clearly communicated to operators, including the corrective actions that must be taken in the event of a CCP failure.
        - Methods and procedures used for monitoring, be it a physical measurement, visual inspection or chemical analysis, must be up to date, and valid for the intended use (including sampling and sensitivity of method).
        - Microbial testing is verification and is generally not suitable for CCP testing. An exception is for the release of certain high-risk raw materials;
        - Equipment and materials used for monitoring must function correctly, be well maintained and calibrated. The frequency of monitoring must be set so as to ensure that if there is a deviation, corrective action is applied in time to correct the problem during production and/or to assure that unsafe product does not leave the factory.
        - Results of CCP monitoring are part of release criteria.

11. **Monitoring of CCPs.** When establishing a monitoring procedure for a CCP, care should be taken to identify all the parameters that will impact the efficiency of the control measure. For instance, it is frequently observed that at the pasteurization step, which is often a CCP, only the temperature is monitored and the residence time is ignored. Or for water disinfection, only residual chlorine is considered and other factors such as contact time, pH of water and turbidity, which impact on the chlorination efficiency, are not considered.

12. **Corrective actions.** While it is a good practice that in times of problems the operator consults his superior, it is nevertheless essential that corrective actions needed to restore control be clearly and precisely defined in the HACCP study. For instance, it should

be stated "reheating the product" or "sieving the product" rather than "call the QA or production manager."

Also, the procedures for blocking and eventually reworking or disposing of products that have not met safety or quality criteria should be carefully examined to prevent or minimize the possibility of any human error or accidental release. The efficacy of the corrective actions applied must be validated.

13. **Effectiveness of HACCP cannot be ensured without validation and verification.** One of the greatest weaknesses in the application of HACCP has been that very little attention has been given to validation and verification activities.

a. **Validation.** A HACCP study whose elements are not valid will have limited benefits. Validation brings assurance in the design of the food safety assurance system. In absence of validation, there is no assurance that control measures will be effective in ensuring food safety and the HACCP studies may indeed become a paper exercise.

Validation consists of proving evidence and documenting that the elements of the HACCP are effective and/or have a scientific and technical basis. It should include:

- Identification and evaluation of hazards
- Effectiveness of control measures (including corrective actions)
- Correctness of CCPs
- Critical limits
- CCP monitoring
- Corrective action
- Suitability of verification activities

Validation does not necessarily require an experimental approach or complicated tests (such as challenge tests) but may simply consist of confirming consistency with regulatory requirements, examining scientific literature, consulting experts, providing historical data and so on to substantiate the elements of the HACCP plan.

b. **Verification.** An equally important principle of HACCP that is sometimes overlooked or carried out independently from HACCP is verification. Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring at CCPs to determine compliance with the HACCP plan. Verification provides confirmation that HACCP is implemented according to the plan, and is effective. Verification includes activities such as:

- Environmental monitoring
- Pathogen monitoring
- End-product testing
- Raw material testing for chemical contaminants
- Audit of the factory and its food safety management systems
- Calibration of equipment
- Consumer complaints monitoring

These activities, even if not part of the release procedures are essential to ensure that preventive measures are implemented correctly.

Therefore, data collected through verification activities should be carefully examined and analyzed in terms of compliance and trends. Where a deviation from acceptable conditions is observed or the trend indicates an abnormal situation, implications for product safety should be evaluated, an investigation should be carried out

as to the root cause of the problem, and the situation should be corrected. The cause may be failure in implementation or shortcomings in validation.

14. **Maintenance.** Maintenance of a HACCP is a means for addressing management of change. The environment and conditions under which food is produced is constantly changing. Examples of changes are:
    a. Emergence of new hazards and/or new information about existing hazards, e.g. knowledge about outbreaks in a sector of the food chain.
    b. Changes in the regulatory requirements.
    c. Changes in the intended use of the product and/or consumer/customer.
    d. Change and differences in the climatic conditions (where the raw material is produced and where the final product is transported and consumed).
    e. Change in the country where the product is to be exported to leading to a number of other changes as mentioned above.
    f. Changes in the source of the raw material.
    g. Changes in practices at the supplier.
    h. Changes in recipe, process or equipment.
    i. Changes in the factory environment, e.g. reconstructions, change of personnel.

    To ensure that the hazard analysis and control measures remain valid, it is important that each time a change is reported, the HACCP study is reviewed and the validation of control measures, critical limits, monitoring procedures, corrective action and verification procedures are reconfirmed. This means that each change should prompt a reflection on possible consequences for food safety and the need for amending existing control measures or setting up new measures.

    Review of the HACCP study does not necessarily mean an immediate and full revision of the HACCP study and associated plan. In many cases, it can be simply a note to document that:

    a. The change in question has been considered and control measures have been modified as follows, or
    b. It has been concluded that the change did not impact on food safety on the following grounds.

    The various notes can be consolidated during the annual review of the HACCP study.

15. **Different (Modular) HACCP plans.** Often, due to the complexity of the production, it is easier to develop different HACCP plans for different parts of the production. This is usually known as Modular HACCP plans as the process is split into "process modules" and HACCP principles are applied to each one. It is important to ensure that a proper link between the different HACCP plans exists and that errors do not occur as a result of this practice, e.g. skipping a step, omitting certain hazards.

CONCLUSIONS

The advance of HACCP has had a significant and positive impact on the management of food safety. However, to fully benefit from the advantages of HACCP, a proper understanding, application and true commitment is needed.

Some of the major shortcomings in the design and implementation of the HACCP plans have been:

- Lack of experience and expertise in the design of the HACCP plan.
- Ignoring previous records of safety of the product, e.g. incidents associated with the products.
- Failing to consider the regulatory or customer requirements.
- Overlooking implications of practices upstream, i.e. at the suppliers, or downstream (transport, distribution, handling and preparation).
- Gaps in the validation of the hazard identification and control measures and taking into consideration the state of prerequisites programs.
- Shortcomings in the review of the verification data (e.g. pathogen and environmental monitoring of food production premises) or end-product testing.
- Shortcomings in the maintenance of the HACCP plan in the light of verification data or changes.

It must be reiterated that HACCP is not a panacea to all problems and it is not a magic wand. It is a tool, among many others, to manage and enhance food safety. Its effectiveness in eliminating or reducing hazards to an acceptable level depends on how it is used.

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CHAPTER

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Management of Microbiological Hazards: Role of Testing as Verification

Tim Jackson
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INTRODUCTION

Microbiological testing programs play an important role in the verification of the effectiveness of control measures for many food products. Such programs may include monitoring[1] of the production environment and processing equipment, and testing of raw materials,[2] in-process and finished products. The relevance and application of testing programs depend upon the design of the product and process, the hygienic status of the processing environment and the availability of other verification information about a product lot. Microorganisms are often distributed unevenly in foodstuffs and the practicality and economics of sampling make product testing ineffective as control measures. Likewise, environmental monitoring provides a snapshot of the hygienic status of the environment or processing equipment at the time and locations that samples were taken. Product and environmental testing are lagging indicators of hygienic failures as they do not directly control the root conditions that lead to contamination. As such, they are most effective when used within a system of risk-based preventive controls, such as HACCP, hygienic zoning and other prerequisite programs, and when they work together with other verification activities to assess the condition of the food safety system.

Microbiological testing may also be used to support the design and validation of control measures in a food safety management system. Testing may be used to determine initial microbial levels on raw materials or in-process product prior to the application of a microbiocidal process in order to establish the level of reduction required. Testing may also be conducted to determine the surviving levels of target microorganisms in a foodstuff after a microbiocidal process is applied in order to confirm that the desired reductions are achieved. It is often difficult to obtain quantitative information on the levels of pathogens present in a foodstuff prior to processing as levels of these organisms are often low and unevenly distributed, and information in verification testing programs and other surveys are based on analysis of presence or absence of the target organism, providing little information

[1]The term "monitoring" is used in this chapter to indicate the use of testing of products or the environment in verification programs. This is different from the use of the term "monitoring" in HACCP studies, which is the taking of measurements during processing to ensure that a critical control point is within established critical limits (Chapter 31).

[2]The term "raw materials" in this chapter refers to raw agricultural products, processed ingredients and food contact packaging materials used in the manufacture of food products.

on population levels (ILSI Europe, 2010; Jongenberger et al., 2012a,b). Where quantitative data are available for indicator organisms, it may be possible to extrapolate these data to estimate worst-case initial loads of the target pathogen. Most often validation studies are conducted using samples artificially inoculated with levels of target organisms sufficient to determine the reduction achievable by the process. Strains used in such studies are representative of those of concern in the foodstuff and are pre-conditioned to most closely approximate their physiological state prior to processing. Regulatory and industry reviews provide additional guidance on the use and application of microbiological testing in validation (ICMSF, 2011; NACMCF, 2006, 2010; Codex Alimentarius Commission, 2008b; Swanson et al., 2000; Zwietering et al., 2010).

The remainder of this chapter will focus on the use of microbiological testing as verification in food safety management systems. The role of environmental, raw material and finished product monitoring programs will be discussed as well as approaches to their development and implementation.

WHEN ARE MICROBIOLOGICAL TESTING PROGRAMS USEFUL FOR VERIFICATION?

Due to their cost and complexity, microbiological testing programs are only applied when they can provide relevant information about a product and process. Understanding the appropriate application of microbiological testing requires an understanding of the significance of microbial levels at various points in the process. The contribution of product, process and environmental factors to the ability to achieve the required microbiological limits in manufactured products is described in a conceptual equation developed by the International Commission on Microbiological Specifications for Foods (ICMSF). This equation illustrates the impact of various factors on the ability to manufacture product that does not exceed a food safety objective (FSO) or performance objective (PO; Codex Alimentarius Commission, 2007b, 2008b; ICMSF, 2002; Stringer, 2004; Van Schothorst, 2009; Motarjemi and Moy, in press):

$$H_0 - \Sigma R + \Sigma I_{(G+RC)} \leq \mathrm{PO/FSO}$$

An FSO is the maximum frequency and/or concentration of a microbiological hazard in the foodstuff at the time of consumption necessary to achieve a public health objective such as an appropriate level of protection (ALOP). This is established by regulatory authorities as part of their risk management activities. Regulators may also define a PO, i.e. the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption, in order to meet an FSO (Figure 33.1). Likewise a performance criterion (PC) may be established to communicate the required outcome for a control measure or series of control measures, such as microbiocidal or microbiostatic controls (Codex Alimentarius Commission, 2007b, 2008b; ICMSF, 2002, 2011).

A PO or PC may also be developed by the manufacturer based upon an established FSO, where one exists, or based upon the levels of relevant microbiological hazards necessary for

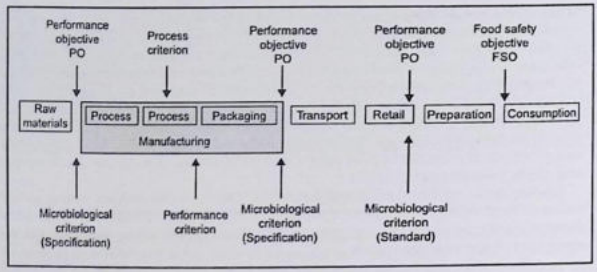

FIGURE 33.1 The role of food safety objectives, performance objectives and microbiological criteria in food safety management *(adapted from Gorris, 2005; Codex Alimentarius Commission, 2007b).*

product safety as determined in the HACCP study. The ability to produce a product that is equal to or below the PO is based upon the initial microbial levels in raw materials (H_0), the presence of conditions that could increase microbial levels during storage and processing (ΣI_G), the presence of conditions that could lead to the recontamination of the product or raw materials from equipment or the factory environment (ΣI_{RC}) and the microbial reduction achieved as a result of process controls (ΣR). Such an understanding of the contribution and interrelatedness of factors affecting microbiological quality and safety can assist those developing a product or process to determine the appropriate combination of control measures to ensure product safety. It can also be used to determine the application and nature of the corresponding monitoring programs necessary to verify the effectiveness of these controls.

Examples of the application of microbiological monitoring programs for the verification of various products are provided in Table 33.1. Testing may be useful to verify the hygienic status of raw materials that are not subject to a lethal process, either in a dry mix or assembly operation, or where they are added after the application of a lethal process. Testing may also be useful for raw materials that are exposed to conditions that would allow the outgrowth of microorganisms to levels greater than that which the applied processes are capable of inactivating. Testing is generally unnecessary for raw materials that will be subjected to a process that will inactivate the levels of pathogens or spoilage organisms present in the raw materials.

Environmental monitoring may be necessary to verify the application of environmental controls where raw materials, in-process or finished products are exposed to the production environment without a subsequent microbiocidal step. Such monitoring may not be relevant for products that are enclosed during processing and packaging unless the hygienic condition of the environment where the finished product is handled may have an impact on the ingress of microorganisms (for example, contact with cooling water or poor hygienic handling of retorted products prior to cooling).

TABLE 33.1 Examples of Testing Applied to Products and Process Controls

Product Type	Monitoring Program Applied	Parameters Evaluated	Location and Frequency
Dry mix product or other product assembled without further microbiocidal process	Raw material	Relevant pathogen and hygienic indicator organisms	Depends upon raw material risk; for example, testing of each lot of high risk material by supplier and/or receiving factory
	Environment	Relevant pathogen and hygienic indicator organisms	Areas where raw materials are handled and product is exposed prior to packaging. Weekly sampling which may involve rotation of sites
	Finished product	Relevant pathogen and hygienic indicator organisms	For new processing lines or where there is evidence of a hygienic concern for the product and process. Periodic testing according to risk
Products receiving a microbiocidal process and exposed to the environment after processing and prior to packaging	Raw material	Relevant pathogen and hygienic indicator organisms	For raw materials added after the thermal process. Depends upon raw material risk; for example, testing of each lot of high risk material by supplier and/or receiving factory
	Environment	Relevant pathogen and hygienic indicator organisms	Equipment and environment where products are exposed post-processing; interface between raw and cooked material handling areas
	Finished products	Relevant pathogen and hygienic indicator organisms	For new processing lines or where there is evidence of a hygienic concern for the product and process. Periodic testing according to risk
Products that are in-pack pasteurized	Finished product	Total plate count and total coliform or total Enterobacteriaceae	Each lot to establish history of performance; ongoing frequency based upon risk
Hot-filled products	Finished product	Total plate count and/or mold and yeast (for high-acid products)	Each lot to establish history of performance; ongoing frequency based upon risk
Product processed for commercial sterility and aseptically packaged	Finished product	Incubation testing	Representative samples from each production line, includes samples from each filler head and samples from events that could affect hygiene (start-up, stoppage, maintenance)
Low-acid products commercially sterilized in hermetically sealed containers	Finished product	Incubation testing	A small number of representative samples from each lot, includes events (start-up, stoppage, maintenance)

(Adapted from GMA, 2012b)

A finished product testing program may have a role in verifying the overall functioning of preventive control measures for products that rely on various supplier, production and environmental controls, such as products blended or assembled without a subsequent lethality control measure, or products exposed to the environment following the application of a microbiocidal process. A finished product testing program is less relevant for products that receive a process in the final package, but may play a role in verifying the application of a thermal process, evaluating the functioning of a production line over time or investigating potential process failures.

Details on the application of raw material, environmental and finished product monitoring programs are discussed in subsequent sections of this chapter.

PREREQUISITES TO THE DEVELOPMENT AND IMPLEMENTATION OF MICROBIOLOGICAL TESTING PROGRAMS

Effective product testing and environmental monitoring programs are developed and implemented only after the implementation of programs that identify and establish appropriate preventive controls:

- Hazard analysis and critical control point system;
- Hygienic design of equipment and processing environment;
- Hygienic zoning controls to prevent entry, harborage and growth of pathogens;
- A well-designed raw material selection and verification program;
- Personnel training to ensure that control measures are applied correctly.

Microbiological testing is of limited value in the absence of such preventive controls; however, microbiological testing and monitoring programs can be effective tools for verification when they are based upon a thorough understanding of the product and process as determined in these programs.

Requirements of Regulatory Agencies and Customers

Finished product requirements may be defined in customer specifications or in regulatory requirements. Regulatory requirements may be expressed as FSOs at the point of consumption or as POs for the finished product after production or for product on the market (see Chapter 31). Often, requirements are expressed indirectly as within-lot microbiological criteria for lot acceptance, increasingly following the format developed by ICMSF and adopted by the Codex Alimentarius Commission (Figure 33.1). For some products, between-lot criteria are established as an ongoing assessment of process control (ICMSF, 2002; Codex Alimentarius Commission, 1997). Some regulatory bodies have systematically established microbiological criteria for relevant categories of ready-to-eat products (e.g. Canada, European Union, Hong Kong). Other regulatory bodies have developed criteria for finished products or raw materials as needed based upon an identified risk or in response to the occurrence of public health incidents or a specific public health concern (NRC, 2003). Where such criteria exist they can be used to determine the appropriate design of products

and process controls necessary to meet these criteria, and the testing programs necessary to ensure that the criteria are consistently met. Microbiological criteria should not be mistaken with FSO or PO. The former define the acceptability or unacceptability of products (in or out), the latter is used for designing the control measures, defining the expected/desired performance in verification programs and establishing expectations in contractual agreements.

In many cases there are no criteria specified for a product in regulation or in customer requirements; instead there is a general requirement for the producer to manufacture safe products. It is therefore the producer's responsibility to determine the necessary PO, PC, microbiological criteria and supporting verification programs for raw materials, processing environments and finished products. For some products, industry guidance has been developed to support manufacturers in the development of appropriate product and process criteria (Chen et al., 2009a, b; GMA, 2010; MAF/NZ, 2011; NFI/NFPA, 2002; Scott et al., 2009).

Hazard Analysis and Critical Control Point Study

Microorganisms of concern for the product and process are identified in the hazard analysis conducted as part of the HACCP study. The study will identify at what point in the process microorganisms will be introduced or multiply and will identify the type and location of control measures necessary to ensure the hazards are controlled. This will be based upon an understanding of the microbiology of raw materials, the effect of processes applied during manufacture, the exposure of the product or raw material during processing and after the application of a microbiocidal process, the behavior of the pathogen in the product (survival, growth, inactivation) and the impact of consumer preparation and reasonably expected misuse. The HACCP study will also identify the procedures, including microbiological monitoring, that are necessary to verify the ongoing functioning of the preventive controls for the identified hazards.

The HACCP study is focused on microorganisms of food safety concern; however, information from the study can also be used to evaluate the impact of product attributes, handling and distribution conditions on product spoilage and thus the relevance of nonpathogenic spoilage organisms in testing programs.

Zoning of the Factory Environment and Hygienic Design of Equipment

Hygienic zoning is the separation of factory areas based upon the risk of product contamination and the corresponding hygienic and preventive controls necessary to ensure that cross-contamination of products and raw materials does not occur (Duffy et al., 2003; Holah, 2005; Scott et al., 2009). Such controls may include physical barriers, cleaning practices, restrictions on the control of the movement of people, materials and equipment, management of tools, air flow and personnel practices required for each area and for movement between areas. Control measures include those specific to the area as well as those necessary at the entry to or transition between zones, for example between areas that must be dry cleaned and areas that are wet cleaned, or between areas where unprocessed, highly

contaminated materials are handled and where products are handled that have received a microbiocidal process, or where raw materials are handled that will be used in a process without application of a microbiocidal process.

Zoning studies consider product design, process flow, equipment design, exposure of raw materials and product before and after microbiocidal processes, movement of people, materials, equipment and waste, air and utilities flow, prior history of the product type and processing facility. The studies identify sensitive areas of the process (e.g. areas where product is exposed to the environment), high risk areas and activities (handling of highly contaminated material such as raw meat, maintenance activities, management of waste) and factors that could lead to cross-contamination into sensitive areas. Good hygienic practices, structural and logistical control measures are identified including cleaning and sanitation practices necessary to ensure protection of the product from contamination. Areas of the factory are classified according to the required hygienic controls (Table 33.2).

The most stringent controls may be needed at the interface between high risk activities and areas of the factory where ingress of pathogens into processing areas can occur (through personnel or other activities), for example:

- To protect areas that must be kept dry to prevent harborage with *Salmonella* from other areas of the factory that must be wet cleaned;
- To ensure that pathogens present in materials where their presence is likely do not enter into production areas where product is exposed following a microbiocidal process;
- To ensure control of the environment where product is exposed that is intended for sensitive populations;
- To ensure the application of hygienic controls is sufficient to prevent the contamination of perishable chilled products with *Listeria monocytogenes* that may grow during storage of the product.

Sampling sites at such interfaces will be included in environmental monitoring programs to evaluate the effectiveness of control measures.

Specific examples of zoning controls are available in regulatory and industry guidance on the control of food borne pathogens (Chen et al., 2009a, Codex Alimentarius Commission, 2007a, 2008a; US FDA, 2008; USDA FSIS, 2012; GMA, 2010, 2012a; NFI/NFPA, 2002; Tompkin et al., 1999). The outcome of zoning studies is often included in zoning maps, which identify the hygienic classification of areas, and includes the movement of people, materials, equipment, waste and air. Such maps are valuable in identifying relevant sites to be included in environmental monitoring programs.

A study of the hygienic design of equipment and manufacturing environment will help to identify where potential harborage points exist in the process. These include points where food or water can collect and/or which are difficult to clean. In many cases the identification of such areas of concern in hygienic design and zoning studies, such as harborage points or hollow bodies in equipment or production areas or traffic patterns, will result in corrective actions to address the concern. Until these areas can be addressed they will be under increased scrutiny in environmental monitoring programs.

TABLE 33.2 Hygienic Zoning Classifications and Sample Prioritization

Hygiene Zone Classification	Definitions	Example	Environmental Monitoring Sites[a]
High hygiene (high care)	Area of factory where products, raw materials or equipment highly sensitive to contamination are handled, processed or stored	Infant formula dry mixing, packaging. Milk powder spray-drying. Post-oven handling/ packaging of chilled RTE foods supporting the growth of *Listeria monocytogenes*. Clean equipment and tools storage for high hygiene activities	Product contact surface/line/Z1 Z2/P1 Z3/P2
Medium hygiene (medium care)	Area where products, raw materials and equipment are exposed or stored and where they are sensitive to contamination: intended for the consumer without elevated sensitivity; where growth of microbial pathogens is not possible in the supply chain	Assembly, handling of frozen processed products. Blending, molding of confectionery products prior to packaging. Dry blending area for soup mixes. Clean equipment and tools storage for medium hygiene activities. Storage of rework, in-process products	Product contact surface/line/Z1 Z2/P1 Z3/P2 Z4/P3
Basic/low hygiene (low care)	Areas where activities will not result in the contamination of products (for example, storage of raw materials and finished products in enclosed packaging), or products or materials are handled prior to a microbiocidal process. If movement of people, material, air and water are not controlled, area could become a source of cross-contamination of sensitive processing areas	Storage of finished products. Storage area for raw material and packaging. Storage of processing equipment prior to cleaning (other than those used in high risk activities). Storage of cleaning chemicals. Storage of in-process materials or ingredients in sealed containers	Z3/P2 Z4/P3
High risk	Areas where materials are handled with a high probability of contamination with microbial pathogens	Handling and processing of raw meat and poultry, unprocessed vegetables, raw milk, raw cocoa beans and nuts, raw cereals	Z4/P3 (at interface between zones, transport equipment, etc.)
Not zoned	Areas isolated from production activities	Offices, lunch room, entry lobby, change rooms	Investigation

[a]*See sample site definitions*, Table 33.4.

MICROBIOLOGICAL MONITORING OF THE FACTORY ENVIRONMENT

Environmental monitoring programs are used as a verification of the effectiveness of control measures to prevent the ingress, harborage and multiplication of microbial pathogens in the production environment, specifically:

- Effectiveness of cleaning and sanitation procedures;
- Effectiveness of environmental controls:
  - Controls associated with hygienic zoning
  - Movement of people, equipment and materials
  - Construction and maintenance activities
- Identification of areas of ingress or harborage so that they can be eliminated;
- Investigation of the impact of adverse findings.

The application and design of environmental monitoring programs will depend upon the risks associated with the product and process. For example, an evaluation may not be needed of the processing areas for products that are processed in enclosed systems and filled aseptically or hot-filled. Likewise, products that are processed in their final package and are not exposed to the environment after processing may not require stringent sampling programs unless there is a risk of recontamination (for example, through micro-leaks in the seams of cans during cooling following a thermal process).

While an environmental monitoring program can be a valuable verification tool, it only provides a picture of the sites analyzed during the day samples are taken. However, when evaluated along with other samples taken from a production line or process environment over time, it can provide useful information regarding ongoing status or trends in hygienic control.

Selection of Pathogens and Indicator Organisms

The pathogens that are the focus of the environmental monitoring programs will be determined by the hazard analysis in the HACCP and zoning studies. Generally, *Salmonella* and *Listeria monocytogenes* are the pathogens of environmental concern, although other pathogens may be included based upon product and risk (for example, *Cronobacter* spp. in infant formula; *Staphylococcus aureus* or *Bacillus cereus* as investigative sampling in areas where outgrowth of the organism during processing is a concern). Environmental monitoring programs include the pathogen of concern; however, the infrequent or sporadic distribution of these organisms often makes them difficult to detect, even when they are present in the factory environment. A program focused solely on the isolation of the target pathogen will only identify a problem when it occurs and may not identify early enough that conditions are or have been present that would also allow the ingress or growth of the pathogen of concern. Because of this, effective environmental monitoring programs include hygienic indicators, selected according to their ability to demonstrate the presence of conditions that would lead to the presence or growth of the pathogen of concern.

Processing Environments where Wet Cleaning is Conducted

Listeria monocytogenes is the primary environmental pathogen of concern in processing environments where wet cleaning is used. The most effective indicator organisms for the presence of *L. monocytogenes* in the environment are other members of the *Listeria* genus (USDA FSIS, 2012; US FDA, 2008, 2013). Because they are very closely related to *L. monocytogenes*, the detection of non-*monocytogenes* members of the *Listeria* genus (*Listeria* spp.) indicates that conditions exist that could also lead to the presence of *L. monocytogenes*. Detection of these indicators will initiate a root cause analysis and increased investigative testing of equipment or the environment from which the isolation occurred to ensure that the root cause is investigated. Recovery of *Listeria* spp. or *L. monocytogenes* from product contact surfaces or nearby areas on equipment or the environment may also initiate or intensify finished product testing to verify that the product is not affected.

Quantitative indicators, such as Enterobacteriaceae, coliforms or total plate counts, may be useful for monitoring the effectiveness of cleaning and sanitation procedures or to assess whether conditions exist that allow multiplication of microorganisms on or around processing equipment. Because they are heat sensitive, Enterobacteriaceae and coliforms are useful for the evaluation of the hygienic status of the processing line after a thermal process.

Total plate counts (TPC) may be used to monitor that conditions are present during processing that could lead to the outgrowth of *S. aureus* or *B. cereus*. High TPC results are followed by investigative sampling of potential harborage sites in or on processing equipment or holding containers (e.g. tanks, totes, mixers), where product and moisture may be present that could lead to the growth of these organisms. Such testing is usually conducted as an investigation of out-of-specification results from finished products. Because TPC is a quantitative hygiene indicator, expected baseline levels are established through an analysis taken of clean surfaces when it is known that cleaning and sanitation were effective. Due to the broad variety of microorganisms that will be recovered for TPC analysis, it is most effectively used for the evaluation of product contact surfaces or nearby surfaces and is less useful for areas of the environment away from the processing line.

The inclusion of mold and yeast may be useful in monitoring programs for the exposed-product environment of products for which yeast and mold spoilage are a concern (such as chilled dairy products, intermediate moisture pasta, etc.).

ATP bioluminescence involves the detection of adenosine tri-phosphate (ATP) present in food material through the generation of a luminescent signal expressed in relative light units (RLU). The intensity of the signal is proportional to the level of ATP present and is an indirect indicator of the amount of biomass present. ATP bioluminescence may be used to verify the effectiveness of cleaning by measuring the presence of signals originating from residues present on product contact surfaces after cleaning (Moore et al., 2001; Powell and Atwell, 1997; Whitehead and Smith, 2008). To properly evaluate signals detected by bioluminescence equipment a baseline signal is established through the analysis of clean surfaces. An elevated signal will indicate that product residues are present, indicating that cleaning was inadequate and the surface needs to be recleaned.

Processing Environments that are Dry Cleaned or Controlled-wet Cleaned

Salmonella is the primary pathogen of concern in factory environments where dry materials are handled or low moisture products are manufactured and where dry cleaning, or in specific cases controlled-wet cleaning, is applied to ensure the absence of moisture from the environment during processing (Duffy et al., 2003). *Salmonella* can enter the environment through the movement of people, equipment and materials or through the failure of zoning controls between high risk and sensitive areas (for example, between areas where raw cocoa beans are stored and handled and roasted cocoa beans and cocoa products are exposed to the environment). When moisture is present, *Salmonella* can multiply; however, even where moisture is absent, the organism can persist for long periods up to years and multiply when moisture re-enters the environment (Scott et al., 2009). Resident strains may remain dormant only to reappear after some time due to a change in activity, such as a construction or maintenance event, or hygienic failure allowing the ingress of water.

Unlike the *Listeria* genus, there is currently no microorganism identified whose presence will closely correlate with the presence of *Salmonella*. *E. coli* has been used as an indicator of fecal contamination in water and as an indicator of post-process contamination in dairy products. While the monitoring of *E. coli* in the environment may be part of a monitoring program where fecal cross-contamination or growth is suspected, *E. coli* can persist in the environment and its presence in dry environments may not correlate directly with the presence of *Salmonella* (Cox et al., 1988; Kornacki and Johnson, 2001).

Salmonella is a member of the Enterobacteriaceae family and the quantitative analyses of the environment for members of this family are frequently included in pathogen monitoring programs for dry environments. Unlike *Salmonella*, which may only enter the environment rarely through a hygiene failure, many members of the Enterobacteriaceae family are likely to be present at some level even in clean environments. An evaluation of the level of Enterobacteriaceae present at a sampling site can provide information on whether conditions are or have been present that could lead to the multiplication of *Salmonella*. As *Salmonella* may or may not be present in the environment, there is not a direct correlation between the presence or population of Enterobacteriaceae and the presence of *Salmonella*; however, the use of quantitative determinations of Enterobacteriaceae in environmental monitoring programs will allow conditions that may lead to the multiplication of *Salmonella* to be identified and corrected. Enterobacteriaceae should only be included on product contact surfaces or near product contact surfaces due to the variability of levels in non-process areas of the factory without strict hygiene controls. (Figure 33.2)

For products intended for infants, *Cronobacter* spp. is a significant concern and is included in environmental monitoring programs for infant formula manufacture where ingredients, in-process or finished product are exposed. As with *Salmonella*, *Cronobacter* spp. is a member of the Enterobacteriaceae family and control measures taken to prevent *Salmonella* entry and harborage in the environment will also be effective for this organism. *Cronobacter* spp. has greater prevalence in the environment than *Salmonella*, increasing the importance of proper management of control measures and the corresponding stringency of monitoring programs. As with *Salmonella*, inclusion of quantitative Enterobacteriaceae as a hygiene indicator can help to identify the presence of conditions that could lead to *Cronobacter* spp. harborage and growth (Codex Alimentarius Commission, 2008a).

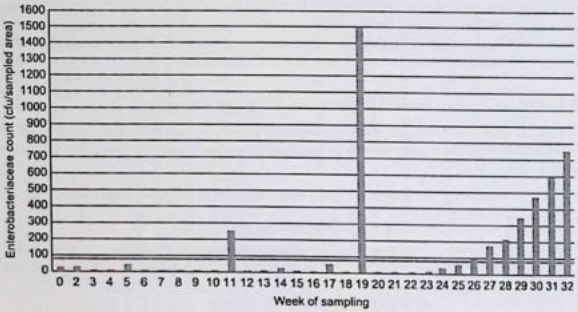

FIGURE 33.2 Enterobacteriaceae count at sample site A64 (near-product contact).

TABLE 33.3 Examples of Reaction Limits and Interpretation of Quantitative Enterobacteriaceae in Product Residue Taken from Equipment Surfaces and Process Environment in a Powdered Milk Factory

Enterobacteriaceae Level	Interpretation	Action
<100 cfu/g*	Acceptable (expected under good hygienic practices)	None necessary
100 to 1000 cfu/g	Marginally acceptable. Conditions may have existed to allow the increase of Enterobacteriaceae (such as ineffective dry cleaning, leakage of water into the environment, maintenance event)	Investigation conducted, potential root causes corrected
>1000 cfu/g	Unacceptable. Likely presence of water or other event has led to high levels of Enterobacteriaceae	Investigation conducted, potential root causes corrected. Increase sampling of finished product and environment for Enterobacteriaceae and pathogen

*For some infant formula and milk powder factories levels <10 colony forming units (cfu)/g may be possible on product contact and near product contact sites; correspondingly reaction thresholds may need to be adjusted.

Enterobacteriaceae is a quantitative indicator, and baseline levels and reaction limits need to be determined to facilitate the interpretation of results and corresponding corrective actions. Levels should be established with an understanding of the product and process and what is achievable under good manufacturing practices. An example of such limits for a milk powder factory is provided in Table 33.3.

ATP bioluminescence may be applied to verify the effectiveness of a periodic wet-cleaning process, but is typically not useful for environmental monitoring programs in factories manufacturing low moisture products that are dry cleaned as the presence of product particulates on equipment surfaces will interfere with the ATP signal.

Selection of Environmental Monitoring Program Sites

Sample sites for environmental monitoring programs are selected based upon risk as identified in HACCP, zoning and hygienic design review, with the primary focus on the following areas:

- Areas of equipment that are difficult to clean and could be harborage sites;
- High-traffic areas;
- Interfaces where movement occurs between hygiene zones;
- Interfaces between areas were raw, highly contaminated materials are handled and where processed materials are handled after the application of a microbiocidal process (such as cooking);
- Interfaces between wet- and dry-clean areas;
- Areas from where pathogens could be transferred into sensitive areas with exposed product or raw materials through the movement of people, equipment and materials;
- Areas where pathogens could enter into the facility from outside the factory or from higher risk areas within the factory.

Sampling sites are classified according to the potential for product contamination if the pathogen was present at that site. Some companies have classified samples according to sampling "zones" while other companies have used other terminology for sample prioritization to avoid confusion with the classification of hygiene zones (Table 33.4). In fact, there may be a variety of sites of different risk classification within a given hygienic zone (Table 33.2). The location and number of sampling sites will vary based upon the nature of the product, the complexity of the process, the degree of product and raw material exposure, the GMP practices necessary for a particular production area, and the movement of people, equipment and materials.

Examples of potential sources and harborage sites for *Salmonella* and *L. monocytogenes* in food processing facilities are available in guidance documents (Chen et al., 2009b; US FDA 2006) and can be valuable resources in establishing sites of focus for hygiene audits and environmental monitoring programs.

The weight of sampling programs is placed on the most sensitive sampling locations. This is reflected in the number of samples selected and the sample frequency, with priority given to more sensitive areas. Product contact surfaces are analyzed according to risk of product exposure and sampling history. The number of sampling sites that are included in an environmental monitoring program is based upon the nature of the product and process and the design of the processing line and factory. The number of samples taken on a given sampling day will often be weighted based upon sensitivity (for example, a proportional split of P1/Z2 60%, P2/Z2 30%, P3/Z3 10%). Greater emphasis will also be placed on historically problematic areas, or those where an investigation has identified conditions that may lead to ingress or harborage.

TABLE 33.4 Prioritization of Sampling Sites

Sampling Area	Example Classification	Definition	Examples
Product contact	Zone 1 (Z1), production line	Surfaces with direct or indirect contact with product	Surface of product conveyor. Nozzles and pipes dispensing products. Areas of product build-up. Product discharge chutes. Interior of pipes carrying product. Inside of storage totes. Inside of filler hopper. Product scrapers/utensils. Cleaning tools in contact with product or product contact surfaces. Contents of vacuum cleaners used to clean product contact surfaces. Surfaces from which product or water build-up during production could fall onto product or product contact surfaces during processing
Near product contact	Zone 2 (Z2), Priority 1 (P1)	Environmental surfaces with close proximity to product contact surfaces where contamination could easily be transferred to product contact surface	External surfaces of processing equipment. Environment near the exposed product/processing line. Floor drains near processing lines. Catwalks. Outside of tunnels. Outside of totes and fillers. Weigh scales. Outside of equipment used for dry mixing or mixing of ingredients without subsequent microbiocidal process. Cleaning tools and vacuum cleaners in contact with Z2/P1 areas
Non-product contact close to production line	Zone 3 (Z3), Priority 2 (P2)	Surfaces of equipment or the production environment in processing areas away from the production line and exposed products. The presence of pathogens could easily contaminate near-product contact sites	Hand trucks/pallet jacks used in processing areas. Forklifts used in production areas. Floors and drains in processing areas away from production lines. Wash stations. Ingredient storage areas. Traffic pathways into production areas. Wall/floor junctures. High hygiene side of shoe change area into high hygiene zone (and shoes). Interface between wet- and dry- cleaned production areas. Interface between areas handling highly contaminated materials and processing areas post-lethality
Non-product contact away from production line	Zone 4 (Z4), Priority 3 (P3)	Areas of the factory away from production	Remote locations in medium hygiene areas. Warehouses. Interface between medium and basic hygiene zones. Bathrooms. Transfer corridors

TABLE 33.5 Example of Sample Frequency Based Upon Site Prioritization and Level of Hygiene Concern

Minimum Sampling Frequencies per Sampling Site or Area			
	Level of Hygiene Concern		
Site Prioritization	Normal/Routine	Elevated	High
Product contact	1x week or based upon risk[a]	2x week	Investigative
Near product contact	1x week	2x week	Investigative
Non-contact near production line	1x month	1x week	Investigative
Non-contact away from production	Periodic	As needed	As needed

[a]Proportion of samples analyzed for pathogens and hygienic indicators determined by risk and history.

An example of sample frequency is included in Table 33.5. The frequency of sampling will vary based upon risk; however, sampling in most cases is conducted weekly and increased as a result of a finding (event potentially affecting hygiene, hygiene inspection finding, finding of pathogen or adverse trend of hygiene indicator in the environment). In some cases sampling will be conducted less frequently, for example according to a production schedule where a product or processing line is only used infrequently. "Due diligence" programs that only involve infrequent sampling occasions (such as monthly, quarterly or bi-annually) are generally not useful as they provide little information of the hygienic status of a process and do not allow a rapid correction of hygienic failures and adjustment of sampling programs when adverse results are obtained.

As their selection is based upon a risk assessment, the majority of sample sites in an environmental monitoring program are predetermined. Sampling programs should include a proportion of investigative samples, taken based upon the results of hygiene audits or of observations taken at the time of sampling. Established sampling sites may be modified based upon monitoring program findings. Where a number of sampling areas are identified, sites may be rotated with a given number of sites sampled at each sampling occasion. For example, a factory may select samples randomly using a numbering system classified by sample priority. Some factories have assigned sampling sites to alternating sample schedules, for example 1 week sampling is conducted for 50% of sites according to Schedule A, the subsequent week for the other 50% of sites according to Schedule B. In most cases the same sites are evaluated for hygiene indicators and for pathogens.

Sites are ideally identified on detailed factory maps, which may include information on hygienic zoning of areas and movement of people, equipment and materials. This facilitates the interpretation of data and also allows communication of data to factory personnel, or to corporate microbiologists or sanitarians in a different location supporting the factory in troubleshooting problems.

The stringency of an environmental monitoring program should be adaptable, increasing upon adverse findings, events or insufficient information on hygienic conditions. The increased intensity is reflected in more frequent sampling, but also may be reflected in an increased number of sampling sites and investigative sampling focused around the area of the adverse finding.

An example of program adaptation is included in Table 33.5. In this example, sample frequencies are categorized by normal/routine, elevated and high concern. The elevation of sample frequency may be applied to a specific production line where it is isolated from other lines, or to a specific processing area that is the focus of the hygienic concern.

Elevated concern could result from:

- Elevated level or adverse trend in quantitative hygiene indicator;
- Maintenance event;
- Exposure of factory area to the adverse conditions potentially impacting hygiene (for example, roof leak, sprinkler operation, burst pipe);
- Breach of hygienic zoning controls;
- Finding of pathogen in the processing area away from processing line.

High concern could result from:

- Finding of pathogen or out-of-specification hygiene indicator (presence of *Listeria* spp., elevated Enterobacteriaceae) in product, on product contact surface or the environment near the processing line.

The increased program intensity continues for a time sufficient to verify that the hygienic status of the line has returned to normal. This could vary due to the nature of the problem leading to elevated concern and the sensitivity of the product. For example, increased sampling may only be needed for a short period following a maintenance event. Sampling at elevated or high concern may be continued for a longer period of time where evidence (hygiene audits, test results) indicate a persistent problem or where investigation of a positive pathogen finding has not determined a clear root cause. Likewise heightened sampling may be conducted for several weeks or months for a new factory or production line. A line sampled under a high concern level may be placed on a sampling program for elevated concern for a period of time before returning to routine sampling.

Collection of Environmental Samples

As important as the selection of sampling locations to the success of an environmental monitoring program is the effectiveness of sample collection procedures.

Samples collected immediately after cleaning and sanitation will verify the effectiveness of this operation and the suitability of the line for the start-up of production. Samples collected during production may indirectly verify cleaning effectiveness but will also verify the effectiveness of control measures aimed at preventing contamination of processing areas or production lines, harborage or growth. Samples collected at the end of production will verify control measures but may provide additional information on microbial growth during production and can provide information on the risks associated with production, build-up of material on the line and the intervals between cleaning and sanitation activities. Samples taken towards the end of a production run are recommended; however, some sampling programs include a combination of samples taken post-sanitation and samples taken during production.

The tools selected for sampling will depend upon the nature of the site to be sampled as well as the level of residue/debris present at the site. Sterile, pre-moistened swabs may be

most effective for the sampling of small cracks and crevices on equipment and the environment where moisture or product may collect, and for difficult-to-access areas. Sterile, pre-moistened sponges are more effective for sampling larger sampling areas on equipment and the environment. Sterile spatulas or scrapers may be used to sample product residue. Other tools, such as sterilized disposable dusting cloths or mop heads, may be useful tools for collecting samples from large areas in the environment during root cause investigations.

Pre-moistened swabs and sponges are available from several manufacturers, in some cases with novel features that facilitate sampling of difficult areas and aseptic transfer of sponge to neutralizing buffer or other appropriate transport medium. In cases where sponges are pre-moistened prior to use, it is important to squeeze the majority of moisture from the sponge prior to sampling. Where pre-moistened swabs or sponges are used in processing areas or processing equipment that must be dry during production, the sampled areas are dried after sampling by the technician taking the sample.

Sampling with swabs and sponges should use sufficient force to ensure that any contamination present in the sampled area is transferred to the sponge. In many cases, defined areas are sampled (e.g. 50 cm^2) which could be identified using a sterilized template, to facilitate comparison of quantitative results between sampling sites or trends in the same sampling site over time.

Agar contact plates are sometimes used to sample equipment surfaces. Sampling is conducted through direct contact with the surface being sampled. Plates are then covered and incubated until colonies develop which are then enumerated. The advantage of such methods for the analysis of quantitative indicators is that they require little or no advanced preparation and no additional preparation after sampling other than incubation. However, they are limited in their ability to transfer contamination present in cracks and crevices in equipment and may lose effectiveness on surfaces with a large build-up of soil.

Where present, the sampling of product residue or soil is preferable to the sampling of "clean surfaces" as such residue is more likely to be a source of harborage. Samples are taken with a sterilized brush, spoon, scraper or spatula, depending upon the material collected, and transferred to a whirl-pack bag. When sampling build-up of product on surfaces or the environment, care should be taken not to focus on the sampling of clean product, but instead to focus activities on areas where the build-up of product and/or moisture could lead to microbial harborage and growth.

Samples should be transported in a suitable buffer or other transport medium. In cases where the residuals of sanitation chemicals may be present, in particular when sampling following a cleaning/sanitation event, a neutralizing buffer should be used. If not analyzed immediately after collection, samples must be stored under refrigeration (0–4°C) until they are analyzed. (In some cases dry samples may be stored at room temperature if storage does not affect the survival or level of the target organism or group.) If analyzed off-site, samples must be shipped under refrigeration, with care taken to ensure that the refrigerant (such as an ice pack) does not freeze the sample. Samples need to be analyzed soon after they are taken, preferably within 36 hours (Andrews and Hammak, 2003; Evancho et al. 2002; Midura and Bryant, 2001).

In some cases, for example when sampling specific high priority sites, the same site is analyzed at each sampling event. However, many locations identified for sampling will be areas of the equipment or factory environment; for these areas specific sampling sites are varied at each sampling event during routine sampling.

When separate samples are collected from the same site, for example for *Salmonella* and total Enterobacteriaceae, care must be taken not to swab the same area for both samples at the same time; in these cases adjacent areas are sampled for the hygiene indicator or pathogen.

Investigative sampling will be conducted in the event of a pathogen finding or out-of-specification hygiene indicator, or will be conducted when issues are observed during sampling or during a hygiene audit that could impact safety. Following a pathogen finding, sampling typically involves re-examination of the location of the finding and the surrounding area and may also include strategic sampling of other areas of the factory to investigate the extent of contamination, the movement of the contaminant through the environment and/or the origin or harborage point of the contaminant. When investigating potential harborage sites in processing equipment, it may be necessary to shut down and open the processing line to allow access to sampling sites. In such cases sampling is done during a scheduled or unscheduled shutdown, or a specific shutdown is scheduled to allow a sufficient examination of the equipment. This is particularly important in an investigation of a pathogen finding.

During routine monitoring, samples are sometimes pooled (i.e. combined into one sample) for analysis. Such pooling is generally done across similar areas or sample prioritization sites (for example, samples taken from product contact surfaces) on a production line or in a production area. Pooling is not recommended across production days, between production lines or between sites of different prioritization. The advantage of pooling is greater efficiency of cost and the ability to sample more sites in the program. The disadvantage is that the source of contamination is more difficult to trace when adverse results are found (USDA FSIS, 2012). For this reason, pooling is not recommended for sampling when conducted under elevated or high concern.

Analysis and Interpretation of Environmental Monitoring Data

Monitoring data from a sampling event represents the hygienic status of processing equipment or the processing environment at the time that the samples were taken. For samples taken in response to an event (maintenance, observation of hygiene failure), such data could indicate the impact of the failure, or, if taken following corrective actions, indicate the effectiveness of those actions.

The presence of a pathogen or out-of-specification hygiene indicator are lagging indicators of a failure of hygienic controls which has led to the presence or harborage of pathogens, or to the presence of conditions that could potentially lead to the growth or multiplication of pathogens. Examples are elevated Enterobacteriaceae in dry environment, elevated coliform in product contact sample and *Listeria* spp. in "wet" processing environment. Unless observations of hygiene deviations were made at the time of sampling, additional investigation will be needed to determine the root cause of the failure and to ensure that any corrective actions taken were effective. Depending on the location of the out-of-specification sample, finished product sampling may be needed to verify that product was not affected. Where pathogens are isolated from product contact surfaces, it is assumed that corresponding product that has made contact with the surface is also positive for the pathogen. Examples of the interpretation and actions in response to findings in monitoring programs are included in Table 33.6.

TABLE 33.6 Example of Changes in Level of Concern and Resulting Actions from Pathogen and Out-of-Specification Hygiene Indicators in Various Sample Types

Location of Sample	Finding[a]	Resulting Level of Concern	Action
Product contact (production line)	Pathogen	High	Block affected product lot(s) and destroy or recondition; initiate or intensify finished product testing; increase sampling of product contact surfaces and environment to investigate; conduct investigation of harborage sites and hygienic practices; conduct raw material review
	Hygiene indicator	High	Initiate or intensify finished product testing; increase sampling of product contact surfaces and environment to investigate; conduct investigation of harborage sites and hygienic controls; conduct raw material review
Near product contact (Z2/P1)	Pathogen	High	Initiate or intensify finished product testing; increase sampling of product contact surfaces and environment to investigate; conduct investigation of harborage sites and hygienic controls; conduct raw material review
	Hygiene indicator	Elevated	Increase sampling of product contact surfaces; initiate investigative testing of the environment; if not in place implement finished product testing; conduct investigation of harborage sites and hygienic controls; conduct raw material review
Non-product contact close to production line	Pathogen	Elevated	Increase sampling of product contact surfaces; initiate investigative testing of the environment; conduct investigation of harborage sites and hygienic controls
	Hygiene indicator	Elevated	Increase sampling of product contact surfaces; initiate investigative testing of the environment; conduct investigation of harborage sites and hygienic controls
Non-product contact away from production line	Pathogen	Elevated or routine/normal[b]	Initiate investigative testing of the environment to determine root cause, impact on sensitive areas; conduct investigation of harborage sites and hygienic controls
	Hygiene indicator	Routine/normal	Increase pathogen monitoring in area; conduct investigation of harborage sites and hygienic controls
Finished product	Pathogen	High	Block affected product lot and destroy or recondition; initiate or intensify finished product testing; increase sampling of product contact surfaces and environment to investigate; conduct investigation of harborage sites and hygienic practices; conduct raw material review
	Hygiene indicator	High	Initiate or intensify finished product testing; increase sampling of product contact surfaces and environment to investigate; conduct investigation of harborage sites and hygienic controls; conduct raw material review

[a]Presence of pathogen; presence (Listeria spp.) or out-of-specification (quantitative) hygiene indicator.
[b]Depends upon the location of the sample and the risk of contamination of sensitive production areas/equipment.

Within-specification monitoring results, along with other verification information (hygiene audits, start-up checklist, visual evaluation of cleanliness) indicate that the environment was of acceptable hygienic status on the day samples were collected. A systematic trend analysis of environmental data over time can provide greater confidence in the hygienic status of a processing line or processing area. A periodic short-term increase in a quantitative indicator such as Enterobacteriaceae could indicate that an event occurred on or prior to the sampling day impacting the hygiene of the area and facilitate a root cause investigation. Upward trends in data could indicate a gradual loss of hygienic status and enable the problem to be identified and addressed before the underlying hygiene issue leads to harborage or cross-contamination with a pathogen.

The results of hygiene monitoring programs should be kept in a database (e.g. Excel using pivot table functionality) facilitating the evaluation of trends and correlations in data and the generation of graphical representations and reports. Results of qualitative analyses (such as presence/absence for *Salmonella*, *L. monocytogenes*, *Listeria* spp.) are often documented on a factory map to facilitate the root cause analysis.

Serotyping or genetic typing to identify strains of isolated pathogens is often useful to the root cause analysis. Serotyping is particularly useful for *Salmonella*, as there are greater than 2500 serotypes. Serotyping may also be conducted for *Listeria*; however, there are fewer serotypes identified and genetic typing, such as through pulsed field gel electrophoresis, may provide greater precision for a root cause investigation (Jadhav et al., 2012). Genetic typing has also been used for *Salmonella*, *Cronobacter* spp. and other pathogens. Recurrence of the same strain in multiple sampling events, on a variety of surfaces, or following cleaning usually indicates harborage in the factory environment. The detection of different strains usually indicates transient contamination due to multiple entries into the environment from one or more routes of entry (such as through raw material or from the environment external to the factory).

Data from monitoring programs communicated to the factory food safety team for review and development of corrective actions are needed. Program results may also be presented to factory personnel at operational reviews and/or through the posting of program results.

ACCEPTANCE CRITERIA AND TESTING PROGRAMS FOR FINISHED PRODUCTS AND RAW MATERIALS

Microbiological criteria may be established for finished products, raw materials and in-process products to define the conformance of a product lot or processing line to performance objectives and to define conditions of acceptance when verification testing is conducted. Criteria may be established as requirements for products on the market or at import by regulatory agencies, as a specification by a food manufacturer for finished products or raw materials or as guidance by regulators or industry groups to food manufacturers. The utility of product testing is limited when contaminants are present at low levels and unevenly distributed. The costs of product testing are often significant due to the need to hold a corresponding product lot during the time testing is conducted. Because of such limitations, food safety management systems that incorporate preventive controls including good hygienic practices and HACCP are much more effective than a reliance on finished product testing in the absence of knowledge of such controls (ICMSF, 2002; NRC, 1985).

Although statistically limited, finished product and raw material testing may be conducted where there is limited information available about the hygienic status of a product lot (for example, a regulator's analysis of imported product or a food producer's analysis of raw materials). Testing may also be used for the evaluation of the suitability of finished products or raw materials where there is information from other verification activities that indicates an increased risk of contamination.

The development and application of acceptance criteria for finished products and raw materials is discussed extensively by the ICMSF (2002). Lot acceptance criteria are expressed in sampling plans outlining the pathogen or indicator organism(s) of concern, the number of samples to be taken from a lot (n), the limits of acceptance (c, m and M) and the methodology to be used in verifying conformance. Sampling plans in specifications are most often defined as two-class attributes plans (acceptable and unacceptable) and three-class attributes plans (acceptable, marginally acceptable and unacceptable). Two-class attributes plans are defined by m, the level separating acceptable from unacceptable and c, the maximum allowable number of sample units yielding a result greater than m. For pathogens m is often set at 0, indicating an absence of the organism in the analytical unit tested. Three-class attributes plans are defined by m, the level separating acceptable from marginally acceptable, M, the level separating marginally acceptable from unacceptable, and c, the maximum allowable number of sample units yielding a result greater than m and less than M. If any sample is above M in a three-class plan the lot is rejected. Three-class plans are most often applied in criteria for quantitative hygienic indicator organisms as they account for variability in levels and allow identification and correction of trends before levels exceed criteria that would result in lot rejection.

The ICMSF (2002) has developed standardized "cases," sampling criteria with stringency based upon the relative risk of the microorganism or group to be analyzed and the effect of handling conditions on the relative product risk. The ICMSF has also developed representative criteria for specific product categories (ICMSF, 2011).

Guidance on the sampling and shipment of finished product and raw material samples for analysis is provided in industry and regulatory guidance, including APHA (Midura and Bryant, 2001), FDA (Andrews and Hammack, 2003) and Codex Alimentarius Commission (2004).

MICROBIOLOGICAL MONITORING OF RAW MATERIALS

The relevance of microorganisms in raw materials is dependent upon the nature of the material, how it is processed and the material's intended use. This will be determined in the HACCP study for the raw material. Where the microbiology of the raw material is important to the finished product microbiology, or where the microbiology of the raw material is correlated to the quality of the material (for example, sensory characteristics reflected in high plate counts), microbiological criteria are established and communicated to the vendor in specifications included with the contractual agreement (Figure 33.1). Such criteria indicate how a given lot of material will perform in analyses when inspected.

Raw material analysis is statistically limited; the presence of a microbial pathogen or an out-of-specification hygienic indicator demonstrates that the lot was non-conforming, but the failure to isolate a pathogen does not necessarily indicate it is absent from the lot. As

a result, raw material testing is most effective when it is part of an overall supplier management program that includes other verification activities, such as on-site audits, supplier certification, evaluation of supplier performance and other inspection (such as sensory evaluation) of incoming material.

When raw material monitoring is conducted for more than one operation, the program design will be based upon the most conservative use of the material. For example, a milk powder lot intended for a dry-mix operation where it will receive no microbiocidal control measure and for a wet-mix operation for a product that will be pasteurized will be analyzed by the manufacturer according to the sampling plan and risk level of the dry-mix operation.

Establishment of Microbiological Specifications for Raw Material

Microbiological specifications for raw materials are only established when there is a specific need relative to the use of the material. It is important that specification limits established are technically attainable by the supplier through the application of HACCP and good hygienic practice. This is determined through an understanding of the nature of the raw material and how it is processed. Unrealistic specifications can lead to the use of a material that is unsuitable for its intended use even if the supplier has agreed to the specification, or to the rejection of a raw material that by its design could not meet the specification limits.

Quantitative limits in specifications may be derived from industry guidance or regulatory standards. In the absence of such standards they are based upon an analysis of the raw material over time and from a number of operations, during normal production. Such limits must also be consistent with the expectations for finished products (as expressed in finished product specifications) and the contribution that the raw material has on the microbiological status of the finished product. Specification development should also consider those already established by the supplier; however, supplier specifications often include parameters that are not relevant to the use of the material, or do not include parameters or limits relevant to the customer need. If a raw material cannot meet expectation due to the method of manufacture of the material, it is not fit for purpose and a new material that can meet requirements should be sourced or the finished product redesigned.

The stringency of microbiological specifications is based upon the risk of the material and consequences of loss of control, and on the level of confidence needed to ensure that the raw material meets microbiological requirements.

Specifications should follow a standardized format, such as that outlined by the ICMSF (2002, 2011). Raw material specifications should be reviewed on an established frequency (e.g. annually) for relevance.

Design of a Raw Material Testing Program

The scope, frequency and location of testing are determined by the raw material risk and vendor performance. Material risk is a function of the likelihood of microbial hazards inherent the materials to be present, the severity of the hazards, and how the material is used. For example, a lower risk and thus a lower sampling frequency may be assigned to a material that has robust controls, that is to be used for a product that will be cooked by the consumer, or is from a supplier with a good history of performance. A higher risk may be assigned to a raw

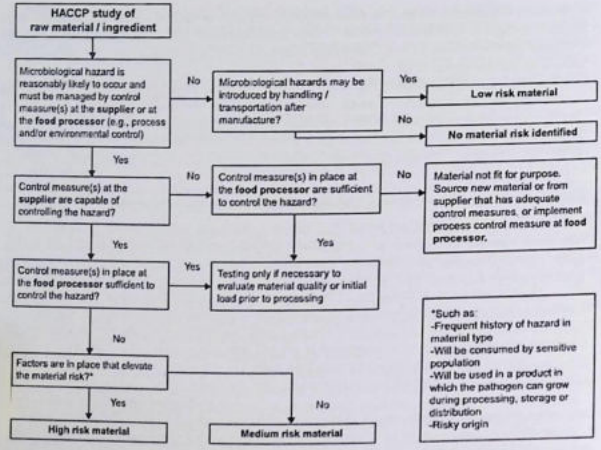

FIGURE 33.3 Example of a decision tree for categorizing raw material risk to determine verification activities. Corresponding verification testing programs are outlined in Table 33.7.

material to be used in a product without the application of a microbiocidal process by the customer that will be used by a sensitive consumer, for a material with frequent history of failure, for a material from a new supplier, or from a supplier with poor or marginal performance. An example of a decision tree to support the classification of materials according to factors affecting raw material risk is provided in Figure 33.3. The risk level may determine the stringency of criteria, frequency of testing or whether a certificate of analysis (COA) will be accepted in place of testing upon receipt by the customer. An example of a raw material verification program that is adapted to raw material risk and supplier confidence is included in Table 33.7.

Verification of the conformance of a raw material lot to specification may be conducted by the supplier and communicated in a COA, indicating through analytical testing the conformance of the specific lot to be purchased. Because testing for COA is conducted by the supplier, often at a supplier's own laboratory, customers requiring COAs from their suppliers often conduct periodic (e.g. quarterly, biannual) testing of incoming material to verify conformance of the lot, and of the COA provided by the supplier to specification requirements. Verification testing may also be conducted by the customer as pre-shipment (i.e. before the lot has left the supplier) or upon receipt at the customer site. In the latter case, the

TABLE 33.7 Example of a Raw Material Verification Program Based Upon Raw Material Risk and Supplier Confidence

Material Risk	Supplier Confidence	COA	Pre-shipment Possible	Testing upon Receipt
High	High	Each lot	Yes	Each lot
	Medium	Each lot	No	Each lot
	Low	Disqualify vendor		
Medium	High	Each lot	Yes	First 15 lots, then quarterly
	Medium	Each lot	Yes	Increase frequency (e.g. monthly)
	Low	Each lot	No	Each lot
Low	High	Quarterly	Yes	First 10 lots, then quarterly
	Medium	Each lot	Yes	Monthly
	Low	Each lot	Yes	Increase frequency

material is blocked and is not used until the results of testing are obtained and evaluated for conformance to specification.

MICROBIOLOGICAL MONITORING OF FINISHED PRODUCTS

Finished product testing may be used to verify the overall effectiveness of a food safety system. Due to statistical limitations finished product testing cannot ensure the conformance of a lot to safety requirements and is not effective as a preventive control; however, finished product testing may be useful to evaluate the conformance of a lot to specified microbiological criteria (regulatory, customer or internal), and verify the overall effectiveness of control measures.

Such testing may be conducted as within-lot or between-lot testing to demonstrate that a lot or production line is under control. Within-lot finished product testing may be conducted periodically or on each lot in response to regulatory or customer requirements. Where such testing is required as part of the contractual agreement with a customer, a COA is usually provided indicating the laboratory results. In some cases regulators may require finished product testing on a periodic frequency. Manufacturers will design control measures and conduct their own testing more frequently to ensure that their system is able to meet regulatory criteria.

The design and use of finished product monitoring is based upon a variety of factors, including:

- Sensitivity of finished product (growth, no growth, application of a lethal process);
- Exposure of product during processing (i.e. assembled, post-lethality exposed vs. in-pack pasteurization or hot fill);

TABLE 33.8 Example of the Frequency of Microbiological Testing of Finished Products in a Verification Program

Level of Hygiene Concern	Finished Product Testing	Notes
Routine/normal	Periodically based upon risk	Periodic evaluation to verify conformance to complete specification. Routine evaluation may be conducted for hygiene indicators, with evaluation against complete specification if threshold is exceeded
Elevated concern	Each production line/week	Evaluation to verify conformance to complete specification, including pathogens, hygiene indicator
High concern	Each lot	Evaluation to verify conformance to complete specification, including pathogens, hygiene indicator

- Performance objective/criteria established for the finished product;
- Results of environmental monitoring or other verification of process environment hygiene;
- Risks associated with raw materials.

In some cases it is practical to routinely examine each lot only for hygiene indicators, such as Enterobacteriaceae, coliforms or total plate count. Products that exceed a threshold on this initial examination are subject to evaluation in a detailed examination to evaluate conformance to complete criteria (including pathogens and indicators as defined in the finished product criteria).

Examples of the application of finished product testing are included in Table 33.1. The necessity and frequency of monitoring may be adapted by the level of concern of hygiene of the product and process. An example of such adjustment is included in Table 33.8.

Development of Microbiological Specifications for Finished Products

Finished product specifications take into account relevant regulatory or customer requirements, the hazards that may be present in raw materials and the environment, the nature of the product and process, and intended use of the material as determined in the HACCP study. Specifications include pathogens of concern as well as relevant indicator organisms, defined sampling plans and methodology. Sampling plans included in specifications should follow ICMSF format, with stringency based upon the severity of the pathogen of concern, the use of the product and the sensitivity of the consumer. Stringency may also be increased for new products or production lines, or where prior history of the product or process lead to a heightened concern. Sampling plan limits for m and M should be based upon an understanding of the raw materials and processes and ideally the results of testing of products manufactured under good conditions on a variety of production days.

Some regulatory authorities have established "process" criteria, which evaluate the number of positive samples as a proportion of samples collected from an operation over a period of time (ICMSF 2007). The period under evaluation is often a "moving window" of time where

new results are assessed relative to a specified number of previous production days. These criteria have been applied to the analysis of pathogens in raw animal products, where control measures can reduce, but may not be able to eliminate, the presence of the pathogen of concern.

ROOT CAUSE ANALYSIS AND CORRECTIVE ACTIONS

The information collected in microbiological monitoring programs is used in conjunction with other verification activities to assess the functioning of process and environmental controls and to determine when adjustments are needed for these control measures.

A positive pathogen or out-of-specification hygiene finding in the environment, raw material or finished product is a significant event and must generate an investigation, including modification of verification activities, a determination of product impact and a root cause analysis to determine what corrective actions are needed (Table 33.6). A positive pathogen result in a product, raw material or product contact sample cannot be negated by additional sampling unless there is confirmed evidence of a sampling or analytical error. Corresponding product will need to be destroyed or reconditioned using a process sufficient to inactivate the level of pathogenic microorganisms present in the material.

A simple conclusion of a "passing contamination" with a cleaning and sanitation event followed by re-examination is not sufficient to ensure that the contamination will not recur. Root cause investigations must include a serious examination of the underlying factors and control-measure failures to ensure that appropriate corrective actions are taken and failures are not repeated. In many cases it is not possible even in an in-depth investigation to make a solid link to a specific root cause. In such situations all relevant factors that may have contributed to the contamination are addressed and monitoring programs continue with heightened stringency until there is confidence that the factors leading to the contamination have been addressed.

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CHAPTER

34

Management of Chemical Contaminants

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INTRODUCTION

Food can be the source of a broad range of chemical contaminants and residues of agrochemicals. Some may be present naturally, or they may occur as a result of contamination or processing, or they also may be applied by the agriculture or manufacturing industry for their functional properties. Sometimes, chemicals are also added for malicious reasons, e.g. economic fraud, tampering or terrorism.

Thus, considering the plethora of chemical hazards that may be present in food, a risk-based approach for the management of these is usually needed. The HACCP system, a risk-based approach to food safety assurance, was originally developed to manage the safety of microbiological hazards in the food supply. But it is recognized that the principles of the system can also be used for the management of chemical contaminants.

This chapter describes the management of food chemical contaminants, based on HACCP principles. However, it is to be noted that the application of HACCP may not be the only approach. In any case it should ideally be based on (1) a conscious and proactive analysis of potential hazards – in particular those for which there are regulatory limits, (2) the analysis of their risk, based on sound scientific evidence, (3) setting in place effective measures to prevent or control their occurrence within agreed acceptable limits, and (4) verifying that the food safety management system is effective.

NATURE OF CHEMICAL HAZARDS

Chemical hazards[1] can be broadly categorized as follows:

- **Environmental contaminants:** originate from the environment (soil, air, water), either naturally or as a result of anthropogenic activity. They are present in/on the raw material and they enter into the product in this way. Examples are toxic metals (cadmium, lead, mercury, arsenic and aluminum), polychlorinated biphenyls (PCBs), dioxins and radionuclides.
- **Naturally occurring toxins:** are produced naturally by plants, algae, fungi or marine organisms. Examples include: plant toxicants (e.g. solanine in potatoes), mycotoxins (e.g. aflatoxins), marine biotoxins (e.g. saxitoxin responsible for paralytic shellfish poisoning). Although some foodborne pathogens also produce toxins, they are often addressed in the context of microbial food safety management.
- **Processing contaminants:** are undesirable compounds that are formed during the treatment of food as the result of the interaction of its components. Examples are acrylamide, chloropropanols, furan, benzene, ethyl carbamate.
- **Packaging contaminants:** are components of packaging material or ink, which then migrate into the product. Examples are Bisphenol A diglycidyl ether (BADGE), phthalates and epoxidized soybean oil (ESBO). They are sometimes grouped under "surface contact contaminants."

[1]Codex Alimentarius considers food allergens as a chemical hazard.

- **Food additives:** certain food additives, when present in high levels in food, may present a health risk. An example is nitrate. In the scope of this text, only food additives that have an established ADI are considered as "potential hazards."
- **Agrochemicals:** include veterinary drugs and pesticides. Similar to food additives, agrochemicals are considered as a hazard if they occur at levels above regulatory limits or internally safety-based norms.

Additionally, foods may be subject to:

- **Accidental contamination** from various chemical agents used for manufacturing purposes; examples are disinfectants, cleaning agents and lubricants.
- **Adulteration,** e.g. use of unauthorized substances such as unauthorized dyes. This is often practiced for economic reasons.
- **Terrorism or sabotage.** These are often deliberately added to food for malicious reasons.

HEALTH CONSEQUENCES

It is well established that the health consequences of chemical hazards depend on three factors:

1. Nature of the agent.
2. Amount present in the food and the intake of consumers.
3. Vulnerability of consumers.

The health effects vary according to the dose. As Paracelsus (Swiss physician and chemist, 1494–1541) stated, "All things are poison, and nothing is without poison; only the dose permits something not to be poisonous," or, more concisely, "The dose makes the poison." At high doses, chemical hazards can lead to acute or fatal intoxication, or allergic reaction in the case of allergens. Upon long-term exposure at low doses, they can also cause adverse health conditions and be a risk factor for various chronic diseases. For a thorough overview of the health risks associated with chemicals, the reader is referred to Moy and Todd (in press).

FACTORS AFFECTING THE OCCURRENCE OF CHEMICAL HAZARDS

Depending on the nature and the source of chemical hazards, different factors may influence their occurrence in the raw material or during processing. Understanding these factors and their consideration in the hazard analysis is essential for evaluating the likelihood of occurrence and deciding on appropriate control measures and verification activities. Examples of such factors are:

- Agronomical
  - General farm/agricultural practices (e.g. conventional, contract, bio).
  - Disease in animals/plants.
  - Nature of soil.

- Price and availability of agrochemicals (e.g. easy access to unapproved or banned agrochemicals).

- Climatic
  - Climatic fluctuations may stress plants and promote fungal attacks, which increase the risk either of mycotoxins or of abuse when using agrochemicals.
  - Stress caused by drought or excessive rain increase the risk of pre-harvest mold growth. Droughts have also led to feeding cattle with plants not intended as feed, thus contaminating unapproved agrochemicals.
  - Insect infestations also stress/damage plant tissues and increase the risk of mold growth and subsequent mycotoxin formation.
- Environmental
  - Industrial activity and pollution can lead to contamination of soil, atmosphere and water with chemical hazards such as heavy metals or dioxins.
  - Soil may also naturally contain high levels of certain chemical agents, such as heavy metals and POPs (persistent organic pollutants). Mining activities can also increase exposure to toxic metals.
- Suppliers' practices
  - Suppliers' farm or agricultural practices.
  - Manufacturing practices and method of processing.
  - Suppliers' QA system (preventive measures, monitoring measures).
- Legislation
  - Regulatory requirements, i.e. if a country lacks appropriate legislation.
- Enforcement
  - If the authorities are not enforcing and monitoring the implementation of the legislation.

REGULATORY REQUIREMENTS AND CHALLENGES

To protect consumers' health and ensure the safety of the food supply, public health authorities establish maximum limits for various contaminants, maximum levels of use for food additives and maximum residues limits (MRLs) for veterinary drugs and pesticides. Specific migration limits are also established for various packaging contaminants.

One of the fundamental considerations in setting standards for chemicals is the health effects of chemicals, from the perspective of both short-term and long-term exposure.

At the national level, regulatory standards, or norms, are generally established based on the consideration of the health risk associated with a given chemical, but also taking into account other factors such as feasibility to comply, nutritional needs and the diet of the population. Therefore, regulatory standards are often a trade-off between the health risk of a chemical and what is achievable and appropriate for society. As such, it is a risk management decision. Nevertheless, regulatory standards established for a chemical hazard are viewed by society as a *food safety standard* and industry has the obligation to abide by these standards. With respect to chemical hazards, exceeding these standards must be seen as a violation of food safety.

At the international level, the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) sponsor the Joint Expert Committee on Food Additives and Contaminants (JECFA) and the Joint Meeting on Pesticide Residues (JMPR), which carry out risk assessment of chemical contaminants, food additives, veterinary drugs and pesticides, respectively. Based on these risks assessments, the FAO/WHO Codex Alimentarius Commission (CAC) establishes international standards for food.

Since the establishment of the World Trade Organization (WTO) and the coming into force of the Agreement on the Sanitary and Phytosanitary Measures in 1995, the work of CAC, e.g. its standards, have become the international reference for food safety. This means that products that comply with Codex standards cannot be rejected on food safety grounds by the WTO member states unless the importing country provides scientific evidence (based on risk assessment) that the product in question is not appropriate for its population.

REGULATORY COMPLIANCE

The food industry has the obligation to comply with all the laws and regulations of the country in which they market the food. Considering that some countries may have different standards, multinational companies will have to produce foods of different standards. This raises the issue of double standards, or even that of dumping of foods of higher level of contamination in countries with lower standards. For ethical reasons, it is thus recommended that multinational companies meet the Codex Alimentarius standards as a minimum; it must be noted that the Codex standards are today recognized as the internationally agreed requirements for food safety.

Where national or international requirements are not established, the food industry still has the obligation to produce safe food; thus in some cases, internal norms may be needed on the basis of the *due diligence principle*.

MANAGEMENT OF CHEMICALS IN INDUSTRY

Prerequisites

HACCP is applied in conjunction with a number of supporting measures, which are generally referred to as prerequisites. The term is used to emphasize that the HACCP system is not a stand-alone system and that its successful implementation depends on a number of programs embedded in the food safety management system such as (1) good agricultural practice (GAP), good animal husbandry practice (GAHP) or good manufacturing practice (GMP), (2) supplier or vendor confidence level and (3) personnel training (including managers, supervisors, shop floor operators, technicians and laboratory personnel).

As most of the chemical contaminants in products come with the raw material and, once present, generally cannot be removed, supplier/vendor management is a key prerequisite in food businesses. Due to its importance, some key guidance is provided below.

Additionally, there are other "measures" or requirements which are not usually referred to as prerequisites, but which in practice are the *conditio sine qua nons* for the management of chemical hazards. Therefore, they deserve to be mentioned here. These are:

- Scientific knowledge (e.g. understanding the mechanism of formation of processing contaminants, conditions for growth of molds, impact of control measures, etc.).
- Legislation (e.g. norms, codes of practices) and enforcement.

Where these measures are not in place, the likelihood of a contaminant being present or occurring is higher. Therefore, before conducting a hazard analysis, the implementation of the above needs to be evaluated, and in case of gaps, their application needs to be improved in the first place. In the interim, the risks which may ensue from the gaps in prerequisite programs need to be considered in the hazard analysis, and the chemical in question must be considered as potentially significant. For instance, during import of a raw material from a region or country where the legislation related to the use of veterinary drugs or pesticides is not established or enforced, the likelihood of the presence of unauthorized residues in the commodity, marketed in the selling country above safe or regulatory levels, must be considered likely.

Supplier Management

Considering that many chemical hazards are introduced into products through the raw material, the importance of supplier management cannot be overemphasized.

Supplier management starts by selecting the supplier. However, before doing this, there is a need to understand the suppliers' expectations and whether they will be capable of producing the material according to specifications. Therefore, the process starts with understanding the requirements, the quality and safety objectives and formulating the specifications.

Specifications

A specification is a description of a material's properties and values (e.g. physical, chemical, sensorial, microbiological, as well as transportation and storage requirements). One may differentiate between purchasing specifications and finished product specifications.

Purchasing specifications is an important instrument to convey to suppliers the requirements in terms of food safety and quality. As such, chemical contaminants that are likely to be present in the raw material at an unacceptable level must be prescribed.

The requirements to be mentioned in the purchasing specifications must follow the hazard analysis during the HACCP study, taking into account the conditions of production or manufacturing of the raw or packaging material. In preparing the specifications, consultation of the supplier is recommended since the supplier will have specific expertise on the subject. The regulatory requirements of the country where the product is manufactured and/or sold are also important when establishing the specification.

For unauthorized compounds, the specification must indicate "absence." The minimum performance criterion of the analytical method[2] expressed as limit of detection (LoD) and/or

[2]Also referred to as the Minimum Required Performance Limit (MRPL) in the EU legislation

limit of quantification (LoQ) has to be given in this case. The units of the limits should be expressed according to SI norms (e.g. mg/kg, ng/l).

Finished product specification relates to norms for the final product and is especially important for certain types of contaminants and products, such as products that constitute an important part of the diet. The finished product specification must conform to the regulatory requirements of the country where the product is sold and/or with the CAC norms, whichever is stricter. The finished product specification represents the final consolidation of all the requirements, be they regulatory, safety or quality related, and it is the key document for compliance verification.

Selection of the Supplier

When selecting and approving a supplier, consideration must be given to the supplier's ability to meet the purchasing specifications, in particular the supplier's:

- Awareness of chemical hazards associated with their products.
- Consideration of regulatory requirements in their HACCP studies.
- Raw material and management of their own supply chain.
- Traceability.
- Implementation of control measures at the CCPs.
- Practices with regard to the processing and storage of raw material and semi-finished or finished products.
- Monitoring activities and records.
- Training program for personnel as well as suppliers' laboratory capabilities and performance.

Certificate of Analysis (CoA)

As a confirmation of the suppliers' compliance with the requirements, a CoA may be required. The CoA is to be viewed as a verification of control measures at the suppliers' level. It is thus a complement to internal monitoring. However, care must be taken that the CoA is provided by a competent accredited or approved laboratory. In absence of accreditation, a periodic independent or in-house verification of the CoA is necessary.

Alternatively, suppliers may provide a certificate of compliance (CoC). This is different from a CoA. It is basically a certificate stating that the material complies with the requirements, including compliance with the regulatory requirements or recognized international standards. It is to be noted that a CoC is not based on the analytical results, and that its validity depends on the measures that the supplier puts in place to meet the set requirements. This has to be verified during audits of suppliers.

In the delivery of the certificate, the following conditions must be respected:

- The certificate must refer to an actual analysis of the lot being delivered, not to an average monthly sample, or to a previously analyzed lot. It must cover all the parameters agreed with the supplier.
- The sampling method and sampling plan must be mutually agreed upon.
- The laboratory carrying out the analysis must be clearly identifiable on the certificate.
- The report must identify the analytical methods used.
- The accuracy of results for chemical parameters must be verified periodically.

Analytical Aspects

Besides the analytical performance of a test method that is used to analyze a specific chemical hazard, the manner of reporting test results may also have an impact on the comparability and validity of analytical data. The following principles that need to be considered in the reporting of *quantitative* test results are as follows:

- **Form of the chemical hazard and unit of measurement:** A test result should be reported in the same form (active – chemical form) and with the same unit of measurement as that given in the specified requirements (e.g. local regulatory limit, Codex Alimentarius).
- **Number of significant figures:** If the requirement provides clear guidance, the same number of significant figures should be reported. Otherwise, the test result should be expressed with one significant figure more than the limit stated in the requirement. In addition, the number of significant figures depends on the uncertainty of the analytical method.
- **Correction for recovery:** Generally test results are not corrected for recovery. They may be corrected if the relative recovery is significantly different from 100% (typically <70% with good precision). In the latter case, both the measured and corrected value should be given, as well as the basis for correction. The recovery of a specific chemical hazard may vary, depending on the sample matrix.
- **Reporting limits:** Reporting limits are the LoD, which is key for banned or unauthorized chemical compounds, and the LoQ. As for the recovery, the LoD and LoQ of a specific analytical test method may vary depending on the sample matrix.
- **Uncertainty of measurement:** In accordance with the standard ISO/IEC 17025:2005, a statement on the estimated measurement of uncertainty (MU) should be included in test reports when:
  - it is relevant to the validity or application of the test results;
  - a customer's instructions so require; or
  - the uncertainty affects compliance with a specification limit.
- The final uncertainty is expressed as the interval (measured value ± expanded MU), at a 95% confidence level.
- **Uncertainty factors:** However, some factors may contribute to discrepancies in the analytical results, and should be considered in further investigation in case of a non-compliance:
  - Heterogeneity of the product batch/lot.
  - Different sampling procedures for analytical testing.
  - Different analytical testing procedures (including sample preparation, analytical method, quantification procedure, quality controls) with different performance characteristics (e.g. detection limit, measurement of uncertainty).
  - Different "rules" to assess the regulatory compliance (e.g. correction for recovery, taking into account the measurement of uncertainty).

It is important to understand the principles that regulatory authorities apply to interpret analytical test results and how they assess the compliance of a product against a requirement. The application of different principles for treating data may affect the conclusion regarding the compliance or non-compliance of a product with a requirement.

Many food business operators make use of external laboratories, or rely on the laboratories operated by suppliers or co-manufacturers. Governments also have their own control laboratories and may verify the compliance of products independently.

In order to be able to rely on the results of tests, it is best to refer to ISO accredited laboratories.

APPLICATION OF THE HACCP SYSTEM TO MANAGEMENT OF CHEMICALS

Identification of Hazards

A first step in the management of chemical contaminants consists in identifying potential hazards associated with the product and manufacturing process. The source of many chemical hazards is the raw commodity or packaging material itself. Most chemical hazards present at source, i.e. raw material, will not be eliminated through processing. Some chemical hazards may also be formed during processing or storage.

To identify potential chemical hazards, expertise is needed; hence the importance of integrating an expert on the subject into the HACCP team. As a complement, or in absence of an expert, the following sources of information can be consulted.

- Regulatory requirements (considering the requirements of the country where the product is to be sold). As products need to comply with the regulatory requirements, the contaminants that should be examined are those for which regulatory authorities have established some guidance or regulatory requirements.
- Scientific literature can provide information on the type of hazards which are associated with food, and their level of occurrence.
- Governmental and industry associations guidance material such as fact sheets, websites. The guidance provided by the International Life Science Institute (ILSI) or the Global Harmonization Database can be a source of such information.
- Reports of surveillance of governments or industry, be it monitoring of chemical contaminants in food and environment or reports of inspection of food control capabilities showing potential weaknesses in control, monitoring or analytical capabilities. A major food recall that occurred in 2001 in Europe in relation to chloramphenicol in honey could perhaps have been anticipated if the report of EU inspectors, showing lack of monitoring and of governmental laboratory capabilities in China for enforcing legislation on veterinary drugs, had been shared with industry associations.
- Portals such as the RASFF (Rapid Alert System for Food and Feed). The accessible RASFF portal database at http://ec.europa.eu//rasff enables a search for RASFF notifications on food and feed of interest or a particular hazard.

Certain chemical hazards, processing and packaging contaminants in particular, are best addressed in the design of the product. Therefore, their prevention and control must be considered during the early stage of product development and reflected in a preliminary hazard analysis using, e.g., the "Safety by Design" approach.

Analysis of the Hazards

For hazards that are identified, a decision should be taken on their degree of risk. Those which are viewed as high risk in the HACCP study are referred to as a "significant hazard." To identify which chemical hazard is significant, the following factors need to be considered:

- The likelihood of occurrence of the hazard above safety/regulatory limits. This may be estimated taking into consideration the factors influencing the occurrence of a hazard (see section on factors influencing the occurrence of hazards above) and the prerequisite programs in place. Data confirming the proper implementation of prerequisite programs must be available. Examples are audit reports of the supplier or manufacturing site and historical records such as monitoring data of the supplier.
- The severity of health consequences of the agent, taking into consideration the target consumer, the nature and the level of the chemical potentially present.

If a regulatory limit or an industry limit is not available, the decision on the significance of a hazard could be based on food safety assessment. To this end, two types of data are required:

- A reference dose: this is the dose below which exposure to that chemical can be considered as safe (e.g. ADI, TDI, PTWI).
- An estimate of exposure[3] based on food consumption data.

The degree of significance of a hazard can then be estimated by comparing the level of exposure to the particular chemical agent through a given food with the ADI or other equivalent reference dose (TDI, PTWI). If the exposure does not represent a significant proportion of the safe reference dose, the agent is not viewed as a significant food safety concern (e.g. ratio of estimated intake to TDI or ADI <1). In other words, the significance of the hazard can be evaluated based on the degree of contribution that it makes to the total exposure of the target consumer. In case that degree is negligible, the hazard is considered not to be a major food safety concern.

To calculate the level of exposure, the worst-case scenario must be considered, i.e. using the maximum consumption of the product and the maximum amount of chemical that may occur in the particular food, and based on historical records or other surveys.

Control of Hazards

Except for hazards that may occur as a result of processing or storage, for a great proportion of chemical hazards, the *control measures* are at the supplier level, i.e. the application of GAP, GAH, GMP.[4] For packaging contaminants, the design and formulation of the material as well as the application of specific GMP measures at the supplier level are the control measures. Thus, sourcing the raw material from reliable and approved suppliers is essential for preventing these types of chemical hazards. Therefore, the customer of a raw material

[3] Estimate of exposure (mg/kg bw/day) = [maximum level of agent in the finished product (mg/g) × maximum amount of food consumed (g/day)]/bodyweight/kg).
[4] In ISO 22000 these control measures are referred to as "prerequisites."

must clearly communicate its requirements (including the intended use of the raw material) to the suppliers. Purchasing specifications is an important tool for this communication.

Testing the raw materials at reception is in principle a verification activity since it confirms the suppliers' quality assurance program and compliance with the agreed specifications. However, in situations where the confidence level is low, it can be considered as a control measure, provided that it is carried out systematically on all lots of incoming materials, using a validated sampling plan. Results of the analysis will then be part of the release procedure.

For some hazards, selecting resistant varieties of raw materials can be considered as one method to control a hazard, in which case the specific variety desired must be mentioned in the raw material purchasing specification.

For processing contaminants such as acrylamide, the design and control of process parameters or the formulation of the product may constitute the main control measure. For certain types of mycotoxins, the control of storage conditions (storage time, temperature, humidity) of raw materials is the key control measure.

For lubricants, food grade quality and good maintenance practices must be considered as key control measures (this is often done as part of GMP).

Preventing accidental or cross-contamination with chemicals requires good warehouse management, e.g. separation of cleaning chemicals from food items, proper closing and labeling of chemicals, dedicated recipients, etc.

The control of hazards must at all times ensure that chemical hazards are prevented, eliminated or reduced to an *acceptable level*.

Critical Limits

The second principle of HACCP is the decision on the critical limit. This is the limit which separates the acceptability from the unacceptability of a control parameter. These limits have to be established based on the parameters that characterize a control measure. For instance, if for the application of antibiotics, the control measure has to take account of a withdrawal period, the monitoring parameter is time, and the critical limit is the number of days required for the residues of antibiotics to decrease to an acceptable level, e.g. 7 days. However, for a raw material where there is low supplier confidence or the supplier is not known, and the testing of the raw material is considered as a means for controlling the hazards, the critical limit is the regulatory standard of the country where the raw material is to be used, or preferably the Codex norms if these are more stringent. For intermarket supplies, attention must also be paid to ensuring that the finished product meets the regulatory limits of the market where the product is sold and/or the Codex norm. If this requires a more stringent norm for the raw material than the regulatory requirement of the country where the product is manufactured, then this should be stated in the requirements communicated to the supplier.

Chemicals used by producers (e.g. agrochemicals) or by food manufacturers (e.g. food additives) should not be used in food production and manufacturing if they have not been evaluated and have not been proven safe for use.

For unapproved or prohibited chemicals, some governments may apply the concept of *zero tolerance*. This concept is based on the idea that if an agent is prohibited, its mere presence at any level is an indication of violation of the legislation. However, many

governments can be tolerant if the industry can demonstrate that the presence of the agent in the product was inadvertent, a due diligence measure was taken to prevent it, the contaminant can have other sources, e.g. environment as was the case with melamine, the level in the product is so minute that it does not present a harm to consumers and corrective measures are taken to prevent it in future. Under such circumstances the governments may allow the product on the market. In other cases, the governments may confiscate the food and punish the producer, but destruction of such a food considered safe would not be wise. At very low levels of contamination, there may be conflicts among the stakeholders of the presence or absence of such a substance and regulatory authorities may determine minimum required performance limits (MRPLs) of the analytical method for such substances.

For processing contaminants, the critical limits correspond to the acceptable limits of the processing parameter(s), e.g. temperature of the heat treatment. Similarly, for contaminants associated with storage, the critical limits will be the acceptable limits of storage parameters (temperature and/or humidity).

CCP Monitoring

Where the raw material is considered as a CCP, the chemical hazard must be tested on every batch and the results of testing must be made a release criterion. Correct and valid sampling is essential. Where the distribution of the hazard is heterogeneous (e.g. mycotoxins) and the raw material is considered as a CCP, the validation of the sampling method is particularly critical for food safety and must be considered as compulsory.

Similarly, in line with HACCP principles, any processing or storage step which is identified as a CCP must be monitored; the parameters and frequency of monitoring must be set so that if the critical limit is violated, corrective actions can be applied in a timely manner. For chemical agents, re-processing is generally not applicable and an infringement of the acceptable level of the agent should lead to the rejection of the raw material or product.

Personnel entrusted with the management of CCPs must be well trained, be aware of their responsibility and must completely understand the consequences of an eventual failure of the CCP.

CP Monitoring and Other Verification

In addition to CCP monitoring mentioned above, depending on the level of risk, a verification procedure must be established to confirm that control measures (preventive measures) are adequately implemented and the HACCP system is effective. For chemical hazards, verification includes activities such as:

- Audit of the supplier.
- Factory audit.
- Verification of identity of the raw material upon receipt in the factory (e.g. visual inspection) to confirm that the right variety is selected.
- Monitoring of the raw material for potential hazards according to the degree of risk as well as other factors (see "Monitoring Plans (see next section page 931),").
- Testing of the finished products.

Monitoring Plans

Frequency of Monitoring

Whether monitoring is implemented at a CCP for controlling a hazard or as a verification measure to verify that the control measures are applied correctly, the frequency of monitoring needs to be decided. In line with what has been mentioned above, this should be decided on a risk-based approach. However, frequently health risk is not a sufficient criterion since a one-time non-compliance may not present a significant health risk for the consumer or may even present no risk, but may jeopardize the reputation of the business or present economic risk in case of violation of regulations and product recall. Therefore, a two-step decision-making process is proposed here.

In a first step, the frequency of monitoring is decided taking into account:

- The likelihood of occurrence of the contaminant above acceptable levels in the raw material, e.g. taking into consideration the prerequisite conditions (e.g. availability of certificate of analysis).
- Health consequences for target consumers in case of non-compliance and the anticipated level of the contaminants in the final product.

In line with the decision tree (Figure 34.1), depending on the level of risk, the raw material is considered as a CCP or Control Point (CP)[5]. If the risk is viewed as negligible, it may

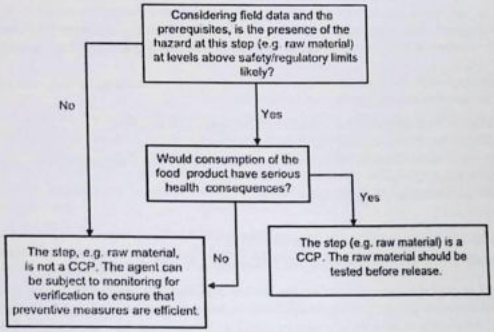

FIGURE 34.1 Simplified decision tree for hazard analysis of chemicals.

[5]Control point is a step in the operation where control measures are applied but the step is not considered as a CCP. Nevertheless, the step is checked or surveyed for verification purposes.

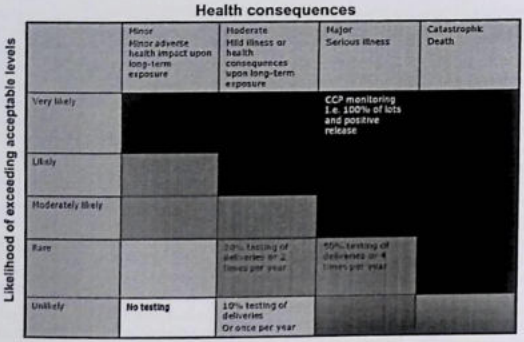

FIGURE 34.2 A schematic presentation of risk-based monitoring.

also be decided that no monitoring is required for food safety reasons. The monitoring frequency decided at this step should in principle set the minimum requirement for testing (Figure 34.2).

In a second step, the frequency of monitoring can be readjusted taking into consideration "other factors and requirements"; examples are:

- Feasibility (availability of analytical method, speed of results).
- Regulatory requirements and/or public perception.
- Economic reasons: amount of raw material and/or product processes and implications in case of a product recall.
- Impact on the image and reputation.

Principles in Setting a Monitoring Plan

In setting up the monitoring plan, the following principles must be considered:

- Time of testing must be adapted to the period associated with the highest risk of contamination (e.g. monitoring of aflatoxin in cereals or nitrate in vegetables may require higher frequency in specific seasons or climatic conditions).
- Samples must be taken at the arrival of the raw material.
- A certificate of analysis can be required in place of, or in combination with, verification monitoring. However, the certificate of analysis must be obtained from an accredited or approved laboratory and be periodically verified internally.

- Except for contaminants that occur during processing and manufacturing, most of the efforts must be on the raw material. However, periodic testing of the finished products is also advised in the following cases:
  - To verify that the HACCP plan is effectively implemented. This is important for significant hazards.
  - To confirm compliance with the legislation.[6]
  - To verify that risks associated with processing or storage are under control.
  - If a certificate of analysis is required by customers.[7]
  - If a certificate of analysis is required for exportation.[8]

Corrective Action

In case of non-compliance, the following actions need to be considered:

- Non-complying raw materials must be rejected and suppliers must be advised. Depending on the situation and the gravity of the non-compliance, the need for increasing the frequency of the verification activities (i.e. frequency of auditing and/or monitoring materials for the potential hazards) or alternatively terminating the contract must be considered. Fraudulent practices must lead to an immediate termination of the contract.
- Non-complying finished products must be blocked.
- Any deviation must be immediately investigated and followed up.
- For chemical hazards occurring as a result of processing or storage conditions, a deviation from set standards must lead to a product reformulation or a change in processing or storage conditions.

Validation

The principles of the HACCP system as well as of the Codex Alimentarius Commission require validation of control measures. Validation consists in obtaining evidence that the elements of the HACCP system are effective. As such, all the decisions relating to the different principles of HACCP need to be validated to ensure that they have a scientific and/or technical basis, and/or are based on accepted practices. These include consideration of the need for validating:

- Hazards which are considered as non-significant and efficiency of control measures (operational prerequisites), e.g. suppliers' practices, monitoring and/or CoA.
- Limits and/or specifications.
- The sampling scheme and procedures.
- The analytical method (e.g. equipment, variability, sensitivity, approved and recognized method).

[6]Provided that there is scientific evidence that the risk is associated with the product or related raw materials.
[7]Idem as 5.
[8]Idem as 5.

- Frequency of monitoring activities.
- Training and competence of personnel, from operators to laboratory (e.g. accreditation).

Necessary data, records and documentation providing the basis for decision-making must be available.

Maintenance of the HACCP Plan

Results of monitoring and other verification activities (e.g. audit of supplier, preventive maintenance) as well as previous records of consumer complaints and or accidents must be the subject of a continuous review. Hazard analysis and decisions on CCPs and/or frequency of monitoring and other verification activities must be re-evaluated and the HACCP and monitoring plan must be updated in the light of these data. Examples of technical or scientific data that should prompt an update of the plan are:

- Alerts (internal or external).
- Surveys by authorities or national food institutes.
- Reports or data on previous incidents or non-compliance.
- New scientific developments (e.g. emergence of new potential hazards).
- New or change in the regulatory requirements.
- Change of supplier or suppliers' practices.
- Change in the country where the product is marketed.
- Change in the intended use, preparation method or target consumer.
- Change in the product formulation or process/storage conditions; change in factors influencing the occurrence of a hazard, such as environmental contamination or climatic changes. The latter may for instance increase the risk of mold growth and formation of mycotoxins, which in turn can lead to abuse of fungicides. Climatic changes may also increase animal infections, leading to a higher use of antibiotics.

While the maintenance of the HACCP plan must be a continuous practice, it is a good practice to periodically review collected data and their trend analysis. Types of data that should be considered during such a review are:

- Results of in-house monitoring, including out-of-norm results.
- Survey or monitoring carried out by authorities (or planned to be carried out) or third parties.
- Verification of certificates of analysis.
- Performance of suppliers (audit reports, supplier's monitoring plan) and future audit plans.
- Information on emerging chemicals.
- Reports on laboratory competences.

The results of this review must lead to an analysis of trends and decisions for:

- Enhancing preventive measures.
- Readjusting the frequency of monitoring.
- Setting up new monitoring activities or surveys.
- Communication to regulatory authorities regarding the feasibility of the legislation.
- Management of suppliers (request for audits, change in the frequency of monitoring or issuing warnings).

In case of any report by regulatory authorities or other third parties (e.g. customer, consumer organization) of non-complying products, a transparent and speedy reaction is important to maintain credibility and the confidence of authorities. The following action is recommended:

- Handling of non-compliance and corrective actions – all non-compliances must be the subject of immediate follow-up action and must lead to the adjustment of the food safety management system, including monitoring activities. Handling of non-compliance and incidents is explained in Chapter 40.

Further Reading

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CHAPTER

35

Food Defense

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DESCRIPTION OF ISSUES

Food defense, as used in this chapter, concerns the *intentional* contamination of the food supply. While governments have begun to take notice of this risk only in recent years, people have been poisoning food since before the pyramids were built.

What is different today is the scale of the impact and the scope of the risk (Tumin, 2009). Modern agricultural methods, large-scale food manufacturing and efficient logistics turn what might only have been a local problem into an international crisis. A single farming region may produce a commodity for much of a nation. A single factory may manufacture food that is distributed across a continent, or produce an ingredient shipped around the world (Cavallaro et al., 2011).

At the same time, terrorist attacks that reach across the world, increased global political unrest and unprecedented global distribution of food magnify the risk. No longer must we be concerned with only personal enemies, but we must also be concerned with extremist political factions with whom we have no contact. Another potential risk is with trading partners half a world away.

DEFINITIONS FOR FOOD DEFENSE AND RELATED TERMS

Some working definitions are appropriate to frame the discussions in this chapter. As a relatively new area of focus within governments and food producers, the terms used to describe protections from *intentional contamination* are evolving. The language may change further as global partners continue to collaborate.

Food Safety

Food safety has its focus on reducing the risk of unintentional contamination in the food supply, be it natural, accidental, a result of negligence or violation of food safety principles due to technical ignorance.

Food safety is a well-established area of effort that has been around for decades. Universities worldwide have well-regarded food safety programs. Most governments have agencies dedicated to food safety. Producers increasingly have food safety management programs based on global standards. Cold-chain practices, risk analysis methods such as operation risk method (ORM) and hazard analysis critical control point (HACCP) are well understood (and highlighted prominently in reference materials such as this one).

Food safety frequently focuses on a relatively short list of well-studied pathogens, such as pathogenic strains of *Listeria*, *E. coli* and *Salmonella*, along with chemical contaminants and physical hazards like wood or metal fragments. Some of these contaminants are inherently found in the environment or production systems. Inspection and detection methods exist for these agents. Many food processing systems include treatments (oxidizing or heat treatments) or compositions (low water activity, pH) that inactivate pathogens.

Key points: Accidental contamination, well-established best practices, known agents.

Food Security

Food security has its focus on the availability of nutrition for a population.

Despite the large-scale agriculture, industrial food manufacturing and global distribution of the global food supply, there is still a great deal of hunger in the world. The Food and Agriculture Organization of the United Nations (FAO) estimates "that a total of 925 million people are undernourished in 2010" with "developing countries account[ing] for 98 percent of the world's undernourished people." Many populations (nations, regions or people) have an insufficient supply of food, and they are "Food Insecure." Populations with sufficient supplies of food have "Food Security." This problem is projected to increase due to population growth, climate change and related factors (FAO, 2010).

Note: Some documents may use the term *food security* to describe measures to reduce the risk of intentional contamination. If you are unsure, you should try to clarify the local context of the term.

Key points: Sufficient food for a population.

Food Defense

Food defense has its focus on the prevention of the *intentional* contamination of the food supply.

Many agents can be used for intentional contamination. In addition to the agents normally identified with food safety, these can include other chemical, biological, physical or even radiological agents. Many potential agents are highly toxic and are not prevented or inactivated by conventional food safety interventions. Most of these potential agents are difficult to detect, or at least difficult to detect when in a variety of foods.

The motivations for intentional contamination can be as varied as the agents. They can range from local grievances to economic advantage to political disruption to mass casualties. The capabilities of perpetrating an intentional contamination also have a broad range, from the limited effort of an individual to the significant capabilities of a well-organized international terrorist cell.

Key points: Intentional contamination, unknown agents, limited detection methods, motivations and capabilities vary with the perpetrator.

Food Protection

Food protection is an "umbrella term" to encompass both food safety and food defense activities.

This pays homage to the fact that it is often the food safety professionals that become responsible for food defense. This reflects various similarities and overlaps in the work of food safety and food defense. For example, both food safety and food defense benefit from control and inspection of incoming materials and from a robust recall and recovery program. Note that in terms of regulatory authorities there are different organizations involved, e.g. food control agencies for food safety versus police or homeland security agencies for intentional contamination.

Note: There are also several fundamental differences between food safety and food defense because of the intentional element. Malicious intent and intelligent adversaries must be considered in food defense. A change in thinking is required when food safety professionals also manage food defense measures. They must begin to "think like the bad guy."

Key points: Emphasizes the similarities with food safety, may diminish the differences.

Bio-terrorism, Agro-terrorism and Bio-defense

Bio-terrorism, agro-terrorism and bio-defense focus on biological attacks of several kinds. These can be attacks against crops or livestock as well as the food we eat.

The inclusion of the word "terrorism" describes crimes that are politically motivated. Food defense is concerned with intentional contamination of food that is politically motivated and motivations that are economic or revenge based.

While intentional attacks against the food we eat or the feed stocks that make our food may be considered bio-terrorism or agro-terrorism, those terms are more often used in the contexts of crops and livestock, or as an umbrella term for all biological-based terrorist attacks against food.

Key points: Attacks against any food, crop or livestock rather than a focus on the food we eat.

Summary

The terms used may be different from one country to the next or in different industry segments, and may continue to change over time. Regardless of the terms used, if you are considering the protection of your food supply from intentional contamination, this chapter is for you.

FARM TO FORK

Food defense borrows the notion from traditional food safety and cold chain to treat the entire food supply as an integrated system. The weakest link between the farm and the consumer may be the place where an intentional contamination occurs. You may also hear comparable terms such as "farm to table," or in Australia, "paddock to plate."

With food defense two factors make protecting the entire supply chain even more critical than with food safety. The first factor is the malicious intent of the perpetrator. If they have studied the food system, they may choose to attack at the location with the fewest defenses,

or the location where they can do the most harm. Some vulnerability assessment methods, in fact, focus on how a perpetrator would choose a target.

The second factor is the difficulty of inactivating some agents that might be used in an intentional attack. Traditional food safety protocols heavily emphasize sanitation conditions at food producers and the critical control points (CCPs) of "kill steps" like pasteurization to reduce the risk of a food safety incident. These measures would be totally ineffective against many potential contamination agents.

Note: Several food safety incidents have illustrated the weakness of relying too heavily on the controls at the food producer. The E. *coli* outbreak in leafy greens in the United States in 2006 caused a significant health impact despite controls at the producer. Significant improvements in good agricultural practices (GAP) were instituted as a result (CDC, 2006).

Most food producers are not vertically integrated to the extent that they can control the entire food supply from "farm to fork." They must instead *influence* the defensive ability of the supply chain that is outside their control in another way. To do this they borrow techniques from traceability methods, looking one step ahead and especially one step behind as part of supply chain verification.

TYPES OF RISK AND HAZARDS

In traditional food safety we look at the various mechanisms (vectors) that could create a food safety incident. In food defense, when we talk about the types of risks and hazards we can consider the various types of *perpetrators* that might commit an intentional contamination. What kinds of people or groups are they? What are their *motivations*? What are their *capabilities*? Are there *targeted mitigations* for those specific perpetrators?

We can also consider the various *agents* that might be used. Taken in combination, these represent the *threat vectors* we need to guard against. The good news is that much of what we do to protect our processes from one potential perpetrator will also protect us from others. The bad news is that this is not entirely true, because their capabilities are different. Consider perimeter fences that will help keep out competitors or local political threats, but would do little to slow down an insider or a well-organized terrorist cell.

Perpetrators: Motivations, Capabilities and Targeted Mitigations

Owners and Managers; Economically Motivated Adulteration (EMA)

While we might first think of intentional contamination with respect to criminal or terrorist activity, often with a political motive, perhaps the most pervasive form of intentional contamination is to improve profits: economically motivated adulteration.

Economically motivated adulteration can take the form of diluting a product, substituting inferior ingredients or adulterating with potentially hazardous ingredients that might improve the apparent value (with the intention of "fooling" the current quality assurance of analytical methods used to establish value). Fake products (imitations/counterfeits) are another form of economically motivated adulteration.

A challenging factor with economically motivated adulteration is the nature of the perpetrator – the owner or key management staff. They have ready access to all systems.

They understand the process thoroughly and have the means to circumvent any physical security measures. Their workforce may be unaware of, unable or unwilling to report, their suspicious activities.

There is another interesting conundrum when considering the potential health impacts of economically motivated adulteration. The owner/perpetrator presumably does not desire people to become ill; their motivation is economic gain not human harm or political impact. So they may dilute or substitute with a material of less nutritional value though not necessarily one that is pathogenic. On the other hand, because the adulteration is more likely to go undetected for some time, the cumulative health impact could be quite great.

As an example, in 2008, about 300,000 children in China became ill and at least six babies died when the milk used for infant formula manufacturing was adulterated with melamine (*The New York Times*, 2011). In 2004, about 50 children died from fake infant formula, which provided little or no nutrition (Watts, 2004).

Special capabilities: To disguise the substitution of one ingredient for another, using the excuse of controlling proprietary information to hide the actual formulation from employees.

Limitations: The selection of agents is limited to adulterants the owner or manager believes will get around QA systems, and those that will be benign, so as to allow the adulteration to be perpetuated over time for the greatest economic gain.

Targeted mitigations: EMA agent informed analysis by the customer.

Employees and Other Insiders

A "disgruntled employee," angry with a supervisor or co-worker, may be one of the most difficult threats to guard against. This person may have access to many areas within the facility, may know the best places to contaminate without being caught and may not raise any suspicion even when away from their normal work area.

The nature of the design and operation of many food manufacturing facilities allows almost any employee to be in almost any work area. Even new or temporary service employees often have relatively unrestricted access. Color-coded hats or uniforms are often used to designate job function, like supervision or quality, and not what area the employee should be working in.

When considering employees, also consider other people who have regular access to your facility: vendors, contractors, sanitation personnel and other temporary support employees can have similar access and motivations.

Many of the physical security measures we might first think of when considering food defense, like fences and guards, are powerless against an inside threat. Even cameras might be ineffective in stopping an insider if they know they are not being monitored in real time. Enhancements of our physical security measures and additional behavioral measures are needed.

The motivation of an insider threat may be retribution for some harm or slight. As such, the goal is to do harm to the owner or company, not necessarily to create a large health impact. So the contamination may be one that becomes obvious, changing the color or composition of the product in a way that is detected before the product would make it to the consumer. There is one exception: the special case where the insider belongs to, or has been compromised by, a terrorist group that does seek to do harm.

Special capabilities: To freely bypass external security measures, and in many cases have access to food mixing operations that make a good place to introduce a contaminant.

Limitations: The agents available to employees are limited. They usually would not have access to highly toxic agents in high concentrations.

Targeted mitigations: Zoned internal security measures, "buddy" systems, surveillance. Background security screening of all personnel, not only full-time employees, but also vendor and temporary support personnel.

Competitors

Like a disgruntled employee, a competitor may wish to harm another company. A competitor likely does not have access to the facility (though this could happen in some cases of prior employment). The competitor would, however, have significant knowledge of the processes and possibly the vulnerabilities.

Special capabilities: To understand the most effective place to contaminate and recognize those processes in another operation.

Limitations: The agents available to competitors could be limited. Access may be limited as it is to other outsiders. There may be restraint on the part of a competitor if they understand that any public awareness of tainted product could damage the entire market including their own business.

Targeted mitigations: Prompt removal of access privileges for all previous employees. Industry education regarding the shared impact of a contamination event.

Local Extremists

Because the threats of local extremists are politically motivated, they can be termed terrorists. They are listed in this chapter separately from global terrorists because the capabilities of these local terrorists may be much different. (In some food defense programs, all terrorists, local and global, are considered as a single category of threat – National Standard of the People's Republic of China, 2010.)

What sets extremists apart from the previously classified groups is their willingness to cause harm to people. While they may attempt to achieve their goals through economic harm and publicity, they may prefer to make their statement by impacting public health.

There have been several intentional food contamination events by local extremists. Fortunately they have been fairly limited in scope. These events have generally been targeted at the "last mile" such as retail food establishments.

As an example, in 1984 in The Dalles, Oregon, USA, members of a religious commune deliberately contaminated salad bars at 10 restaurants. A total of 751 persons were stricken with *Salmonella* gastroenteritis associated with eating or working at these restaurants (Torok et al., 1997). This was a test run on their ability to impact voter turnout at a local election.

Special capabilities: To organize and conspire with others committed to a cause. They may research methods and agents in advance.

Limitations: The most esoteric methods and most toxic agents may not be available. They may be restricted only to simple access points.

Targeted mitigations: Special emphasis on retail food establishments. Facility access controls in manufacturing environments such as fences, guards and access badges. HR practices.

Global Terrorist Threat

Highly organized global terrorist attacks could target the food supply with the intention of causing significant illness and deaths. The impact could be more tragic than bombing a hotel or crashing an airplane.

There is evidence that global terrorist groups have at least considered attacks on the food supply. This evidence includes captured notes from a raid on an Al-Qaeda camp (Tarnak Farms Afghanistan) in 2001 that illustrated portions of the food supply and listed potential actions (Hoffman and Kennedy, 2007). There is no confirmed evidence to date that global terrorist groups have executed an *actual* attack against the food supply, although such events have aroused suspicion.

What we realize, however, is the historic vulnerability of our food supply to a potential attack. The supply chain is vast, from fields, to factories, to endless distribution routes and countless consumers. It is broadly recognized as the most complex of supply chains (*Food Safety Magazine*, 2011).

We also realize the devastating impact a significant attack could have. How many people have become sick or died in some of the major *food safety* incidents of the last decade, and how many more people could be harmed by a well-orchestrated attack on a food plant? How many more people could be harmed using highly toxic agents that are not inactivated by current processes and not detected by current methods?

Special capabilities: To organize, conduct surveillance of potential targets, practice attacks and coordinate asymmetric attacks against multiple targets. They are also able to recruit or place an insider in an organization, giving them many of the capabilities previously discussed for company insiders. Potential access to any agent desired.

Limitations: The planning activities required to organize a coordinated attack make them susceptible to detection by government authorities. Surveillance or trial exercises may make them detectable by alert plant personnel.

Targeted mitigations: Collaboration with law enforcement or national security organizations and a comprehensive and layered food defense system that includes trained and alert employees or authorities.

Agents

In food safety we concentrate on a list of established agents identified as contaminants. They are naturally occurring and/or unintentionally introduced and have been reasonably well studied. The situation is much more complex in food defense.

A broad range of toxic agents could be used for an intentional contamination, including biological, chemical, physical and radiological agents. Many of these agents are not well understood and we have little experience detecting them in the food supply or inactivating them.

It is natural to think that we should know what agent we are guarding against, but in one respect, this really is not necessary. When we "think like the bad guy," we look for an agent and a contamination point that is not inactivated by the normal manufacturing process.

If we create a food defense plan based on some specific agent, we might overlook potential vulnerabilities based on our ability to inactivate that agent, such as points upstream of a pasteurization point. If we create a food defense plan based on the idea that the agent that

will be used will cause harm and will make it through our process, we can address additional vulnerabilities.

[Hint: Create your food defense plan based on an agent called "really bad stuff" that is highly toxic, difficult to detect and will not be inactivated by your process or supply chain.]

After you have created an agent-agnostic plan, there are two additional benefits to going back and looking at the specific characteristics of different agents.

1. You may be able to create some additional agent-specific mitigation that further reduces your vulnerability to specific agents or types of agents. For example, a slightly higher pasteurization temperature may inactivate a broader range of biological agent as many US dairy processors have done (Detlefsen, 2005). (Remember that contamination could occur after pasteurization, so you cannot leave those downstream systems unguarded.)
2. You may improve your ability to debunk a hoax of contamination. In the event of a hoax that claims a specific contamination of your product, you are better prepared to explain to the public how that agent would be inactivated by your process, or how the quantity added would be incapable of causing mass harm.

Much of the information on specific agents is either limited or classified as there is no "normal" reason to need it or provide information beneficial to potential perpetrators. Additional information and references on chemical and biological agents (Kennedy and Busta, 2007) of concern is, however, available.

Detection: Methods to detect the introduction of intentional contaminates are being studied. Today there are no commercially available broad-spectrum test methods available.

Summary

Multiple perpetrators and multiple agent characteristics (since agent specific available data are limited) must be considered to create a food defense plan that can reduce the risk from multiple vectors. Some mitigation measures are important for any type of risk, but there are targeted mitigation measures that can help address each individual type of risk.

METHODS OF VULNERABILITY ANALYSIS

Risk analysis for food safety focuses on known hazards that do occur with reasonable probability to analyze the impact, with a goal of creating mitigation measures to reduce the impact. The focus is on controls.

There are several methods to assess food safety risks, including the eye of an experienced practitioner. Hazard analysis critical control point (HACCP) is the global standard and is fundamentally based on operational risk management (ORM) principles.

The ORM analysis is usually displayed as a two-dimensional health risk assessment model as displayed in Figure 35.1 by the Food and Agricultural Organization of the United Nations (FAO, 1998).

For food defense, the math is very different as it focuses on vulnerability assessment rather than risk assessment. An event of intentional contamination has no normal likelihood of occurrence, and an unknown potential for occurrence but the consequences could be

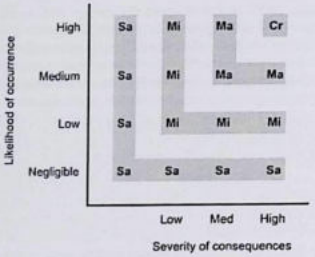

FIGURE 35.1 Example Operational Risk Management analysis, usually displayed in a two-dimensional health risk assessment model.

devastatingly off the chart. For this reason the analysis is on vulnerabilities in food defense, with a goal of creating mitigation measures to take an already low likelihood of occurrence and reduce it even further. The focus is on vulnerabilities instead of controls.

There are several methods to assess the vulnerabilities of a food production facility or system, including the eye of an experienced practitioner. CARVER + Shock, or a derivative of this method, is often used though there is as yet no apparent global standard.

CARVER + Shock

CARVER + Shock is a seven-attribute scoring method used to assess the most vulnerable operations in the food supply chain. It can be used across supply chain elements or within an individual production facility.

CARVER + Shock was adapted from a military targeting method used to select targets by giving those targets a preference score. Some targets are more hardened, others better guarded, some are easier to recognize, others easier to rebuild and some will cause more disruption.

Consider the possible military targets in Figure 35.2 and decide how you might score them low to high against Table 35.1 that lists the seven CARVER + Shock attributes.

When we use CARVER in the food industry, we score each unit operation (also known as process step) for each of the seven attributes. This results in a target preference score; if a "bad guy" were to target our operation, the higher scoring operations would make the most desirable targets.

FIGURE 35.2 Examples of possible military targets that could be scored from low to high against the seven CARVER + Shock attributes listed in Table 35.1.

Knowing *where* the best targets are helps you understand where you should focus mitigation measures. Knowing *why* some unit operations are the most preferred targets helps you understand what mitigation measures might be most effective in making those targets less desirable.

The goal of the CARVER analysis is a *ranking* of unit operations, not the actual score that is calculated, as a score is not transferable across a supply chain. The process steps with the highest ranking are the locations where you want to consider additional mitigation measures.

The CARVER analysis starts with a flow chart to describe the process flow within a portion of the supply chain such as your facility. A flow chart used for HACCP planning can usually be adopted for this purpose, but operations that would not be a food safety risk need to be added.

Scoring tables used for a CARVER analysis are often based on a catastrophic event on a national level. The scoring can be adjusted for an individual facility. The key factor is that the analysis helps you *differentiate* one unit operation from another.

Note: CARVER + Shock analysis often uses the term "nodes" for what we might call a unit operation or process step.

CARVER + Shock Software

The United States Food and Drug Administration (US FDA) has developed a software tool to assist in performing a CARVER + Shock analysis. It helps guide the user using an interview process, and does all the behind-the-scenes math that would be needed to score all of the unit operation (nodes).

TABLE 35.1 CARVER Attributes

C	Criticality	Do I hurt their economy, their health, their ability to fight?
A	Accessibility	How close? How easy to get to? Physical access?
R	Recuperability	How quickly can they rebuild?
V	Vulnerability	Can I damage the target? Is it hardened? Guarded?
E	Effect	Do they have backups or alternatives?
R	Recognizability	Can we recognize and find the target?
Plus	Shock	Psychological effects, like women and children?

Adopted from http://www.fda.gov/Food/FoodDefense/CARVER/default.htm#what is, What is CARVER + Shock, What Does C-A-R-V-E-R + Shock Mean?

To locate and download the free software, enter the address for US FDA Food Defense, www.fda.gov/fooddefense. Use the site SEARCH tool to search for "VULNERABILITY ASSESSMENT."

The software has three main components. The first is to outline the facility using a flow diagram. The second is to respond to a series of interview questions that is generated based on the flow diagram. The final component displays the ranked scores as well as some suggested mitigation measures.

[Hints (based on software for manufacturing, version 2):

1. Choose a representative operation or line. Many of the insights you gain from one analysis will be appropriate for other similar lines.
2. Keep the flow chart fairly simple. The number of interview questions is proportional to the number of chart elements. Group like operations in the same area together and score for the worst (i.e. all "blending" might be described as a single chart element).
3. Rename each chart element with a preceding numeral in order of the process flow. The interview questions are asked in "alphabetical" order of the chart element names, not in the sequence of the process flow.
4. Choose a representative product and answer the interview questions based on that product. Many of the insights you gain from one product will be appropriate for similar products.]

Alternative Assessment Methods

Guidance Documents and Checklists

There are many guidance documents and checklists now available that suggest mitigation measures that a food production facility should consider. At the time of this writing, most of these are suggestive in nature, and not required by law.

Exercising one (or several) of these checklists can identify vulnerabilities when you realize a suggested mitigation measure is not in use in your facility. While not as stringent as

a CARVER + Shock analysis, these checklists can still be beneficial on their own. This is because they have been created based on the results of numerous stringent vulnerability analyses, like CARVER.

Checklists are available for many industry segments and from many sources including government agencies and universities. You can search the internet for current checklists and guidance documents. There are several available from the US FDA and the United States Department of Agriculture (US DA): http://www.fda.gov/fooddefense and www.usda.gov. There is active research on new methods as well, so the tool set is evolving (Newkirk, 2010).

"Mini" CARVER + Shock

When analyzing entire industry segments and comparing one segment to another, there is some benefit in using all seven attributes in the CARVER + Shock method. Within a single organization, and certainly within a single facility, some of the attributes do not help to differentiate one unit operation from another, so they no longer add value to the analysis.

As an example, if there is a major contamination event at your facility, you either do or do not have backup manufacturing capability available (the EFFECT score). This is true regardless of what point of your operation is contaminated. So there is no benefit to you to scoring each unit operation for EFFECT; every process step would have the same score!

In fact, the second version of the US FDA CARVER + Shock software puts more emphasis on only four of the scoring criteria to simplify the interviews. This had no impact in the validity of the scores. The software scores are based primarily on CAV (Criticality, Accessibility and Vulnerability) with a little impact from R (Recuperability).

Taking this one step further within a single facility, Criticality and Recuperability will usually be scored the same or very similar. Since the goal is a *ranking* of unit operations, not a specific numerical score, using a score based only on AV (Accessibility, Vulnerability) will still provide a valid ranking of your most at risk operations.

As an example, the exercise tools used for Asian Pacific Economic Cooperation (APEC) Food Defense workshops use a simple two-attribute scoring system: Accessibility and Vulnerability (Periscope Consulting, 2010–2012).

Food AG Sector Criticality Assessment Tool (FASCAT)

The National Center for Food Protection and Defense (NCFPD) at the University of Minnesota developed an assessment tool that looks across entire systems of the food and agricultural sector. It is designed for national or state agencies to evaluate their many food operations to determine which types of operations might be more critical. It helps to retain equity in cross-sector critical system identification, using attributes like overall size and nature of distribution and the potential consequences of various threats (Hennessey, 2010; Food and Agriculture Sector-specific Plan, 2010).

A practitioner evaluating an individual factory and not a supply chain will find FASCAT of limited benefit as it is a systems analysis tool. A large producer with many facilities, especially facilities of different types, may find FASCAT or future derivative tools beneficial in determining where to emphasize their food defense efforts.

MSHARPP

MSHARPP is an Air Force targeting matrix to analyze likely terrorist targets. It is being evaluated by some countries for potential use in evaluating likely food industry targets (Air Force Antiterrorism Standards, 2005).

The scoring attributes have some similarity to CARVER, with the acronym standing for Mission, Symbolism, History, Accessibility, Recognizability, Population and Proximity.

The Eye of an Experienced Practitioner

After conducting numerous checklist-based assessments, workshops and CARVER + Shock analysis, there are some individuals who will have a very good "eye" for vulnerabilities and can develop a basic vulnerability assessment by walking through your operation. You might use an approach like this to get your food defense program started quickly.

If you use a food defense practitioner to give you a vulnerability assessment based on a tour and discussion to get your program going, you should get all recommendations in writing. It would be then prudent to consider continuing with a more detailed and systematic assessment to assist you in refining your program over time.

PREVENTIVE MEASURES

To reduce the risk of intentional contamination, the focus for industry is on mitigation measures that reduce the vulnerability of an attack (Khan et al., 2001). The focus is on *prevention*.

You may also hear the following terms used in the context of food defense: *detection*, *response* and *recovery*. These are the focus of government agencies and in some cases universities. *Detection* may be used to describe the detection of an intended attack or detection methods used to detect arcane contaminants within our foods. *Response* describes the laboratory capacity and information sharing as well as the regulatory and law enforcement work needed after a contamination event occurs. *Recovery* deals with restoring the ability of our facility or system to produce after a contamination, including the discarding of cleaning materials, decontamination of surfaces and restoration of consumer confidence.

While you may want to stay abreast of what government agencies are doing in the areas of detection, response and recovery, industry can have the most impact by helping to *prevent* a contamination. It is mitigation measures that make it more difficult to succeed that help to prevent an attack.

This section will focus on two different types of mitigation measures. First, there are *basic mitigation measures* that apply to nearly any food manufacturing facility. Second, there are additional *targeted mitigation measures* put in place after performing a vulnerability assessment (as described previously).

You can think of the basic mitigation measures like the prerequisite programs you put in place for your food safety program (GMPs, sanitation, etc.). They give you a good foundation and partially reduce your risk.

You can think of the targeted mitigation measures like the CCPs you put in place with an HACCP plan: they are specific to your particular vulnerabilities, and further reduce your risk.

Many of the mitigation measures recommended in food defense are already in place for other reasons. For example, good traceability and recall programs support food defense needs as well as food safety needs. Traceability and recall, as important as they are in food safety (*Food Safety Magazine*, 2010), are even more time critical in food defense as models show how many more lives could be harmed each day following a major intentional contamination.

But you may need to adjust these existing measures when you begin to "think like the bad guy." For example, your emergency evacuation procedures may need to address preventing others from entering your facility during the evacuation, not just getting everyone out.

Comparison with HACCP

While it is helpful to make a comparison between the *processes* of creating a HACCP plan with the *process* of creating a food defense plan, the details are quite different. In food defense, the mitigations are put in place to further reduce the *risk of occurrence* of events of exceedingly low probability, not to reduce the *impact* of events of known probability.

There is also some danger in thinking like an HACCP practitioner. Once you begin to rely on some control, like pasteurization, to reduce the *impact* of an intentional contamination, you might overlook the small risk of occurrence of a contamination *after* the pasteurizer and fail to further reduce that risk with appropriate mitigation measures. Even more easily, you might overlook the small risk of contamination upstream of the pasteurizer by a heat stable compound and fail to further reduce that risk.

Basic Mitigation Measures

Basic mitigation measures generally apply to all food establishments and should at least be considered by every practitioner of food defense. They include physical security measures like fences and door locks. They also include behavioral or procedural measures like developing employee awareness and auditing your performance. Many organizations have taken specific steps to deter intentional contamination such as tamper-evident seals on packaging.

While sophisticated physical measures can enhance your food defense program, overreliance on them can present its own danger. Even the most sophisticated locks have little value if employees intentionally jam them.

Besides being classified as physical and behavioral, basic mitigation measures are often classified in additional ways. These are artificial classifications used for administrative purposes. They organize similar topics together and help assure that a broad range of mitigation measures are included. The US FDA uses these classifications (US FDA, 2007):

- Management (systems)
- Human element – staff
- Human element – public
- Facility
- Operations

An alternative organization system (Periscope Consulting, 2010–2012) uses:

- Outside (perimeter) security
- Inside security
- Logistics, production, and storage security
- Management systems

It is beyond the scope of this chapter to provide an exhaustive list of potential mitigation measures. The food defense practitioner is encouraged to research sample plans, assessment checklists and guidance documents, including the FDA guidance document referenced above. The World Health Organization (WHO) also provides a helpful checklist (WHO, 2008).

Below, however, are a few examples of basic mitigation measures in each classification (Periscope Consulting, 2012).

Outside (Perimeter) Security

Outside (perimeter) security has to do with the walls, fences, doors, etc. that keep an attacker out of your operation. These are most effective against outsiders, but provide little protection from employees and other insiders.

There are two important considerations with perimeter security. The first consideration is the concept of "layered" security. You will see this in military history: an inner and outer city wall, for example. This means that not only is each perimeter barrier impenetrable, but that collectively they slow down an attacker, making it more likely that they are detected.

The second consideration is that you must ensure the barriers remain effective. If the fence is not inspected for damage, and underbrush is not cut away from the wall, or doors are not closed and locked, your defenses will not be effective.

Table 35.2 shows some sample mitigations to consider.

Inside Security

Inside security has to do with measures in place once an attacker has got inside, including lighting, cameras and internal access restrictions (zoning). These measures are effective against outsiders, but also provide protection from employees and other insiders.

There are two important considerations with inside security. The first consideration is the concept of detection. What can you do to make it easier to detect or recognize an attacker? Ideally this would be prior to an intentional contamination. But even detecting the contamination event has benefits, since you would not knowingly ship a contaminated product and thus would reduce the health impact.

The second consideration is to create additional *layers* of security, like the layers described in outside security. Zoning the facility, authorizing access only to individual work areas and putting in additional access controls (walled areas with locked doors) all reduce the risk of contamination. These measures do not prevent all people from accessing sensitive areas.

Table 35.3 shows some sample mitigations to consider.

Note: Closed circuit television (CCTV) is a popular security measure in many larger facilities. You should understand that cameras are primarily forensic in nature – providing information after the fact to prove what happened and capture the perpetrator. You must actively monitor any cameras and respond to unusual activities for them to be effective.

TABLE 35.2 Justifications for Exterior Defense

Mitigation Measures to Consider:	Reason for the Mitigation Measures:
Are the facility's grounds secured to prevent entry by unauthorized persons (e.g. by locked fence, wall, or other physical barriers)? Are there regular security patrols?	Physical barriers such as a fence, wall or water can be used to restrict access to the facility. Guard patrols may substitute when no physical barrier is practical or provide an additional layer of defense when used in addition to physical barriers.
Is there enough lighting outside the building to properly monitor the perimeter (fence) and the space between the perimeter and the manufacturing operation?	Good lighting at the perimeter reduces the time someone can spend getting into the facility without detection.
Are primary entrances like exterior doors and gates secured? Have the number of entrances been reduced to a minimum? For entrances that must remain open during operations, is there a procedure to secure them after hours? Are existing locks really used on a regular basis to keep the facility secure?	Having doors that lock is critical. The fewer access points (doors) the better. Just having locks available is not sufficient unless you can confirm those locks are being used.
Are operational entrances like loading dock doors locked or latched from the inside when not in use?	Some access points may be open to allow normal operations, but should be secured after hours/ weekends when the facility is not operating.

TABLE 35.3 Justifications for Interior Defense

Mitigation Measures to Consider:	Reason for the Mitigation Measures:
Is there adequate lighting throughout the facility? Is there an emergency lighting system in the facility?	Good lighting makes it more difficult to commit an intentional act without detection. It enhances the ability of CCTV (where used) to adequately record events.
Does your plant have monitored and recorded security cameras (CCTV)?	CCTV recordings are among the best ways to investigate a crime after it occurs. Recordings may help prove or disprove a threat of intentional contamination. While recorded CCTV can act as a deterrent, active monitoring of the CCTV improves the deterrent effect. Recordings should be tested from time to time so you know they are working correctly.
Is access restricted to production, storage and other sensitive areas? Are these restricted areas clearly marked? Is there a method to identify who is authorized to access these restricted areas?	Restricting access to sensitive areas provides a third layer of defense in addition to perimeter and building security. Creating zones in the facility and lists of approved persons can help you detect if only authorized persons are in an area. Color-coded uniform elements enhance this. Locked doors, keys or access cards can further protect sensitive areas.

Logistics, Production and Storage Security

Logistics, production and storage security is concerned with measures in place with materials stored in your facility as well as moving materials into and out of your facility. These measures are effective against any attacker and also help to extend protection up and down the food supply.

TABLE 35.4 Justifications for Logistics, Production and Storage Security

Mitigation Measures to Consider:	Reason for the Mitigation Measures:
When choosing suppliers for your packaging materials, labels, ingredients and raw materials, do you consider whether or not they have implemented food defense measures?	Contractual agreements, vendor/supplier surveys, audits and certification programs for your suppliers can be used to insure they have food defense measures comparable to yours.
Are trailers/trucks on the premises maintained under lock and/or tamper-evident seal when not being loaded or unloaded? (This includes during any short-term storage time before unloading or before shipping.)	Any storage outside your facility should be controlled much like you control your warehouse storage. If you temporarily hold trailers/trucks full of materials or finished product, they should be protected.
Are incoming shipments of raw materials, ingredients and finished products required to be sealed with tamper-evident or numbered seals (and documented in the shipping documents)? Are these seals verified prior to acceptance? Are suspicious alterations in the shipping documents investigated before acceptance?	Closed trailers should be sealed with tamper-evident seals to detect unauthorized access to the shipment. Seals should be numbered to reduce the risk of counterfeit. Seal numbers should be verified and the documents inspected for alteration for the same reason. Locks may be used in addition to seals to provide additional security, but locks alone do not provide tamper evidence.

There are two important considerations with logistics, production and storage security. The first consideration is the concept of "farm to fork." Because a contamination can occur anywhere in the supply chain, it is important to guard the entire supply chain. While you cannot directly control your suppliers, you can use your contractual agreements and supplier audits to help ensure that their food defense measures are comparable to your own.

The second consideration is the critical importance of ingredients. If key ingredients are contaminated on your site or at your supplier, you will inadvertently, deliberately and effectively mix those contaminated ingredients into large batches of food that result in many consumer portions affecting the health of many people. This is why extra scrutiny of suppliers, inspection and testing of incoming ingredients, and protected storage of ingredients becomes so important.

Table 35.4 shows some sample mitigations to consider.

Management Systems

Management systems are concerned with the policies, procedures and training you put in place to create and maintain a robust food defense program. These systems knit your program together into a cohesive whole and perpetuate the program over time.

There are two important considerations with management systems. The first is that your greatest risk is the people on your site. Careful selection and monitoring of all employees, contractors and temporary employees is important. Training and awareness for all employees is equally important – to promote vigilance and the reporting of unusual circumstances.

The second consideration is the importance of monitoring the program itself. Without surveys, inspections or audits, it is easy to overlook the measures you promised to implement. Without periodic review and update, your program will not improve as new best practices are established.

Table 35.5 shows some sample mitigations to consider.

TABLE 35.5 Justifications for Management Systems

Mitigation Measures to Consider:	Reason for the Mitigation Measures:
Are background checks conducted on all employees who will be working in sensitive operations?	Background checks of employment and criminal history can help reduce the risk that people with a negative history will have easy access to your product.
Are background checks conducted on all contractors (both permanent and seasonal) who will be working in sensitive operations?	If you conduct background checks of your full-time employees, you should also conduct similar checks of any other people with access to sensitive areas, whether they are part-time, temporary or contracted employees. Keep this in mind if you use contract services for work such as sanitation of your production equipment.
Do all plant employees receive training on security procedures as part of their orientation training?	All employees should have basic food defense awareness training that can be provided when they become employed. A refresher course once a year can improve their awareness.
Do you conduct regular food defense drills to test the effectiveness of your food defense measures?	Testing, inspections and audits help identify weaknesses in the plan, or shortcomings where you are not performing as your procedures indicate. This information may be used to strengthen your plan.

Targeted Mitigation Measures

In order to target mitigation measures at specific vulnerabilities, a vulnerability assessment should be completed. (See the section above on vulnerability assessments.) Based on those vulnerabilities (e.g., product access in transportation, etc.), additional targeted mitigation measures (e.g., locks and seals, etc.) can be added to your food defense plan.

Because the vulnerability assessment looks at unique characteristics of your process, the targeted mitigation measures are often specific and process related. The mitigations you choose will usually be related to the reason that location was deemed more vulnerable. For example, a blending operation is especially vulnerable because the blend tank is completely uncovered; therefore you may decide that a good mitigation measure is to add a lid. But if that measure is not practical, you could reduce the vulnerability in other ways, such as adding additional video recording or supervision of that location.

Creating zones within your facility can have special importance for the sensitive areas highlighted by your vulnerability assessment. In the case of the vulnerable blend tank just mentioned, you can install additional access controls to the specific area and designate that area only for your most trusted employees to work in.

If only your most trusted employees have access to your most sensitive work areas, you are well protected. If you want to further reduce your risk, you can consider a "buddy system" where no single employee is permitted in the area alone, as well as video recording those areas. These measures can help further reduce your risk in this special case.

Mitigation lists and databases are worth considerating. The CARVER + Shock software previously mentioned displays some sample mitigations on its results screen. The self-assessment checklists previously mentioned can be scoured for suggestions; they are

available by searching online. There are also mitigation strategies databases from the US FDA and the US DA available online. These databases let you look up sample mitigation strategies based on your selection of processing operation.

Mitigation Databases

- US FDA: http://www.accessdata.fda.gov/scripts/fooddefensemitigationstrategies/Card.cfm?card=55
- US DA: http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/Risk_Mitigation_Tool/index.asp

(Alternatively these databases can be accessed by visiting www.fda.gov or www.usda.gov and searching for "food defense mitigation.")

Regulatory Requirements

There are few government regulations dealing with food defense. Much of what is published is in the form of guidance documents recommending best practices, rather than mandatory requirements.

If you operate in or export to the United States, you should familiarize yourself with the BioTerrorism Act (BT Act) and the Food Safety Modernization Act (FSMA). The BT Act requires the registration of companies supplying to and an advance notification of shipments prior to their arrival in the USA. FSMA requires the FDA to address intentional contamination; future regulations to support this law will likely require food defense plans and a consideration of mitigation measures similar to those outlined in this chapter.

In China, the Certification and Accreditation Administration (CNCA) established under the Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) has put forth guidance and regulation requiring food defense plans for exporting companies.

The UK and Germany have robust food defense initiatives. Canada has its own study of vulnerability assessment methods. This is by no means an exhaustive list, but an indication of the global progress of food defense initiatives.

You should inquire about the food defense requirements in your own country. This is an area that will probably see a great deal of development in the next few years.

HOW TO MANAGE THE CASE

Case studies and table-top exercises can reinforce your knowledge and allow you to practice your skills. There are excellent case studies and exercises available at no cost.

The US FDA has created a set of five exercises: Food Related Emergency Exercise Bundle (FREE-B). They include scenarios based on both intentional and unintentional contamination events. While these are targeted towards agency use, they include the provision for the private sector to participate, and they may be instructive on their own. They are freely available at www.fda.gov/fooddefense (search for FREE-B.)

The following case studies focus on recall and were based on food safety incidents. Recall is also important to food defense, and two of the three studies have a section entitled "What if Contamination were Intentional?"

FOOD RECALL CASE STUDIES

(http://foodindustrycenter.umn.edu/EducationalResources/index.htm)

1. Westland/Hallmark 2008 Beef Recall: A Case Study by the Food Industry Center (.pdf)
   Seltzer, J., Rush, J. and Kinsey, J. The Food Industry Center, University of Minnesota. January 2010.
2. Natural Selection 2006 *E. coli* Recall of Fresh Spinach: A Case Study by the Food Industry Center (.pdf)
   Seltzer, J., Rush, J. and Kinsey, J. The Food Industry Center, University of Minnesota. October 2009.
   Natural Selection Case Study Learning Module
   Problem Set Instructions (.pdf)
   Problem Set Instructor's Guide (.pdf)
   Problem Set Data (.xls)
3. Castleberry's 2007 Botulism Recall: A Case Study by the Food Industry Center (.pdf)
   Seltzer, J., Rush, J. and Kinsey, J. The Food Industry Center, University of Minnesota. August 2008.

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Periscope Consulting, 2012. The excerpts of mitigation tables are used with permission from Periscope Consulting, taken from their Food Defense Plan Builder Tool, copyright 2012.

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CHAPTER

36

Effective Leadership

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INTRODUCTION

What makes a "good boss" a good manager? This is a question that has always intrigued leadership and management theorists. According to Drucker and Maciariello (2009), managers bear responsibility for their contribution and that of their staff to the achievement of the company's objectives. Managers form an elite with social and ethical responsibility. Among the most important abilities of a manager are decisiveness, a systematic approach to decisions on human resources and communication skills. The manager of the future, according to Drucker and Maciariello, must be a good integrator whose primary goal is to acquire and to satisfy customers. As long ago as 2002 Drucker was putting the focus of modern management on the person and calling marketing and innovations the general functions of every enterprise.

For Malik (2007), management is "the transformation of resources into results." Every manager must perform five tasks: provide objectives, organize, take decisions, monitor and develop people. Managers have seven tools available to help them: meetings, written

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communication, job design and assignment control, personal working methods, budgeting, performance appraisal and "systematic waste disposal." In contrast to other authors, Malik insists that management can be learned and is the same everywhere. For him, management is communication, because the right communication brings the right solutions. Management is not a primarily economic system, but rather a system of social behavior which is about not only maximizing profits but also balancing and integrating different interests (Malik, 2008).

Porter (1985) sees the primary task of a manager as developing successful competitive strategies. He has written numerous publications on strategic management. For him, a competitive strategy is essential to a company's profitability and survival. He has developed various and now globally recognized methods, such as structural analysis and the value chain for the analysis of industries and competitors.

According to Sprenger (2002), in most companies mistrust rather than trust prevails. Trust is often vehemently claimed, but seldom lived. He is convinced that trust can be employed as a control mechanism in an organization. The first step and the key to a new relationship of trust consists in trusting others and thereby making oneself vulnerable. Sprenger (2007) also points out that the direct supervisor often exercises the greatest demotivating influence on staff. He talks of the "myth of motivation," characterized by the paradox according to which all motivation necessarily leads to demotivation, and thus praise, rewards, bribery, threats and punishment are sins of personnel management. For him, incentives have the effect of making workers not more highly motivated, but instead ever more unsatisfied. To avoid demotivation, then, a good manager should thus concentrate on intrinsic rather than extrinsic motivation.

In his book *Die Fünfte Disziplin*, Senge (2008) calls for a fundamental reorientation towards an integrated understanding of the world and of self. The orientation to linear cause–effect chains and the concentration on unconnected individual elements are inadequate for the highly complex systems that determine our modern world. At the heart of all management therefore is the learning organization, the foundation of which is systems thinking – the fifth dimension (the other four dimensions being personal mastery, mental models, a shared vision and team learning). It is oriented to interrelationships and considers individual elements relationally, i.e. it always puts them in relation with all other elements of the system. "We tend to blame outside circumstances for our problems. Systems thinking shows us there is no 'outside'; that you and the causes of your problems are part of a single system."

An interesting dimension of management is revealed by Covey (1989, 2005) in his best-seller, *The 7 Habits of Highly Effective People*. He describes seven ways to effectiveness in which moral principles such as fairness and reliability are a prerequisite for good management. He states that man is not a being conditioned by incentives, but has the freedom to have meaningful reactions. A good manager spends a lot of time discovering, planning and facilitating new possibilities. He makes the win–win paradigm a guiding principle for his action, can communicate simply and listen empathetically. Leadership personalities are thus people who understand themselves as part of a whole, synergistic and trailblazers for the next generation.

Most authors are agreed, however, that successful leadership personalities must have a particular mix and manifestation of various qualities that are specifically aligned to the expectations and objectives of the company. It is also assumed today that leadership can

be learned, although putting it into practice is not always easy or comfortable. Talent is of course helpful, allowing what has been learned to be exploited to the full. It is also not disputed that good leadership cannot be exercised off the cuff but is instead a separate job description that must meet the same standards as every other job exercised professionally.

THEORIES ON THE SUBJECT OF LEADERSHIP

Various models and theories of leadership have been put forward both to explain leadership success and to deliver recommendations for action to improve leadership practice or to solve problems. Even the practice of promoting executives primarily according to their specialist knowledge, still common in some organizations today, has not proven its worth.

One of the most influential theories that has accompanied and furthered the development of leadership skills arose as long ago as the 1930s. It was the concept of leadership styles. Kurt Lewin, for instance, described the authoritarian, the cooperative and the laissez-faire style. This was followed by numerous variations, such as employee-oriented or task-oriented, participative, bureaucratic, etc. One of the best known theories to arise, which is still used in many leadership seminars today, is the "situational leadership" theory of Hersey and Blanchard (Pelz, 2004). However, there is as yet no sustainable empirical evidence that any particular leadership style is more successful in practice than another. Leadership styles have such a high degree of abstraction that they can at most be applied as a (subsequent) description of behavior.

Equally, there is as yet no empirical evidence that particular personality characteristics are associated with leadership success. The study by Harvard University (Nohira, 2003) can be cited as an example. It reveals that personal characteristics such as "visionary," "energetic," "enterprising," "passionate," "power-conscious" or "modest," "empathetic," "nurturing," "self-assurance," etc. have virtually no influence on leadership success. What is much more important is the specific observable behavior of the manager, as in the empirically validated model of the transformational leader developed by Bass and Avolio (1994). According to them, a successful manager must perform the following tasks:

- Be a role model and inspire trust in order to gain loyalty (idealized influence).
- Provide motivation with challenging, meaningful targets and thereby enhance the willingness to engage (inspirational motivation).
- Stimulate independence and creativity (intellectual stimulation).
- Encourage employees individually so that they are able to continue to develop their personal skills and strengths (individualized consideration).

In summary, it can be stated that research on the subject of leadership has so far been unable to supply a convincing concept and, despite countless publications, is still in its infancy. Many studies have determined and explained characteristics and skills of the ideal manager and, while the answers may be correct and stimulate discussion, the opinion held by many researchers that the results can be applied with general validity continues to be an illusion. Malik (2007) puts it succinctly: "The ideal managers could well be as they are presented in the studies. It is not the answers that are wrong; it is the question."

MODELS OF EFFECTIVE LEADERSHIP

It was held for a long time that leadership was a phenomenon that could not be explained; it was simply a gifting of particular "charismatic personalities" (Weber, 1922). The consequence of this was that for many decades there was no systematic development of managers in companies. It was thought that the "right" person would come through in any case (Yukl, 2006). This view, which is still sometimes put forward today, is not surprising, given that the age of industrialization to the postwar period is dominated by many charismatic leadership personalities. In recent years, experience in the theory and practice of management development has led to a new trend (Carter et al., 2005; Thomas, 2008): first, the significance of theories and models has diminished markedly, and second, attempts are being made to define leadership ability by a limited number of company-specific skills that are operationalized through behavioral descriptions that are as precise as possible (Hale, 2004). Thus managerial competence can now be summarized as the sum of company-specific behavioral expectations that may differ from one company to another and from one hierarchy level to another. The challenge associated with the search for managers is thus to arrive at the most precise possible description of these behavioral expectations. If, for instance, a technology company might seek a person who has the behavioral expectation of a "willingness to take risks," the manager should be able regularly to analyze the environment in respect of possible risks and hazards, assume responsibility for risks that actually come about or create a positive, constructive culture of a willingness to take risks.

Building models comes with the danger that circumstances are simplified so much that they no longer reflect the complexity of the reality. Krönung (2007) rightly speaks of the "management illusion" of many management "gurus" who supply simplified success models that are not appropriate to the complexity of entrepreneurial action and allow mechanistically thinking managers to believe that they can simply copy these models. Nevertheless, a model of effective leadership is described below. This model is to be understood not as a management instruction but rather as a guide to diffuse management jargon and as a basis for discussion of the definition of behavioral expectations. The model of effective leadership does not lay any claim to completeness.

The model in Figure 36.1 is read from the inside out. The core of effective leadership is formed by the areas of quality, business culture and innovation. For these areas to be developed requires skills, namely leadership, management and entrepreneurial skills. Leadership is about enhancing effectiveness (do the right things), management about enhancing efficiency (do the things right) and entrepreneurship about developing the company (do new things). There are methods, instruments and processes for each of these elements. To enhance effectiveness, for instance, one needs instruments of strategic management, to enhance efficiency controlling instruments or quality management and to develop the company innovation management or human resource management. The model is surrounded by the "Deming cycle" (plan, do, check, act), which is intended to highlight that the different areas first interact and second require constant improvement (the *kaizen* principle). As already mentioned, the purpose of this simplified model is to show that the technical occupational skills of a leadership personality should primarily be the leadership skills that can be trained and learned. The individual areas are investigated in more detail in the following sections.

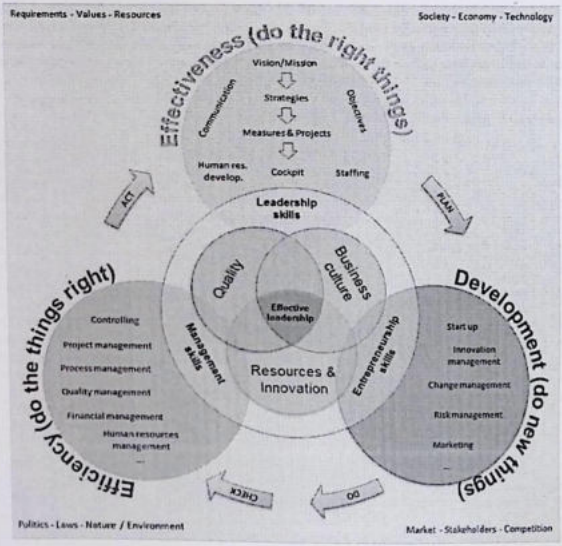

FIGURE 36.1 Model of effective leadership.

Quality, Culture, Innovation

At the heart of effective leadership are three areas: quality, the business culture and innovation. These three areas are a matter for top management and should not be delegated; they are among the fundamental leadership tasks. The first, quality, is a prerequisite if customers are to be acquired and retained in the long term. With the customer the company generates the turnover that is essential for survival. The second element, the business culture, influences the efficiency and effectiveness of the employees. Various studies have shown that there is a relationship between business culture and productivity. That is why many companies, such as Google, attach great value to a positive business culture. A lot is undertaken in order to ensure that employees feel comfortable in the work environment, because greater productivity strengthens the market position of a company. Finally, the

third area, innovation, ensures the future development of the enterprise, aptly summed up by the widely disseminated slogan, "Innovate or die." It should be noted that a distinction is made between innovation and innovation management. The former is a basic attitude that is firmly anchored in the corporate culture, while the latter is the "managing" or organization of the innovation. The same applies for quality and quality management.

Leadership and Strategic Management

Leadership has become an increasingly popular term in management discussions over recent years. Leadership is often used as a synonym for management. There is as little crystal-clear differentiation between these concepts as there is a recognized definition of the individual terms. In the literature the words are sometimes used distinctively, sometimes to mean the same things. To give an example, House et al. (1999, p. 184) defines leadership as "...the ability of an individual to influence, motivate, and enable others to contribute toward the effectiveness and success of the organization...," while Drucker (2006) states tersely: "The only definition of a leader is someone who has followers." It is not the object of this chapter to open a definitional discussion of these terms. Nevertheless, a distinction is made below between leadership and management to the extent that leadership is understood to take place at strategic level (doing the right things) and management to take place at operational level (doing the things right). Covey (2005) provides an apt and interesting analogy: imagine that the objective of a company is to cross a jungle as quickly as possible. The task of the manager consists in organizing the team so that it moves forward efficiently and reaches the destination as quickly as possible and without problems. The leader, on the other hand, looks for the highest tree, climbs up and ascertains whether they are in the right jungle.

Leadership is usually associated with charismatic personalities who have forward-looking visions, whose vital energy is used almost solely to achieve the visions, who are single minded and who know how to enthuse and mobilize a group of people for their idea. Leaders are conspicuous by their farsightedness, their perseverance and their ability to establish and maintain networks. They always keep the long-term objectives in sight and know how to motivate and drive people forward even in difficult situations. There have in the past been personalities to whom considerable leadership skills have been ascribed: in the political sphere these may include people such as Mahatma Gandhi, Winston Churchill and Martin Luther King; in the scientific field names such as Albert Einstein and Robert Oppenheimer would be mentioned; and in business many entrepreneurs such as Werner von Siemens, Henry Ford, Steve Jobs and Bill Gates have shaped notions of successful leadership.

These usually very personal characteristics of a leader are difficult to describe and explain. It is hardly surprising, therefore, that these abilities have in the past been dismissed as innate talent. The strategic management approach does indeed supply possibilities of operationalization. Kaplan and Norton (2009) call for a systematic procedure according to a fixed process in which the strategy is to be developed on the basis of mission, vision and values. From the strategy are derived goals, success criteria and finally measures and projects. Instruments such as the strategy map or balanced scorecard help to maintain an overview. The authors insist both that the goals are measurable and that the operational level is separated from the strategic.

A possible systematic process with some disseminating instruments of strategic management might look something like the following (Figure 36.2).

FIGURE 36.2 Strategic process.

The starting point of the strategic process is always an in-depth analysis of the current situation of the enterprise. This is where questions such as "Who are we?" and "Where do we stand?" are answered. There are numerous instruments for this phase, such as the stakeholder analysis, the PESTLE analysis, analysis of the industry structure, portfolio analysis or Porter's value chain. In the second phase the future options and their consequences for the company are assessed. This entails discussing developmental and mega trends and then elaborating possible future strategies (e.g. best case, base case and worst case). The third phase, the actual development of the strategy, begins with the SWOT analysis, which serves as a basis for formulating the vision, the mission and the strategies. Finally, in the implementation and controlling phase, the strategies are used to derive action plans and projects that go into a leadership cockpit and help managers to achieve the formulated objectives.

The results of the strategic process, i.e. the vision and the strategies, objectives and measures derived from it, form the basis of a good leader. This basis must be periodically controlled and adapted: the vision at least every 3–10 years, the strategy every 2–3 years and the measures monthly or quarterly. The next step, then, is to mobilize the employees for the set objectives. A good leader thus needs good communication skills and integrative abilities. Experience has shown that implementation critically depends on actively engaging the employees, or at least management level, throughout the whole process. This increases considerably the comprehension of the initial situation, the commitment and the identification with the elaborated objectives and hence the willingness to implement the proposed measures. Furthermore, during this participative process one can integrate team-building elements that in turn foster the development of a shared corporate culture.

The greatest danger in this phase is that the results obtained will fall victim to a bureaucratic exercise and waste away their existence on paper in some drawer somewhere. If this is to be prevented, three things are required: first, leadership strength, second, the operationalization of the measures in the form of concrete project tasks and, third, a controlling ystem. The controlling can be realized by means of a leadership cockpit, for instance, that tegrates the balanced scorecard approach of Kaplan and Norton (1992).

anagement

Management traces its origins to the organization of armies and the principle of command and obedience. Today, management is considered not as an isolated science but rather as a collection of techniques, methods and processes (Drucker, 2002). To enable better differentiation of the leadership tasks arising, the model of effective leadership (cf. Figure 36.1) distinguishes between management and leadership. It proposes that management is primarily about techniques for increasing efficiency, i.e. the question of how the tasks arising can be performed as quickly as possible and in sufficient quality. Examples of these tasks include controlling, quality management, marketing and project management. By way of elucidation, the following two sections deal briefly with two central elements, namely quality and project management.

Quality Management

The list of publications on the subject of quality management is just as long as the list on the subject of leadership. Quality management is usually understood as an integral part of

leadership. In his book on quality management, Crosby (2000) notes that quality problems are a sign of poor management. He rightly goes on to point out that the introduction of quality management is a full-time job. Harvey and Green (2000) distinguish five formal and non-area-specific dimensions: quality as perfection (absence of defects); as fitness for purpose (the extent to which a product fulfills its purpose); as value for money (adequate compensation); as transformation (a qualitative change in the sense of further development); or as an exception (quality is distinctive, e.g. excellence or conformity with standards). Although such differentiations may impress, the problem with them is that they often describe quality as an entirety of characteristics of an entity or understand it as a thing, a characteristic or even an object. There is agreement, by contrast, that quality must be a part of corporate culture or, as Imboden (2004) notes, that quality is not achieved until quality is no longer talked about but is instead lived.

For quality to become part of corporate culture, quality management must be implemented as a continuous process (cf. Figure 36.3).

The starting point for any quality management is a vision that is shared by all employees and the associated strategies as well as clearly defined quality objectives. It also requires sufficient resources and tried-and-tested work processes. As already mentioned, quality cannot be delegated, but quality management can. The updating of the work processes, the organization of quality audits or the tracking of checklists and documents are among the activities that can be delegated. The initiation and maintenance of the quality spiral as shown in Figure 36.3, however, is emphatically a matter for the managing director. Only through continuous planning (plan), implementation (do), control (check) and correction (act) can a constant improvement in quality be achieved (Deming, 1986).

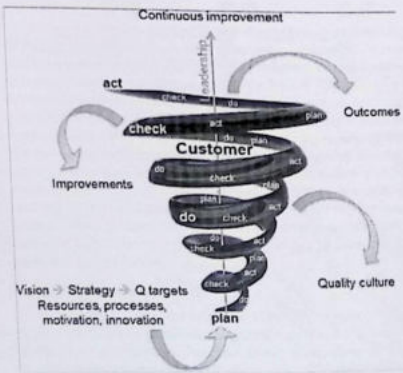

FIGURE 36.3 Quality management as a continuous process.

The significance of quality as a concept has undergone an evolution over the last 80 years. The understanding of quality has developed from the purely technical, i.e. "the machine must function," approach, through the customer perspective brought by Edwards W. Deming (1986) and Juran (1995) to excellence, where the needs of all stakeholders are to be satisfied. There is scarcely a job description at middle or senior management level that does not demand quality management skills. Good quality management knowledge and experience have now become indispensable for effective leadership. There is a great deal of literature on the subject that describes the methods, techniques, tips and tricks and the various implementation concepts. Ultimately, however, every leadership personality must gain their own experience if they are to be credible and professional leaders.

Project Management

Given the rising complexity of tasks, professional project management is increasingly becoming a factor in the success of a company. Project management may be defined with different words, depending on the source, but there is widespread unanimity in terms of its content. Figure 36.4 shows a possible subdivision of project management into five phases.

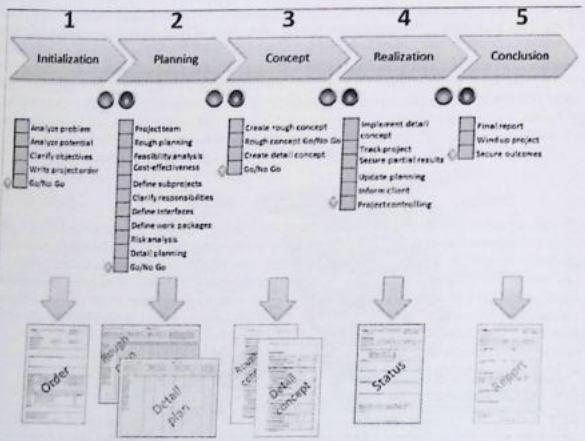

FIGURE 36.4 Project management in five phases.

In the first phase the initial situation is analyzed, the project objectives are determined and the project order is clarified with the project client. The second phase covers the planning. The project team is determined, the responsibilities clarified, the interfaces defined and the rough and detail plans created. In the next phase the rough concept and then the detail concept are created. The detail concept clarifies the feasibility, highlights the individual steps of possible implementation, sets out the resource requirement and draws attention to possible implementation problems. In the fourth phase the detail concept is implemented and finally, in the fifth phase, the concluding activities are performed, culminating in a final report.

The CHAOS study from the Standish Group (www.standishgroup.com) deals regularly with the success and failure factors in IT projects. It is among the best known and most important long-term studies in the project management field, with more than 40,000 individual projects having been scientifically examined since 1994. The Chaos Report reveals figures such as, for instance, that 70% of all IT projects fail, that the average cost overrun is 189% or that the project cancellation rate is 31.1%. Although on the one hand the high figures for the project cancelation rate and the average cost overrun are doubted by many, on the other hand the estimated number of unreported cases is high because many projects that failed according to their original definition are subsequently "sexed up," so that many project managers consider the figures to be perfectly correct from their experience. The fact is, nevertheless, that poor project management can lead to high wastage of resources for businesses and that it therefore makes absolute sense to train employees in project management.

Entrepreneurship

"Entrepreneurship is, firstly, the exploitation of business opportunities and the creative design of the business process in an organization or a phase of business change and, secondly, a scientific sub-discipline of business administration. Entrepreneurship research is concentrated primarily on scientific issues relating to the founder personality and environmental factors and on research into strategies and organizational forms that entrepreneurs make use of in order to build successful organizations" (translation from the German, *Springer Gabler Wirtschaftslexikon*, 2012). In the model of effective leadership (cf. Figure 36.1) the entrepreneurship skills are understood as the former, i.e. the exploitation of business opportunities and the creative design of innovation and human resource management processes. It deals in particular with the question of how the company can be developed further and less with the question of the foundation of the company. For a good leader, innovation, change, risk, information and human resource management (HRM) are key instruments and methods. The two central elements are innovation management and HRM. These are explored briefly below.

Innovation Management

According to the three-phase innovation process developed by Thom and Ritz (cf. Figure 36.5), innovation management is the design and control of the process, from the generation of ideas to the economic realization of an innovation. It should be noted that innovation management does not ultimately generate any innovations, but instead

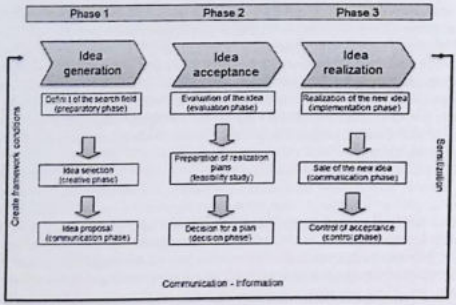

FIGURE 36.5 Innovation process according to Thom and Ritz (2002).

encourages the complex process of idea generation, idea acceptance and idea realization by providing suitable framework conditions.

The first phase, idea generation, is primarily about generating ideas in the first place. These ideas do not necessarily need to be unique and attention grabbing. The majority of innovations are in fact unspectacular optimizations of processes, products or services. The biggest challenge for leadership in this phase lies in creating an environment that allows and encourages creativity. This can also be assisted by various thinking and creativity techniques. Once an idea has been generated, the next hurdle is of a more communicative nature. Some more introverted or less articulate staff report trouble in getting their ideas across. For a good manager, the principle in this phase is that there are no bad ideas, i.e. stock phrases such as "That won't be possible" or "We don't have the budget for that" or "Unfortunately we don't have the time" should be avoided as much as possible during this stage of innovation management. It is worth taking every idea at least to the second phase, the idea acceptance phase. This is where the idea is thoroughly evaluated, realization options are discussed and a decision is taken on whether the idea will be realized. In the last phase, the idea is realized, communicated and controlled in terms of whether it exists on the market.

Experience has shown that innovation killers include disinterest or destructive feedback from the supervisor, getting neither praise nor recognition, fear of being blamed and an unwillingness to take risks. Internal resistance should not be underestimated either, because innovation also means destruction: old patterns of behavior must be abandoned in order to make space for the new. Innovation management is a complex and not to be underestimated task of a good managing director. Unfortunately, and particularly in small and medium-sized enterprises, innovation is still not managed systematically. Innovations arise almost by chance, only when problems occur or customers' wishes change.

Human Resource Management

The core task of human resource management (HRM) is to provide human resources and to use them appropriately. In the last few decades the working world has realized that the productivity, motivation and creativity of human resources are a decisive competitive advantage. This is demonstrated, for example, in the fact that in progressive businesses the HR director sits on the board and HRM takes on ever greater significance.

The core elements of HRM are summarized in Figure 36.6. Strategic human resource management is a meta-function, while HR controlling, HR marketing and the organization of human resource management are cross-departmental functions.

Before personnel are recruited, the HR requirement must first be determined. This can be done by asking the following question: How many employees with what skills will probably be required at which locations when and for how long so that the tasks in the company can be managed effectively and efficiently? Seventy-four percent of managers consider attracting good employees to be their biggest challenge (KMPG, 2001). HR recruitment consists in procuring personnel (searching for potential employees) and selecting personnel (choosing the "right" people). There are several selection instruments (e.g. tests, assessment centers, etc.) that can supply the manager with the foundation for making decisions. The final decision, however, cannot be derived from any instrument. The first working day is an important day for both the new recruit and the company, because first impressions count. It is worthwhile planning this day in minute detail.

Human resource development (HRD) is not just about bringing the requirements profiles of the posts into the best possible harmony with the skills profiles of the post-holders, but also about retaining the "marketability" of the employee. Various development instruments

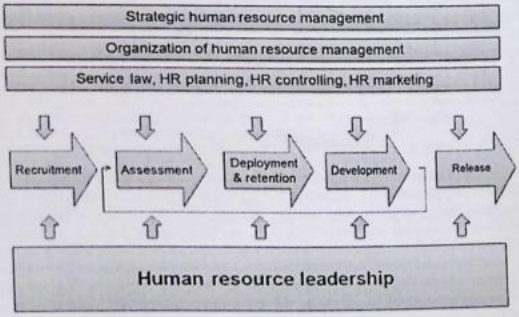

FIGURE 36.6 Human resource management, based on Thom (2001, p. 118).

are available: on-the-job measures, e.g. job enlargement, job enrichment, job rotation or coaching; off-the-job measures, such as conferences, seminars, further training; or along-the-job measures, e.g. career planning, employee appraisals and development assessments.

Retaining personnel is probably one of the most difficult leadership tasks. It requires promoting the commitment and job satisfaction of the employee. A variety of instruments are employed in an attempt to tie good workers to the institution. Motivation plays a critical role in this regard. Motivation research assumes that extrinsic incentive systems (e.g. pay, bonuses) are less effective in the long term than intrinsic motivation factors (e.g. interesting tasks, assumption of responsibility). For that reason many companies today are considering which "motivation mix" is the right one.

The release of human resources, whether voluntary or not, is another key leadership task. Normally jobs are shed when there is an excess of human resources. The problems associated with shedding personnel have been widely discussed, particularly in the last few years when markets have been liberalized and the weakness of the economy is forcing many companies to restructure. Before redundancies are announced, all available means (e.g. flexible working-time models, outplacements, management buyouts, internal transfers, short-time working, etc.) should be exhausted. As with recruitment, the last day at work is important for both the company and the person leaving, because the last impression that the employee takes with him will influence his future attitude towards the employer. Any departure must be preceded by at least one exit interview that gives the person leaving an opportunity to ask any questions that may still be relevant for him and to discuss any future plans.

"Able to go, but happy to stay" is a very apt summary of the challenge in HRM. Although employees have the opportunity to leave at any time, they are happy to remain. Behind this seemingly banal statement are many different considerations. For the working population, what is important is to remain employable. Retaining employability is a high-priority task of the supervisor, who should give the employee the opportunity to develop continuously. Since the mobility of the employee also rises as his employability on the job market improves, the associated risk of the employee going elsewhere presents the employer with a dilemma. This quandary can only be resolved with the second part of the above sentence: "...but happy to stay." The supervisor must create a working environment so that his employees are always content with their work and happy to remain.

FINAL REMARKS

Effective leadership is possible, but it places demands on leaders. This is because every leadership situation is always bounded by its context and requires creative and sensitive reactions. Effective leadership can be learned, but this entails a considerable cost. Leadership is not actually just something that can be done off the cuff; professional leadership is an independent occupation that one must spend a considerable amount of time learning and experiencing. Talent is of course helpful and allows what has been learned to be utilized. Effective leadership thus means applying the right mix of leadership, management and entrepreneurship skills in the right place and at the right time in order to achieve the set company objectives and in order to motivate and continue developing the employees.

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CHAPTER

37

Human Factors in Food Safety Management

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OUTLINE

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INTRODUCTION

In the past three decades, management of food safety has taken a leap forward and many systems and various technological or managerial tools have been devised to improve the safety of the food supply. The progress and development in food safety management have touched all segments of society, both in the private and public sectors. Box 37.1 shows some of the developments that have taken place at national or international level.

In the governmental sectors, these range from reconsidering the process of decision-making in risk management, strengthening of food laws and regulations, monitoring the safety of the food supply, surveillance of foodborne diseases, and promoting education of

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BOX 37.1

MAJOR DEVELOPMENTS IN FOOD SAFETY MANAGEMENT

- Increased general awareness about food safety driven by national and international media.
- Greater knowledge of pathogens, chemical contaminants and technologies and increased scientific and technical know-how.
- Development and emergence of high-performing food technologies and analytical methods.
- Increased availability of epidemiological and scientific data on foodborne pathogens and chemical contaminants.
- Improvement of the procedures for risk assessment and risk management.
- Strengthening of national legislation (standards, codes of practices), and its enforcement (inspection, monitoring).
- Strengthening of the international requirements (Codex Alimentarius, Agreement on the Application of the Sanitary and Phytosanitary Measures of the World Trade Organisation, ISO 22000).
- Increased preventive measures by the primary industry.
- Improvements in quality assurance, including application of the HACCP system.
- Strengthening of the foodborne disease and food contamination surveillance systems, alerts, traceability and incident management.
- Increased training of professionals specifically in food safety (governments, food industry and food service sector).
- Recognition of the importance of risk perception and good risk communication.
- Educational campaigns for consumers and the general public, including more informative labeling.
- Improved waste management, protection of the environment and of water and sanitation facilities.

consumers and food handlers. In the food industry, there have also been major changes, including the advance of the hazard analysis and critical control point (HACCP) system and its validation, traceability and recall, and the development of technologies and analytical methods. Consumer awareness has also increased and nowadays consumers are more actively expressing their expectations, preferences and values. Different factors have contributed to these developments; a description of these factors goes beyond the scope of this chapter and the reader is referred elsewhere (Motarjemi, in press).

In spite of the laudable efforts for improving food safety management, one area still has not received the attention which it deserves; yet, it is at the center of all the systems and tools that the society has devised to manage food safety and is a precondition for their successful implementation. That area is the role of people, from workers, managers, scientists to top management of businesses. None of the systems or controls used for the management of food safety will be effective without the proficient actions of those who have to implement them. Thus, in all sectors, from the legislator, inspectors, workers in the field or

in a processing line, to the domestic or professional food handlers, management of people should be a central and integral part of food safety management. Management commitment is a *conditio sine qua non* for this. The question is then: what is management commitment and how does it impact on food safety.

The importance of management commitment is often mentioned in different text books and technical literature without going into the depth of the subject. The ISO Standard 22000 provides some insight into this subject. It explains that:

> *Top management shall provide evidence of its commitment to the development and implementation of the food safety management system and to continually improving its effectiveness by:*
> *a) showing food safety is supported by the business objectives of the organization,*
> *b) communicating to the organization the importance of meeting the requirements of this International Standard [referring to ISO 22000 standard], any statutory and regulatory requirements, as well as customer requirements relating to food safety,*
> *c) establishing the food safety policy,*
> *d) conducting management reviews, and*
> *e) ensuring the availability of resources.*

While the above requirements are a good start in explaining what is expected from management, they do not convey the day-to-day behavior that is expected from the management, as they have been developed for auditing purposes. Yet, the management of food safety relies heavily on the "quality of management" and good people management is an integral part of this.

Additionally, management of food safety requires sound judgment, objectivity in decision-making, competent managers and employees, etc., i.e. many intangible criteria which should be part of the soft skills of managers and which cannot be ticked off on a checklist. It is a question of company culture and leadership. With regard to the ISO 22000 requirements on business objectives mentioned above, there have been cases where food safety has been associated with company objectives; however, these have been less than effective, as managers have often been complacent with food safety in order to meet company production objectives and to receive their associated bonus.

Management's commitment to food safety requires first an understanding of the concept of food safety management and second, creating an organizational culture, structure and working conditions which enable and empower personnel in charge of food safety to meet their responsibilities. This is particularly important in the food business environment where there are risks with raw materials, processes, use of equipment or technologies, practices of staff and where change in any of these can impact the others. Additionally, experience from the food industry has shown that many executives and managers ignore or misperceive fundamental food safety principles, and these false perceptions can cause failures in decision-making (Table 37.1).

An analysis of organizational incidents, or "near-miss" situations, and how these take place illustrates the importance of management commitment, of an organizational culture and of the human factor and proficient food safety management. What follows is an application of the concept of Swiss cheese to food safety put forward by James Reason (1997).

TABLE 37.1 Common Misperceptions and Correction in Management of Food Businesses

Misperceptions	Correction
Food safety management is in conflict with economic interests	– There is no business without food safety – A good management of food safety can promote the business and its long-term sustainability
Food safety management is addressing food safety problems	Food safety management is about taking necessary measures to "prevent" food safety problems (including confirming that the measures are effective (validation) and are implemented correctly (verification)!
Our products are safe, as we have never had any incident	A past record of safety is no guarantee for the future, especially given the improved epidemiological tools now available
Our products are safe because the tests were negative	End-product testing is not evidence of microbial safety but merely a confirmation of the effectiveness of the food safety management system. Safety is based on the solidity of preventive measures in place.
Regulatory requirements are impediments to the business	Regulatory requirements and their enforcement will: – Facilitate fair trade and a healthy competitive environment – Ensure that all stakeholders in the food chain fulfill their role; this decreases potential risks with suppliers and their raw material – Provide guidance to businesses, in particular small and less developed businesses, on matters related to food safety, such as norms needed in designing and validating food safety assurance systems – Increase the confidence of consumers in the food supply and reassure consumers that commercial products are safe and meet the nationally and/or internationally agreed safety and quality standards

SWISS CHEESE CONCEPT

As illustrated in Figure 37.1, assuming that a potential hazard and its risk (i.e. the likelihood of its occurrence and the severity of its consequences) are known, a defense mechanism, or a series of such mechanisms, is devised to prevent the hazard from materializing. In food safety, these defenses are referred to as "control measures." In food safety assurance systems, a series of control measures are usually recommended. These can be grouped under three lines of defense: (1) basic good hygienic practices, (2) an HACCP system and (3) verification measures (Motarjemi, in press, Chapters 1, 31 and 32 in this book).

When an incident occurs, it is usually the result of a gap, or a combination of gaps, in these defenses. These gaps may be a shortcoming or an error in the design of the food safety plan or a fault in its execution. Usually, in good food safety management, a single gap in any of these defense mechanisms should not lead to an incident as the second or third line of defense should be able to detect the gap and allow for corrective actions before the contaminated or defective product reaches the market and/or consumers are exposed. Such a situation, i.e. where a failure takes place but an incident is prevented due to early detection and corrective action, is referred to as a "near-miss" situation. However, where food safety management is poor, there will be more holes in the system and the eventual alignment of these gaps increases the likelihood of an incident. Thus the more holes there are, the more

FIGURE 37.1 Swiss cheese model according to James Reason. The figure illustrates that incidents occur as a combination of a number of gaps in the food safety controls.

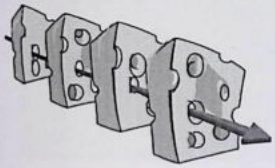

FIGURE 37.2 Figure showing that an incident occurs as a result of gaps in the defense systems. *Adapted from Reason 1997.*

the risk of an incident. The concept is referred to as the "Swiss cheese" model (Reason 1997) (Figure 37.2)

It is for this very reason that any gap in the food safety assurance system, even if *per se* not significant to produce an incident, should be addressed immediately. In other words, any detail can have its importance and should not be dismissed or neglected. Many accidents in aviation, healthcare, petrochemicals, etc., are the result of mishaps which were perceived as details. A notorious example is the case of the Concorde. The plane crashed due to a small piece of metal on the runway from which the Concorde was supposed to take off. The metal had fallen from another plane. Similar situations have occurred in the food industry. A case in point is the major outbreak that occurred in Israel and was associated with infant formula imported from Germany. The product was deficient in vitamin B1 (thiamine). Consequently, a reported 15 babies suffered from damage to their nervous system and two died. The primary failure was an error in product formulation, but a second failure was in the verification of the composition of the product before its release, which itself was due to a number of other errors. Similarly, in another incident of infant formula contaminated with the isopropylthioxanthone (ITX), a combination of gaps in the regulatory requirements, suppliers' test and practice, and customer's awareness of risks were the origin of the problem.

ROOT CAUSE OF FAILURES

A second concept that needs to be understood is the root cause of failures, which can be divided into active or latent failures (Reason 1995 and 1997) (Figure 37.3).

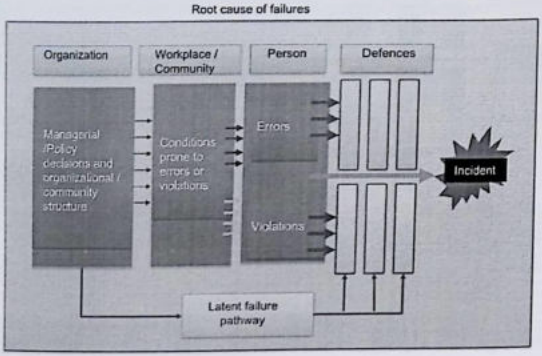

FIGURE 37.3 Figure showing the different levels and types of failures leading to an incident (Reason 1995).

Human Factors

Behind any control measure, there are people who have to implement those measures or verify that controls are implemented correctly. These can, for instance, be a worker on the line packing food, a farmer milking, an operator in the food manufacturing industry monitoring the temperature recorder, a truck driver who has to manage the temperature during transportation, a food handler who has to wash his hands before preparing food, or wash his knife and cutting board between raw and cooked foods, etc. Their failure to perform the control measures is referred to as active failures since their actions will have a direct and immediate bearing on the safety of products (Table 37.2). These are the types of failures that, in case of an incident or a "near-miss" situation, are normally investigated. In due course, the employee responsible is reprimanded, or worse fired, and the investigation ends at this point. The same process and relationship also exist between regulatory authorities and a food establishment that is incriminated for an incident. Once the vehicle of the outbreak, i.e. the implicated food item, and the error are determined, and in due course the products are recalled, generally the investigation is closed. However, it is important to pursue the investigation and understand the reason for the failure of the person(s) in charge of the control measure.

Active failures come in different forms. They may be classified by their causes or by their consequences. In the latter, the failures are described in terms of the proximal action contributing to the mishap. For instance, the consequence of an error such as the use of a wrong thermocouple may be transgressing the "critical limit," or an error in the handling of the computer system may lead to the erroneous release of a defective and blocked product.

TABLE 37.2 Frequent Active Failures in an Industrial Setting and during Food Preparation

Frequently Observed Failures in an Industrial Setting	Examples of Failures During Food Preparation
Failures in supplier management	Failure in respecting hand hygiene
Failures in design and maintenance of equipment	Food handlers handling food when suffering from a transmissible illness
Failures in hazard identification	Failure to wash utensils/equipment and allowing cross-contamination of ready-to-eat food
Failures in establishing "critical limits"	Failure to cook or refrigerate, thus allowing time–temperature abuse of food and subsequent survival and growth of microorganisms to a disease-causing level
Errors in GMP implementation	Improper use of recipients and contamination of food with chemicals/detergents
CCP monitoring failure	Failure to information consumers about essential food safety matters
Failure in applying the right corrective actions	
Human error	
Error during a change process	

Causal classification of human failures makes assumptions on the psychological mechanism implicated in the error. They are grouped by:

- *Failures in intention or "mistakes"*: These are errors in planning or problem-solving and are often related to scientific and technical misjudgment, leading to a plan which is inadequate in achieving the intended outcome. An example would be when the HACCP team decides a wrong "critical limit."
- *Execution failures such as slips, lapses*: These are failures where the plan is adequate but where the actions are not implemented as intended. There may be different psychological reasons, such as failure in attention, memory, recognition, etc.

Human errors are to be differentiated from violations. Violations are deviations from the rules, procedures and standards. They relate to deliberate action and intention. Violations also fall under different groups, depending on the incentives and reasons for violations, and range from routine or optimizing violations, such as taking a shortcut and not following the procedures, to necessary violations. The latter is when the rules and procedures are inappropriate, and violation of the rules is the only way to get the job done. Sometimes, the violation may also be the result of lack of knowledge of the rules on the part of operators. For instance, in many countries, the small or less developed businesses may simply be ignorant of the legislation and the violation of the law is not always an intentional non-compliance. Therefore, while as a principle the violation of food safety rules should not be tolerated, the cause of these should be determined and the decisions on penalties, if any, should be taken on a case-by-case basis.

Working Conditions and Environment

If root cause analysis of incidents or near misses is carried out, it can be noted that often human failures are due to the working environment and conditions. Some examples of conditions that may lead to a person committing an error or violating the rules are given in Table 37.3.

TABLE 37.3 Examples of Conditions Prone to Error or Violation

Conditions Leading to a an Error	Conditions Leading to a Violation
Unfamiliarity with the task	Misperception of the risks associated with hazards
Mismatch between the training and the education of the person with the task required	Belief that a bad outcome will not happen
Time shortage, work overload	Lack of tools, time pressure
Information overload or contradictory information	Ambiguous or apparently meaningless rules, or rules which are not applicable to the local conditions
Poor human–system or human–equipment interface	Manifest lack of organizational safety culture, or of a culture which encourages taking risks
Complex tasks or situations	Management not following the rules, or perceived lack of management's care and concern
Mental state: monotony of task or boredom, fatigue, stress	Inadequate training
Hostile environment, e.g. crowded, noisy environment	Unclear instructions
Poor instructions, procedures and definition of responsibilities	Professional attitude hostile to procedures
Poor communication or language barriers	Work conditions promoting conflict of interests
Lack of adequate scientific and technical tools or systems for performing a task	Conflicts and poor people management discouraging involvement, responsibility and ownership
Change in routine	

(Adapted from Reason 1995).

Responsibility of Management

The above-mentioned situations (Tables 37.2 and 37.3) often result from management decisions. The failure of the management to create conditions optimum for managing food safety is referred to as latent failures. The consequences of these decisions, taken at higher level in the organizational and managerial structure, may not be directly perceptible and they may not have an immediate impact on food safety, but they will create conditions favorable for non-compliance or accidents.

Latent failures have been the cause of numerous accidents in the petrochemical, transport and financial industries. While there is an abundance of reports on foodborne illnesses in the scientific literature and media, few provide in-depth information on the latent conditions leading to failures. Investigations often fail to examine these factors. A case in point is a report on an outbreak of foodborne illness associated with peanut butter in the United States. While the report provides extensive information on the epidemiological aspect of the outbreak, with regard to its cause the report is very short and gives the reader the impression that contamination of industrially produced peanut butter with *Salmonella* is to be expected. There is no information that could increase our understanding of the latent failures (CDC 2007). As a consequence, a few years later the incident repeated itself in another establishment.

Examples of the managerial decisions that lead to poor working conditions are:

1. Failing to provide the necessary policies, organizational structure and culture, adequate financial qualified human resources, or suitable equipment;
2. Appointing managers who do not have credibility or competence matching their responsibility;

3. Management behavior in contradicting, or in violating, the policies and instructions; or
4. Requiring impossible tasks which force the staff to take risky shortcuts or to violate the rules.

To alleviate the workload, but also to increase efficiency and consistency in the execution of tasks, industry has increasingly resorted to "systems," be it automation of equipment or development of checklists, for ensuring systematic coverage or handling of operations. However, it is the behavioral experts' view that while facilitating the systematic execution of tasks, automation or other systems do not fully overcome problems associated with human error or mistakes in the judgment of the scientific and technical data. Where there is too much reliance on systems, they may either inhibit critical thinking or cause boredom. As such, in the food industry, we can often see that the HACCP system is applied mechanically, without fully understanding its purpose. At times, the system is applied without adequate input from qualified food safety experts, and as a consequence the HACCP study and subsequent plan are not effective for addressing food safety.

Management style can also be the cause of failures in food safety management. A repressive or non-motivating environment may be deleterious to open and constructive working conditions and may deter employees from reporting potential problems, which helps in the early detection of gaps and in remedial action. Micro-management prevents the sense of responsibility and ownership, as well as bottom-up initiative. Unclear definition of responsibilities, expectations and procedures can create conflicts which may lead either to loss of efforts and resources, or to motivation in the execution of tasks. Therefore, the management of a company bears the ultimate responsibilities in ensuring food safety. In case of incidents, their eventual failure in providing this needs to be investigated.

Thus, *management commitment* should, among others, provide the organizational structure and culture and working conditions adequate for a professional, objective and transparent management of food safety.

The organizational culture should enable employees to openly report issues and provide them with the opportunity to see that their constraints are adequately and fairly addressed. An open and fair organizational culture is fundamental for motivation of the staff and the core of food safety management.

The organizational structure should ensure a process of decision-making based on expertise and should prevent situations of conflict of interest, for instance where audits and investigation of incidents or near-miss situations are carried out or supervised by the same person as the one who is responsible for the design and implementation of the food safety management system. It is also important that any near miss or incident be thoroughly investigated and a root cause analysis be conducted. This means that not only the primary cause of the failure, e.g. cross-contamination in a restaurant, error in a thermocouple in industry, use of contaminated water in agriculture, is examined, but the latent failures, i.e. the working conditions and management failures are also determined. In the above hypothetical cases, one may discover that the manager did not provide adequate training to the food handler or there was a lack of knives and cutting boards, the consequence of which was that the workers took a shortcut to meet the demands of the restaurant. In a food industry environment, a thermocouple may be misused because the personnel in maintenance may not appreciate the importance of the temperature for the safety of the product, or a transport

company may fail to observe cold storage or the risk of cross-contamination during the transport of its product. To take an example at the agricultural level, an agriculture policy may have a direct impact on the use of safe water or fertilizers. In the case of a cholera epidemic in sub-Saharan Africa, it was seen that an increase in the price of the fertilizers led farmers to use contaminated manure for irrigation of their vegetables.

From the above it follows that proficient people management is a fundamental element of food safety management. In this respect, the factors that will influence employees in meeting their responsibilities and performing their tasks can be divided into three types of factors (WHO 2000):

1. *Predisposing factors*: These entail providing employees with the technical and scientific knowledge that they need to (a) perceive the risks associated with their job, (b) understand control measures needed to control the risks, and (c) impart the skills and competence that they need to perform their task.
2. *Enabling factors*: These consist of all infrastructures that are required for individuals to carry out the required tasks or to adopt the desired behavior. These factors can be of (a) a logistic nature such as adapted tools and equipment, having easy access to hand-washing facilities, or rapid cooling food, or (b) managerial nature such as providing the staff with the authority they need to perform their job, time for the execution of their task, etc.
3. *Reinforcing factors*: These relate to all those cultural values of the organization that encourage the individual to adopt the behavior in question, e.g. influence of peers. Management commitment and management practices are fundamental to this factor.

MANAGEMENT COMMITMENT

From the above it can be concluded that *management commitment* starts with management understanding that managers must have exemplary behavior, and stand behind the policies on a daily basis. In doing so, management must:

- Realize that any non-compliance or complacency at the higher level of management will set a bad example for the entire organization and will have serious repercussions on the entire organization, i.e. it will have a multiplying effect;
- Apply zero tolerance for leaders who violate their policies, and adapt penalties proportionate to the gravity of violations and the hierarchical level of the leaders;
- Understand what food safety means and requires in terms of measures, and realize that food safety management is not a question of the number of incidents experienced, consumer complaints received, or the results of end-product testing, but is about the measures put in place to meet the set standards, on an everyday basis;
- Ensure that their policies are not a declaration of good intentions but a description of ongoing practices, and
- Provide leadership by prioritizing food safety at levels of decision-making and ensuring that managers implement measures flawlessly.

Additionally, management commitment is founded on good people management, including:

- Ensuring that people are competent for their job and that appointments for positions are made transparently and based on merit;
- Ensuring that staff unequivocally understand their responsibility and their authority, that they have a clear job description and that there is an alignment between their responsibility and their authority;
- Providing staff necessary training and coaching according to responsibility so that they can meet what is expected from them;
- Foreseeing a succession plan and back-up positions;
- Providing necessary resources, including infrastructure, streamlined organizational structure and clear procedures so that implementation of necessary measures becomes feasible;
- Showing that the work is valued and motivating, and driving job satisfaction and providing staff with a career path;
- Creating an environment and organizational culture tolerable towards human error and allowing staff to report their impediments and the reason for their non-compliance. A fear culture and repressive style of management are banned for the benefit of early detection and the management of gaps and non-compliances;
- Being open-minded, frank with their own shortcomings or failures and investigating the incidents, or near misses, until the latent failures are determined and addressed; and
- Protecting staff who report non-compliance and whistleblowers from any retaliation.

CONCLUSIONS

A responsible food management, with a specific consideration for human factors, is central to the performance of any organization, be it a governmental institution or a business, and it is fundamental to food safety. No technological development can replace the competence and skills of managers in meeting their responsibilities. These include: good judgment in decision-making, skills in communication, training, but above all motivating and coaching staff in performing their tasks.

Management commitment is about creating an organizational culture and working conditions where the management supports the staff, so that each can become a leader in their own field and managers can exercise exemplary behavior. Good management of food safety should aspire to flawless execution; to achieve this, employees must be competent in their job, motivated and at all times vigilant.

This also means that, over and above monitoring critical limits and verifying the implementation of prerequisite programs as proposed in most food safety assurance systems, any gap or near-miss situation, such as transgression of critical limits or non-compliance practices, needs to be investigated, and their root cause, including managerial failures, determined and addressed (Figure 37.4).

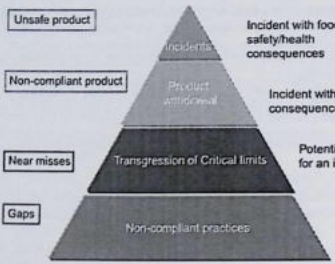

FIGURE 37.4 Every failure can be a potential for an incident. Monitoring the failures, understanding their cause, communicating and acting upon them as early as possible can reduce the risk of incidents.

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CHAPTER

38

Assessment of Food Safety Management Systems

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INTRODUCTION

At first, it is important to clarify the use of the term *assessment* in this chapter. For the purpose of this book, the term assessment refers to an industry or governmental activity to verify that the food safety management system is implemented correctly and effectively, and is maintained. The primary reason for assessing a food safety management system is to establish whether a food business has the ability to consistently produce, manufacture or distribute "safe" food and to ascertain that the food safety management system provides adequate assurance.

In industry, the term is better known as *audits*, which itself is used in a variety of ways (audit of systems, processes and procedures, projects, laboratories, manufacturing,

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organizations and their management) and in different contexts such as financial, environmental or quality management.

In the framework of the enforcement of laws and regulations, governmental authorities are also led to verify the compliance[1] of industry practices with laws and regulatory requirements. This activity is usually referred to as *inspection*. In the past, inspections consisted of a snap-shot visit for checking compliance with good hygienic practice. With advances of HACCP and the development of an integrated approach to food safety management, the procedures and scope for inspection have also evolved. Today, it consists of a more comprehensive procedure similar to industry audits, referred to as regulatory audits.

Therefore, while the industry and regulatory audits differ in the purpose for which they are carried out and the authority that carries out the task, in essence they use similar processes and methods; and in both cases they are carried out with the aim of verifying compliance with a given standard. Therefore, this chapter will cover food safety audits from the perspective of both governments and industry. As will be seen later, auditing processes may also be used for reasons other than verifying compliance, such as evaluating the capability of a supplier to provide a raw material according to given safety specifications, evaluating equivalence in control measures in case of export–import certification, or evaluating the status of a factory or a business. Therefore, for the purpose of this chapter, the more neutral term of assessment is used.

In simple terms, we can distinguish different types of food safety assessments:

1. Internal assessments carried out by industry (part of self-control); and
2. External assessments carried out by either
   a. Regulatory agencies (known as inspection); or
   b. Third party assessments by customers or certification bodies.

BACKGROUND

During the past few decades, the management of food safety has greatly evolved in both the food industry sector and the governmental agencies (see Chapter 1). This change has also made an impact on the role and responsibilities of the industry versus regulatory authorities, and on the importance that is given to inspection or audits in food safety management.

While in the past the onus of safety was on governments, i.e. detecting an unsafe marketed product, with advances of the HACCP system in the last two to three decades, the responsibility for ensuring food safety and providing evidence for this has been shifted to industry. This means that the industry is to provide evidence that it is aware of the risks associated with its products and is taking the necessary preventive measures to control these.

Over and above establishing clear food safety laws, standards and regulations, the role of the regulatory authorities is to verify that the industry is complying with these; the assessment of the food safety management systems of industry is part of this verification. In industry, assessments are also used as part of self-control to verify that food safety management is effectively implemented and maintained.

[1]Compliance means that products and/or practices meet regulatory requirements.

In other words, regulatory or internal assessments are not for the purpose of controlling hazards but for confirming that control/preventive measures are implemented correctly and are effective. Governmental or supplier inspection cannot be a measure to ensure safety, but a measure to verify that the processor is implementing necessary control measures and complying with safety standards and other requirements to ensure food safety.

There are many books on the general aspects of assessments (audits or inspection) and the reader is referred to these sources, in particular to the ISO Standard ISO/TS 22003:2007 (see "Further Reading"). The objective of this chapter is not necessarily to turn the reader into a food safety assessor, but to highlight some essential points in an industry or regulatory assessment.

DEFINITION AND PURPOSE

As mentioned before, an assessment is an evaluation to verify the actual practices against set standards and codes. The purpose of an assessment may vary. It can include:

- Confirming the compliance (or identifying the divergence) with the internal rules and/or regulatory requirements. This is perhaps one of the most frequent objectives of assessments.
- Evaluating the ability of a supplier or a contractor to produce, manufacture or transport a food according to the set requirements. This can happen when choosing a supplier, a contract manufacturer or even purchasing a new business.
- Investigating violations or incidents, for example investigating a recurring CCP-related violation, employee complaints, alerts by internal whistleblowers, frequent consumer complaints or a fully fledged incident.
- Obtaining a certificate of assurance for customers that their requirements are met. This may be with customers nationally or internationally.
- Benchmarking or analyzing gaps in view of identifying the need for improvement, including the need for technical assistance, training and guidance on competences and/or improving the infrastructure (equipment, design of premises), etc. This can happen when a new factory or business is purchased, or when companies are merged. Experience has shown that small or medium-sized businesses are often not resourceful enough to know the regulations and that they often learn about these when they are visited by an inspector or assessed by a customer or the representative of a certification body. In such a situation, to avoid conflict of interest it is important that those involved in guiding the business are not the same individuals who will also assess for compliance.

SCOPE AND FREQUENCY OF ASSESSMENTS

As mentioned before, the scope and content of assessments have also evolved with time. Some years ago, depending on the stage of the food chain, such assessments were limited to verifying compliance with good fishery, agriculture, farming, manufacturing, transport or hygienic practices. Later, they were developed to include assessment of HACCP. Today, with the advance of an integrated approach to food safety management, particularly the development of ISO 22000, assessments include a variety of elements, from prerequisite

programs (e.g. GMP) to HACCP, supplier management, product development, training, communication with other stakeholders of the food chain and regulatory authorities, and incident and crisis management. In this chapter, an appeal is made to give particular attention to management of people and to management commitment (see Chapter 37) since the people in a company, from the general manager to the workers on the line, play a key role in food safety management.

The decision on the scope and frequency of assessments or inspection will depend on a number of considerations, in particular whether the assessment is a first assessment or a follow-up assessment. Whether a full or partial assessment is carried out will depend on the original purpose of the assessment. For example, partial assessments might be appropriate for closing out non-compliances, for investigatory purposes after an incident or where a previous assessment has confirmed that a sound system is in place.

Classification of risks is an important criterion for prioritizing and deciding on the frequency, i.e. having more frequent assessments at higher risk premises or suppliers of high risk material. The following information can be considered in the classification of risks and in deciding on the frequency and scope of the assessments:

- The potential hazards known to be associated with the product and/or process;
- The history or level of previous compliance;
- The state of the food safety management systems and other management systems that may be in place, e.g. ISO quality management systems and certification, TQM as well as the level of in-house expertise;
- Other considerations such as processing methods, intended use and population at risk, size of operation (e.g. number of employees, volume of production, turnover), type of products and processes, complexity of operation, quantity of product affected by the raw material used, market or trade requirements.

Similarly, the following could be considered in the scope of an assessment:

- Whether it is an initial assessment or follow-up;
- Size of operation, e.g. number of employees, volume of production, turnover;
- Type of products and processes;
- Complexity of operation;
- Level of in-house expertise;
- Amount of available resources;
- Presence of management systems, e.g. ISO quality management systems, TQM;
- Results of previous assessments; and
- Population at risk.

A change in the system (process, formulation, etc.), or the aftermath of a natural accident or disaster, e.g. fire, flood etc., can also justify an assessment or an inspection. As mentioned previously, assessments may also be triggered as results of a previous food safety incident.

Subsequent frequencies for assessments and their scope can be considered in the light of the findings.

Table 38.1 presents the elements that could be the subject of a food safety assessment and presents some highlights of issues to be considered.

TABLE 38.1 Elements of Food Safety Management Systems and Some Highlights of Issues to be Assessed

Elements to be Assessed	Examples of Issues to be Considered During the Assessment
Management commitment, resources and management of people	This consists of ensuring that: – Management is aware of their responsibilities as listed below and set the example by following company policies. – A food safety policy is established and is communicated to all levels of the organization. – The food safety management system is described in an accessible language and is available at all levels. – The food safety management structure guarantees integrity and transparency. – A food safety leader is appointed with clear definition of his/her responsibilities and authority. – The food safety leader reports directly or has direct access to the top management of the company; he/she can report non-compliances without negative repercussions on his/her career. – The food safety management team is supported by an adequate infrastructure, equipment and material, and resources proportionate to its responsibilities and according to its scope of activities. – The responsibilities, interactions, reporting system and authorities are clear and mapped out. – The members of the team are knowledgeable, have integrity and are competent for their job. They receive training commensurate with their responsibilities and they are updated with development in the food safety areas, e.g. incidents, emerging risks, etc. – Periodic audits are used to verify the well functioning of the team as well as to provide an overview of the effective implementation of the food safety management system. – The system of corporate governance guarantees independence of audits and corrective actions, root cause investigation of gaps and incidents and their reporting to the higher management. – A system of whistleblowing is established and personnel grievances as related to their work are followed up, investigated objectively and corrective actions are implemented. – The management is open to providing necessary resources or investment where needed, supporting testing of products, making recalls in case of incidents. – The management gives priority to consumer health over business interests. – The crisis manager, if different from the food safety team leader, is also identified and competent for his/her job. – All important decisions, instructions, reports of non-compliance or possible risks, follow-up and closing out of issues are well recorded and documented.
Product traceability, recall and crisis management, incident management	– An effective traceability system is in place at the factory. – It is possible to trace every consumer unit. – It is possible to identify all finished products manufactured from a given consignment of incoming material, including rework. – Traceability exercises are carried out regularly, at least once a year to ensure that the traceability system is effective. – A formal written procedure for product recall is available and the system is tested periodically. – A formal early warning, crisis management procedure and crisis committee are in place and the role and responsibilities of the members are specified. – Incidents are thoroughly investigated, root causes established and lessons learned from the incidents are disseminated across the organization to prevent their recurrence. – Senior management is engaged in incident debriefs and preventive action.

(Continued)

TABLE 38.1 (Continued)

Elements to be Assessed	Examples of Issues to be Considered During the Assessment
Raw materials and supplier management	– Supplier management is in place: suppliers are selected and approved based on their capability to ensure safety of the raw material and are periodically audited and monitored. – Suppliers are aware of the intended use of their products and of the regulatory requirements of the country where their product will be used or these are indicated in the specifications. – Supplier auditors have the appropriate experience and training to enable them to carry out a risk-based assessment at the supplier's manufacturing location. – Raw materials (ingredients and packaging) have clear specifications and are signed to indicate agreement between the supplier and customer. – Certificates of analysis (where used) come from a laboratory that is able to competently test and samples are appropriately handled. The sensitivity of methods used are adequate for meeting the safety and regulatory requirements
Good hygienic practice (GHP)	– Incoming raw materials are inspected for their integrity authenticity and final goods are stored safely. – Warehouse management is in place, e.g. first in first out (FIFO) is respected, and raw material is properly labeled – Pest management is effective. – Adequate security measures are foreseen and visitors are screened for both health and security. – Housekeeping issues are respected, e.g. where applicable tools are labeled, chemicals are kept in a safe and secure location, identification (e.g. color coding) systems are used for tools, 5S system is used for maintaining order. – Training of employees is comprehensive and validated for effectiveness of learning; personal health and hygienic behavior protocols are observed as verification that knowledge is being reinforced in the facility. Employee facilities for hygiene, such as lockers, bench barrier entryways (where needed) and hand-washing facilities are readily available. – Basic rules of food hygiene are also respected in canteens. – Buildings (including drains) are designed to minimize risks and meet hygienic requirements. Doors and windows are appropriately closed and screened. – Zoning (including air flow and the need of a filter) and flow of people are managed to minimize risk of cross-contamination throughout the facility. – Hygienic design of equipment and maintenance programs, including calibration of equipment, are followed rigorously according to the state of the art. – Food grade lubricants are used. – Industrial services are managed to maintain a safe production environment. – Cleaning procedures are correctly laid out, are valid and the implementation is verified. – Rejected raw material or final products are correctly handled and disposed of. – In case of maintenance work, the impact of the work is considered in risk and control measures. – Foreign matters are prevented through various measures and policies, such as glass-free policy, jewelry-free policy. – Consumers', customers' and regulatory authorities' complaints are properly recorded and investigated and followed up in a timely manner. – Products are correctly labeled (content, visibility, clarity) and where consumers' practice is critical for safety, the communication of safety information is validated for accuracy and clarity. – Before launching or modifying any product, it is ensured that regulatory or safety requirements are met. – Examination of the area, such as security measures for the premises and screening of visitors and subcontractors for security as well as their health status.

(Continued)

TABLE 38.1 (Continued)

Elements to be Assessed	Examples of Issues to be Considered During the Assessment
HACCP system and implementation	– Adequacy of the hazard analysis. All potential hazards are adequately identified and evaluated, and if this evaluation indicates the risk is insignificant, is this validated by data? – Validity of control measures, i.e. the control measures eliminate or reduce the hazards to acceptable levels. – CCPs are identified, and critical limits are identified and operating within food safety and regulatory limits. Evidence should be obtained as to how these were determined, including the expertise used and any supportive document to validate these. – Evidence should be obtained that the monitoring of the critical limits indicates adequate control of the hazards. The adequacy of training in relation to personnel working at the CCPs and engaged in monitoring should also be considered, e.g. whether suitable instructions have been given to such personnel, and their role in relation to appropriate and timely actions. – An assessment as to whether the corrective actions would adequately restore control and are adequate to prevent an unsafe product from reaching the consumer. – An assessment of what, how, when and by whom the verification procedures have been undertaken, and whether these are adequate and effective. This may be indicated by an assessment of the validation data, sampling results, internal and external audit documentation as well as the frequency and thoroughness of all verification activities. The assessor should also consider whether changes, deficiencies in the HACCP plan, new emerging hazards, etc., are adequately provided for. Assessors should consider what actions are taken as a result of inadequacies in the HACCP plan or its prerequisites, or any other non-conformity[a]. – Additionally, assessors should consider whether records and documents are complete and in order. Where records indicate an issue or non-compliance, how these have been followed up. – The assessors should also evaluate the adequacy of the implementation, i.e. whether the HACCP plan and the prerequisites for HACCP have actually been implemented in the food business, maintained and are functioning correctly. – Root cause of CCP violations, or near miss investigations are carried out and short- and long-term corrective measures are in place.
Verification activities[a]	– Internal audits are carried out regularly by a competent team; they cover all levels and aspects of the operations and unsatisfactory reports are subject to an investigation and root cause analysis. – Consumer complaint handling system is valid and is working effectively, i.e. personnel are trained in what to do, how to ask questions and they have the ability to connect different sets of information to detect a pattern or a cluster of non-compliances. – Suppliers are audited according to a risk-based program by a competent team. The results of the supplier audits, including the monitoring activities of the suppliers (e.g. their end-product testing), are considered in the hazard analysis and maintenance of the HACCP plan. – The assessment of GHP and equipment maintenance programs is carried out on a regular basis. – The system for recording consumer complaints is verified and it is ensured that it is working effectively. – The pathogen and environmental monitoring as well as raw- and end-product testing are carried out effectively and results are regularly reviewed and used for the validation of the GHP program, and also for the maintenance of the HACCP system. – Laboratories carrying out chemical and microbial testing are audited for good laboratory practice and are accredited.

(Continued)

TABLE 38.1 (Continued)

Elements to be Assessed	Examples of Issues to be Considered During the Assessment
Verification activities[b]	– HACCP teams receive the results of various verification activities. – Hazard analyses are reviewed based on the verification data and where necessary, e.g. a non-compliance or a change, the HACCP plan is revised accordingly. – A release procedure is in place for finished products and raw materials. – Senior management reviews the status of the food safety program, including reports of audits, incidents, consumer complaints or other non-compliances reported by the staff. – Periodic traceability, recall and crisis management exercises, or other verifications, are carried out in an effective manner.

[a]*Conformity means that activities are carried out according to the established procedures.*
[b]*This is part of the HACCP system; however, as described in Chapter 1, to highlight the importance of verification activities for the validation of the hazard analysis and maintenance of HACCP, they are mentioned separately.*

COMPETENCE OF ASSESSORS

The validity of assessments depends to a great extent on the competencies of assessors and their integrity. Food safety being a multifaceted subject, a carefully selected team of experts will be required. The composition of this team and the expertise of the members will be all the more important as the responsibility for protecting public health is significant. In any case, for a full scope assessment, the following competences, skills and qualifications need to be considered:

- The technical competence;
- The skills in assessing and investigating (audit skills);
- The interpersonal skills and values, i.e. communications skills, diplomacy, resilience, patience, self-discipline and open mindedness. In addition they need to be curious and analytical in how they should interpret what they observe;
- Finally, a good assessment requires the cooperation and openness of the assessment entity in providing truthful information.

Other factors such as time and financial constraints and availability of documents also play a significant role. With regard to technical knowledge, the following are needed at the very least:

- Understanding the basic hygienic requirements, their relevance in supporting safe food production, and experience in assessing them;
- Knowledge of laws, regulations, standards and general codes of hygiene and/or criteria for the specific category of products;
- Knowledge of relevant industry products and processes (including past failures in the category);
- Knowledge of the HACCP system and its application, including:
  - The identification and assessment of potential hazards which may occur during food production, handling, preparation, storage and transportation, including biological, chemical and physical hazards;

- The ability to assess the effectiveness of control measures (validation) of the HACCP plan and its verification;
- Understanding the role of the human factor and of company culture in food safety.

THE PROCEDURE AND METHODOLOGY

The procedure for an assessment must be defined and carried out in accordance with a set format. Assessors should ensure that they plan the process properly, i.e. that:

- The scope of the assessment is predetermined and sufficient time is allocated;
- The required skills are available within the team;
- Tools needed are made available;
- Arrangements are communicated and agreed upon with the site being assessed.

The procedures for assessment will need to include the following stages:

1. A planning process to prioritize establishments, operations and their frequency and scope of assessments;
2. A desktop assessment;
3. An on-site assessment;
4. An evaluation process to analyze findings, determine compliance and decide corrective actions and follow-up requirements;
5. Reporting and follow-up.

The Planning Process

Initial planning is important to clarify the scope of the assessment and the approach that will be taken on-site. It helps to ensure that assessors have the necessary information and tools to complete an effective assessment. Information that will help in this planning process includes:

- Relevant company documentation;
- Previous file records, data on premises and products; and
- Results from previous visits or assessments.

The information obtained at this planning stage will also help to determine the focus of the assessment and the skills that might be necessary, particularly where assessments are carried out by a team. It also provides an opportunity to refine any checklist and protocols that might be used and, where appropriate, to communicate arrangements of the visits to the establishment. Any material such as camera, flashlight, tool kits, safety shoes, documentation and manuals can also be foreseen at this stage.

The Desktop Assessment

The assessment itself is best carried out in two steps. The first stage, desktop assessment, consists of the initial review of documentation, which may be carried out on- or off-site.

Although it is possible to carry out an assessment without a prior review of documentation, experience shows that a review of these prior to visiting the site leads to a more focused, thorough and informed assessment.

A review of the documentation allows assessors to get an idea of the standards that are relevant to examine and become familiar with the site products and processes. It will give the assessors an opportunity to carry out some research to build up knowledge of the product technology, legislative control measures and/or industry standards.

A desktop review also has the advantage of enabling assessors to plan their work, e.g. to judge how the CCPs have been established, check the personnel required for detailed discussions, review the specific questions to be asked, draw a list of priorities to focus on and/or examine areas to visit during the on-site assessment.

If the assessors find on the other hand that the document review has indicated obvious inadequacies, they may decide to stop the assessment at this point instead of proceeding to the on-site verification. Based on the findings, the assessors may decide to communicate to the company the type of measures which it needs to take.

A review of the company documentation is best carried out off-site, particularly when government agencies are concerned. In some instances, there may be some constraints that make this difficult or impractical, for example where the assessment is of an urgent investigatory nature or where it is intended to be unannounced. However, even where this can only take place on-site, it is important to review and make use of relevant documentation prior to a further physical examination of the site premises, processes and procedures. A review of the flow diagram or site plan, for example, will provide information on the nature and scale of activities carried out. This will help to target the assessment, particularly the further necessary scrutiny of records, equipment and processes.

Examples of documents to review:

- The food safety policy.
- The organigram, the responsibilities of the managers and food safety management team, and their respective technical expertise and competences.
- The operation and the type of products produced.
- The range and number of raw materials used and their origin.
- A site layout plan may give an idea of the flow of products through the site, the scale of the operation and the products produced.
- The HACCP-related documentation, including:
  - A process flow diagram and specifications relating to it;
  - The HACCP study (showing how potential hazards have been identified and on which basis they are considered as non-significant if this is the case);
  - An HACCP plan, including the monitoring plan and the validation of the control measures;
  - Records of CCP monitoring and corrective actions following the violation;
  - Verification data, e.g. consumer complaints, monitoring data for raw material, environment or end products, reports of incidents and root cause analyses.
- Training programs, e.g. the manual or other tools used for training.
- Incident and crisis management procedures.

- Records of investigation and root cause analysis of incidents (both active and latent failures) as well as evidence of follow up and corrections of gaps and dissemination of lessons learned from the incidents.
- Reports of management review of food safety and quality.

Together with the type of products and operation, such information is crucial for planning the assessment, particularly of high risk products but also to gauge if the number of personnel and their qualifications are adequate to manage the safety of the products. Many organizations use a pre-assessment survey to organize the information required for this type of desktop assessment.

On-site Assessment

The second stage is the on-site assessment. This will normally start with an initial or opening meeting to confirm, with the key people being assessed, the assessment scope, timetable, facilities and personnel required and in general to ensure cooperation. The time and location of the closing meeting could be confirmed and any additional documentation required for on-site document review could be requested at this stage.

As a regulatory authority, inspections may be carried out unannounced. This has the advantage of examining the place and practices as they are on an everyday basis and of obtaining the best picture of the real practices. However, there is also a disadvantage in that appropriate personnel may not be available to answer questions or that the inspection may disrupt the workflow, which itself can create other opportunities for mistakes leading to risk for consumers.

In an announced visit, it is helpful to prepare an agenda for the assessment program to ensure that relevant personnel are available during the assessment, and that their routine work is not disturbed more than it needs to be.

The purpose of this step of the assessment is to confirm that procedures and practices described in the food safety management system of the company or the regulatory requirements to ensure food safety are properly implemented in practice.

The scope of the assessment should have been decided during the planning stage. However, it could change depending on the findings of the on-site review of information, particularly if an off-site review (pre-assessment) was not done and the on-site assessment represents the first examination of the material. The scope of the assessment should also be changed during the assessment if serious non-compliance/deficiencies are seen. The on-site assessment will consist of a combination of activities. It should start with a review of the relevant documentation, their adequacy and accuracy.

A special focus should be put on HACCP, understanding the flow diagram, the competence of the team, the hazard analysis and validity of the decision taken in the HACCP study.

It will then move on to a physical examination of the processes, practices and records, by observation, measurement or interview to assess whether the actual operation in practice complies with the documented procedures. An important activity during this process is the evaluation of the state of prerequisite programs, including good hygienic practices

according to the Codex General Principles of Hygiene or any other hygienic codes which may be applicable for the product or process in question. Such an examination will include the criteria listed earlier in Table 38.1.

During the on-site visit, specific attention should be given to HACCP implementation, including:

- Confirming the accuracy of the process flow diagram(s). This is facilitated by an initial walk through the site. The assessor will subsequently need to engage in a range of questioning and investigative activities to assess the efficacy of the HACCP system.
- Evaluating the hazard analysis taking into consideration the state of the prerequisite programs mentioned above.
- Confirming the suitability of CCPs, critical limits and corrective actions.
- Confirming that monitoring schedules are established and operating correctly.
- Confirming that persons responsible at CCPs perform activities correctly, understand the importance of the step for safety and their responsibility in case critical limits are violated. This will require specific interviews with the personnel.
- Establishing whether effective verification procedures are carried out.
- Reviewing monitoring data of raw materials, products, environment, CCPs, as well as reports of internal assessments, suppliers' assessments (inclusive of supplier monitoring programs), consumer complaints, personal reports and complaints. It is particularly important to corroborate these results with the hazard analysis (for instance, if a contaminant is considered as not significant in the raw material, this is confirmed through the monitoring carried out for verification).

During these activities, the assessors will need to keep sufficiently detailed records and to collect supporting evidence to enable conclusions to be made. Use of checklists together with a narrative, notebooks or, where appropriate, tape recorders, will assist this process. Depending on the judgment of the assessors, checks might be made on items of equipment, on-site measurements may be carried out, or product or environmental samples may be taken for subsequent laboratory analysis.

Additionally, assessors may

- Carry out tests to verify the well functioning of the traceability system.
- Check awareness of the regulatory requirements of the country where products are produced and/or marketed.
- Evaluate the knowledge and training of key personnel in food safety in relation to the job they are required to do.
- Review the handling of non-compliances (incidents of food contamination) or complaints from the regulatory authorities.
- Examine the organization's management structure to determine whether there are issues which may create conflict and undermine the reporting of non-compliances and/or investigation of incidents. The reporting system to ensure that top management is informed in a timely manner of food safety incidents or serious gaps in the company program, including managers' attitude and behavior, is a critically important element.

Evaluation Process

Where the assessment is being carried out by a team and a range of skills are being utilized, the evaluation and conclusions drawn will need to be agreed in advance of any final meeting with the site representatives. The assessor (or the team) will need to identify and analyze all information obtained during the assessment in order to draw up preliminary conclusions of deficiencies found, if any, and their effect on food safety, regulatory compliance or other trade-related concerns. Assessors should use the findings of their investigations to evaluate the effect any deficiencies may have on food safety and the speed with which they would need to be rectified.

The assessors(s) should evaluate findings based on objective evidence drawn from qualitative or quantitative information, records, statements, observations, measurements or tests which demonstrate that the prerequisites for HACCP or the HACCP system itself would not compromise food safety. Information and records gathered should be organized into a format that would support and justify the presentation of findings. It is beneficial to provide feedback on any positive findings of the assessment, where appropriate. This helps in presenting a balanced view.

At the exit meeting, the assessor will need to discuss non-compliances/deficiencies and agree on the expected corrective actions. The approach taken at this stage will depend on the purpose of the assessment, for example when the assessment had been triggered off by a serious food safety problem or where the assessment was to exclude previously identified deficiencies. However, in all circumstances, it is preferable to present any findings in a methodical manner, specifically highlighting best practices as well as areas of critical non-compliance or deficiencies.

The company should be given the opportunity to put forward its own solutions, as these may have substantial economic consequences such as capital expenditure, recruitment of new personnel, retraining of personnel or change of suppliers.

A timeframe for corrective actions should be decided according to the importance of the gaps identified. At the conclusion of any assessment, the company should be clear on any immediate remedial action required. The remedial action should be communicated to the site representatives with the appropriate responsibility. In some cases, written assessment reports might only follow more detailed off-site evaluation of the findings by the assessor. However, in all cases, it is necessary for the assessors to engage in follow-up activities to ensure that reported non-conformance is rectified.

The actions taken by government agencies where deficiencies are noted will depend on the nature of the identified deficiency, i.e. whether it is a non-conformance or a non-compliance. Some deficiencies will not have a direct impact on food safety. Assessors will need to have sufficient skills and competencies to evaluate the impact of deficiencies.

Other factors which will influence the action taken will include evidence of a repetitive pattern suggesting insufficient control that could lead to an adverse food safety problem.

Reporting and Follow-up

The format of assessor reports varies according to company policy and prior agreements with assessment bodies. However, it is essential that the results of the assessment be

communicated to the management of the company and to all relevant persons within the organization (i.e. with responsibility for safety) in a timely manner.

Where an assessment report indicates critical or serious gaps, these need to be followed up rapidly, and root cause analyses of these gaps are also made to identify the latent cause of the failures (see Chapter 37).

THE DEVELOPMENT AND USE OF A CHECKLIST

Very often, to assess an operation assessors work from a checklist, i.e. a list of points to be considered during an assessment. Such a checklist is a useful tool for the assessment of the food safety management system provided that assessors are aware of its limitations and do not refrain from pursuing additional avenues of inquiry. Such a list has certain advantages and disadvantages (Table 38.2).

A checklist should be designed so that a quantitative or qualitative measure of the evaluation can be recorded. An example of qualitative evaluation would be the use of the terms: "excellent, good, medium, and poor" or "critical, serious, major, minor." Space should also be provided for written comments and objective evidence to be recorded next to each heading. The content of a checklist will depend upon the purpose of the specific assessment being undertaken and a specific checklist should be designed for each specific sector of the food chain. To facilitate their application, checklists should be supported by an assessment reference manual to guide the assessor in their correct and consistent application.

As an example, a list of commonly used questions in regard to assessment of HACCP is provided below. It does not represent a comprehensive checklist; it intends to show how a list may look and the sort of questions and activities which may lead to an effective assessment (Table 38.3).

TABLE 38.2 Advantages and Limitations of a Checklist

Advantages of Checklists	Concerns and Potential Misuse of Checklists
– Function as an aide-memoire – Help maintain the focus and objectivity of the assessment – Act as a record of the assessment itself – Ensure the completeness of the assessment – Are a useful tool in ensuring consistency of approach between different assessors – Help, together with associated reference manuals, to evaluate the comparability of different assessments, different companies or different assessors – Ensure transparency of the assessment process – Create confidence in the assessment process by all concerned, including government, industry and consumers – Enable assessment data to be more easily entered into a database which, in turn, can be used for reporting and trend analysis	– If designed or used improperly, may restrict the initiative and judgment of the assessors and discourage critical thinking and evaluation – It is important that the use of a checklist not evolve into a simple "tick-box" approach where there is no critical evaluation – A checklist may be improperly designed so that it may include unnecessary or irrelevant items, or may omit critical points

TABLE 38.3 An Example of Checklist for the Assessment of the HACCP System

Preparatory activities	What evidence is there of management commitment to HACCP use? *HACCP team* – Who was on the team? – Are all disciplines relevant to the product in question represented? – What is the likely knowledge level of the individuals (evidence of training, qualifications, experience, etc.)? – Has external expertise been sought where necessary? – What is the decision-making leverage of the HACCP team leader? *HACCP system* – How does the system fit with the overall food safety management system? – Is HACCP included in the food safety policy? – Has the scope been clearly defined? – Are previous records of safety (e.g. incidents) known to the team? – Has the product been properly described? – Are intrinsic control measures identified? *Process flow diagram (PFD)* – Is the PFD comprehensive? – How was the PFD verified for accuracy and by whom? – Are all raw materials and process/storage activities included in the flow diagram? – Are there rework opportunities and have they been included? – Is the PFD correct? – Have changes been made since the PFD was drawn up? – How is the HACCP team notified of changes to the process or product parameters? – How were the changes recorded and approved? – Were any changes discussed with the HACCP team before implementation?
Principle 1 "Conducting a hazard analysis"	How was the hazard analysis conducted? – Have all raw materials (including rework) been included? – Have all process steps been considered? – Have the potential hazards been specifically identified by type/source or have they been generalized? – How did the team assess the likelihood of occurrence? – What information sources were utilized? – Where potential hazards have been considered as insignificant have these been validated? Have appropriate control measures (CMs) been identified for each hazard? – Will the CMs control the hazards to an acceptable level and how was this validated? – Have regulatory requirements been considered in making these decisions? – Are all the CMs in place at the plant level?
Principle 2 "Determining the Critical Control Points"	How were the CCPs identified? – By expert judgment? – By the use of a decision tree (has the decision tree been used correctly?)? – By the use of consultants? – Have all necessary CCPs been identified? – Did each identified hazard undergo a systematic consideration? – How are the hazards which are not controlled by CCPs addressed?

(Continued)

TABLE 38.3 (Continued)

Principle 3 "Establishing Critical Limits"	How were the critical limits established? – Have critical limits been established for each CCP? – What validation exists to confirm that the critical limits control the hazards identified? – Is there evidence (experimental data, literature references, etc.)? – How do they differ from operational limits?
Principle 4 "Establishing a system to monitor the control of the CCP"	Have realistic monitoring schedules been established? – Do they cover all CCPs? – Has the reliability of monitoring procedures been assessed where appropriate? – What is the status of monitoring equipment? – Is it evidenced as being in place and calibrated appropriately? – Are the CCP log sheets being used at all CCPs? – Have CCP log sheets been filled out correctly? – Is there any evidence that procedures are not being followed consistently? – Does the frequency of monitoring adequately confirm control? – Are the sampling plans statistically valid? – Are statistical process control records being used to demonstrate that the process is in control on a day-to-day basis? – Check that records agree with stated activities. Are monitoring personnel properly identified and trained? – How was the training undertaken? – Are the monitoring records being reviewed by designated appropriate reviewers? Are violations of CCPs investigated and root cause analysis made?
Principle 5 "Establishing the corrective action to be taken when monitoring indicates that a particular CCP is not under control"	– Have the corrective actions been properly defined so that control is regained? – What evidence is there to demonstrate that this is being done in the event of a CCP deviation? – Has corrective action been recorded and how is the effectiveness being verified? – How has the authority for corrective action been assigned? – How are non-conforming products controlled and is this clearly recorded? – Are there clear disposition actions listed?
Principle 6 "Establishing procedures for verification to confirm that the HACCP system is working effectively"	– Have verification procedures been clearly and appropriately established? – How are these procedures communicated through the business? – Have responsibilities for verification procedures been allocated? – Are they being carried out effectively? – Are all CCPs covered by the verification program? – Are hazards considered as non-significant validated through verification programs? – Is there a formal system to trigger amendments? – Are control parameters being achieved? – Have process capability studies been carried out? – How are the data from HACCP being used to improve the system? – Are prerequisite support systems included within the verification program? – How is consumer complaint data being used within the verification system? – Is there a regular review of CCP failure and product dispositions?

(Continued)

TABLE 38.3 (Continued)

Principle 7 "Establishing documentation concerning all procedures and records appropriate to these principles and their application"	What format is being used to document the system? – Does the documentation cover all of the HACCP system operation, including: (1) the description of the product and its intended use, (2) the process flow diagram with the location of CCPs and related parameters available, (3) the HACCP worksheets on which are mentioned the hazards, the control measures, the CCPs, the critical limits, the monitoring procedures and the corrective actions, (4) data used for validation of hazard analysis, critical limits and monitoring parameters, corrective and verification activities, (5) the list of verification activities, (6) the results of monitoring and verification of the HACCP plan, and (7) the appropriate records necessary to ensure adequacy of prerequisite programs, particularly those used for validation of hazard analysis? – How is the documentation controlled with regard to update and issue, etc.? – Are the records accessible and are they clearly identified by unique reference numbers? – Are all documents accurate and current? – How is change control managed?
Implementation	Have the HACCP plan and the prerequisites for HACCP been implemented? – Personnel are trained in managing CCPs and know what to do when the CCPs are violated. – Personnel involved in verification activities and prerequisite activities are aware of the significance of their work for supporting the HACCP system and of the importance of reporting any non-compliance.

CONCLUSIONS

Assessment of food safety management systems is an opportunity to improve food safety management and close the gaps. It should be carried out with objectivity and integrity. An unsatisfactory audit report should not always and necessarily be a reason for reprimanding the managers; rather, over and above closing the gaps, a root cause analysis of the situation should be made and short-term or long-term corrective action should be made. Not infrequently, the root of the problem may be in the management.

Reports of audits and food incidents have shown that some of the major sources of food safety problems are:

- Raw material and supplier management.
- Failure in the design of equipment and its maintenance.
- GMP violation.
- Failure in hazard identification.
- CCP monitoring failure.
- Failure in corrective actions.
- Human negligence or error.

Acknowledgment

The authors would like to acknowledge that this chapter is based on personal experiences but also inspired from an earlier work, i.e. the FAO/WHO Expert Consultation that they convened on the subject of the Role of Government Agencies in Assessing HACCP (Geneva, 2–6 June 1998). The report of this meeting is available from the link http://www.who.int/foodsafety/fs_management/en/haccp98.pdf under the title Guidance on Regulatory Assessment of HACCP. The contribution of all experts in providing the guidance during the consultation is thankfully acknowledged. In spite of the date of publication of the report, much of the guidance is still up to date and relevant.

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CHAPTER

39

Consumer Information and Labeling

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INTRODUCTION

In effective economic markets, consumers fulfill two important roles through their purchasing decisions. First, they satisfy their own needs as individuals and second, their collective decisions ensure the competitiveness of the market-players.

American president John F. Kennedy on 15 March 1962 said that consumers by definition include us all. He added that consumers are the largest economic group, affecting and

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affected by almost every public and private economic decision. Yet, they are an important group whose views are often not heard.

President Kennedy then postulated four basic consumer rights, which are rights to safety, information, choice and representation. Some years later Consumers International (Consumers international, 2013) added four more consumer rights, which are satisfaction of basic needs, redress, consumer education and healthy environment.

In the United Nations Guidelines for consumer protection, as expanded in 1999 (United Nations Guidelines for Consumer Protection, 2013) is stated:

> The legitimate needs, which the Guidelines for consumer protection are intended to meet, are the following:
>
> a. The protection of consumers from hazards to their health and safety;
> b. The promotion and protection of the economic interests of consumers;
> c. Access of consumers to adequate information to enable them to make informed choices according to individual wishes and needs;
> d. Consumer education, including education on the environmental, social and economic impacts of consumer choice;
> e. Availability of effective consumer redress;
> f. Freedom to form consumer and other relevant groups or organizations and the opportunity of such organizations to present their views in decision-making processes affecting them;
> g. The promotion of sustainable consumption patterns.

WHO IS THE CONSUMER?

Nobody is just a consumer and consumers are not a separate group of people within society. The overwhelming majority of people are both producers and consumers during their lifetime. At some stages in an individual's life the producer role may be more important. At others – after retirement from work, for example – the consumer role may be dominant. On this basis, the individual's role as a consumer is distinct from her or his role as a producer. Put into operational terms, this concept might be rephrased as "the consumer is an individual who is offered, buys or uses goods and services, whether publicly or privately supplied, for personal or family use." In The Codex General Standard for the Labelling of Pre-packaged Foods (General standard for the labelling of prepackaged foods, 2013) consumers are defined as persons and families who purchase and receive food in order to meet their personal needs.

The word "consumer" therefore describes a person who is a buyer of goods and services as well as one who consumes goods and services and does not use these goods or services for producing and selling other goods.

In business to business communication the word "customer" means any person or business that is offered or buys goods and services for further use in the process of production and/or sale of goods and services. In the food chain a customer is any person or business that buys and sells goods and services and this includes those businesses offering catering or restaurant services and goods, including institutional catering/restaurant services to consumers. The "customer" therefore is a part of food chain business operators.

In business communication the "consumer" is sometimes referred to as "a customer, a guest, a visitor, a tourist, etc.," thus it should be prudent to use the term "consumer" in HACCP analysis as it is used in HACCP standard documents and all other legal acts.

CONSUMER PROTECTION

Governments should provide or maintain adequate infrastructure to develop, implement and monitor consumer protection policies. Special care should be taken to ensure that measures for consumer protection are implemented for the benefit of all sectors of the population, particularly the rural population and people living in poverty.

When formulating national policies and plans with regard to food, governments should take into account the need of all consumers for food safety, and should support and, as far as possible, adopt standards from the Food and Agriculture Organization of the United Nations and the World Health Organization, Codex Alimentarius or, in their absence, other generally accepted international food standards. Governments should maintain, develop or improve food safety measures, including, *inter alia*, safety criteria, food standards and dietary requirements and effective monitoring, inspection and evaluation mechanisms as well as food and health education policies and programs. Governments should also support and promote the role of consumer NGOs as consumer protection providers, since international consumer organizations on food to consumers aim to, according to the Consumers International organization food program:

- Facilitate informed and healthy choices by consumers, including vulnerable groups;
- Prevent misleading information and ensure that information can be trusted;
- Protect children from the promotion of unhealthy food;
- Ensure food sold to consumers is safe.

All enterprises should obey the relevant laws and regulations of the countries in which they do business. They should also conform to the appropriate provisions of international standards for consumer protection to which the competent authorities of the country in question have agreed, as per United Nations Guidelines (United Nations Guidelines for Consumer Protection, 2013).

GLOBAL REGULATORY MEASURES

The global or international trade in food brings to markets a wider choice of foods and at the same time provides consumers with a better choice of products. Since the establishment of the World Trade Organization (WTO) in 1995 and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement) the role of Codex Alimentarius standards became a legal base for food safety legislation in all countries that are members of WTO.

Codex Alimentarius General Principles of food hygiene (General principles of food hygiene CAC/RCP 1-1969, 2013) recognizes the role of consumers as: consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures.

Human and animal health and plant health protection measures are thus established and they are to be based on assessment of risk. The SPS agreement incorporates, therefore, safety aspects of foods in trade and applies the standards and related texts of the Codex Alimentarius Commission. Many countries have already incorporated HACCP (hazard analysis critical control point), Codex General Principles of food hygiene (General principles

of food hygiene CAC/RCP 1-1969, 2013), into their legislation, including the European Union (Official Journal of the European Union (28 January 2002), Regulation (EC) No 178/2002, 2013).

CONSUMER CHOICE, INFORMATION AND EDUCATION

Food is a basic human need. Around the world consumers choose food for different reasons. When the choice is driven by hunger then hunger limits freedom of choice as well as concern for safety. When the choice is driven by pleasure, it means that basic human needs are satisfied. Also, there are as many drivers to food choice (besides pleasure, happiness, fun, friendship etc.) as there are consumers. Choice may also be influenced by certain experience in a given time, for example a food scare or a recall, or if some general and media information represents a threat. It is known that one bad experience may erase 10 good experiences from the brain (Maličev, 2012) and thus the freedom of choice is limited by bad experience.

Consumer choice in food may be influenced also by education, information and advice. At the early stages in life (childhood), consumers learn about food through food providers, mainly in family settings, where they also develop food preferences through experiences. This informal education continues throughout the lifespan, experiencing food in different settings and/or media exposures. Information to consumers on labels and other media used by food traders (also in advertisements) should be considered part of empowering consumers about food and its intended use, as well as safe use.

Formal education should be given by the state (health education policies and strategies) in order for the information to be autonomous and equal to all. Mostly it is given at a too early age, i.e. at elementary school, where cognitive functions are not developed yet. Consumers are then exposed to different venues of information about food and their awareness and knowledge may become biased. In this respect, information to consumers given by the food provider, such as trader, caterer or producer, is important; it is not only a legal requirement in most countries, at least the members of WTO, it is also a necessity for empowerment of the consumer to exercise an informed and safe choice. Informed choice is possible when food information provided on food or via any other means (e.g. oral, as a presentation, internet and other electronic means) to consumers is easily understood, reliable, readable, complete and not misleading.

The EU regulatory act (Official Journal of the European Union (25 October 2011), Regulation (EU) No 1169/2011, 2013) on food information to consumers is a new legal act that postulates mandatory information, taking into account that information to consumers is not only a label, but also an empowering tool (empowering also means using the information to learn how to use a product or service, which is an educational tool) and the principles are postulated as:

> Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories:
> a. information on the identity and composition, properties or other characteristics of the food;
> b. information on the protection of consumers' health and the safe use of a food. In particular, it shall concern information on:
> i. compositional attributes that may be harmful to the health of certain groups of consumers;
> ii. durability, storage and safe use;

iii. the health impact, including the risks and consequences related to harmful and hazardous consumption of a food;

c. information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices.

In order to achieve a high level of health protection for consumers and to guarantee their right to information, it should be ensured that consumers are appropriately informed as regards the food they consume. Consumers' choices can be influenced by, *inter alia*, health, economic, environmental, social and ethical considerations.

In order to follow a comprehensive and evolutionary approach to the information provided to consumers relating to the food they consume, there is a broad definition of food information law covering rules of a general and specific nature as well as a broad definition of food information covering information provided also by means other than the label.

The producer should consider a consumer or a vulnerable consumer group (e.g. children, pregnant women, patients) as a risk factor that is likely to occur due to poor education and empowerment thus misinterpreting the food information, when HACCP is being applied. It would be prudent also to conduct research or at-home interviews (face-to-face, not a phone question and answer exercise) or focus group discussions in order to define consumer understanding of information on the food product or need for improving understanding of the label or any other information necessary for safe use.

CLEAR AND LEGIBLE LABEL, A LEGAL REQUIREMENT

Food labels should be clear and understandable in order to assist consumers who want to make better-informed food and dietary choices. Studies show that easy legibility is an important element in maximizing the possibility for labeled information to influence its audience and that illegible product information is one of the main causes of consumer dissatisfaction with food labels. "Legibility" means the physical appearance of information, where the information is visually accessible to the general population and which is determined by various elements, *inter alia* font size, letter spacing, spacing between lines, stroke width, type color, typeface, width:height ratio of the letters, the surface of the material and significant contrast between the print and the background (Official Journal of the European Union (25 October 2011), Regulation (EU) No 1169/2011, 2013).

Figure 39.1 clearly indicates poor legibility due to a small font size and poor contrast. What type size and typeface should be used? If we consider a newspaper or a book as a benchmark, then the typeface must be of sans serif type, such as Arial or Tahoma, and as a minimum the size should be 8pt or greater, providing that a distinct contrast (black on white) and proper spacing are used. Any producer, trader or caterer should consult individual country legislation regarding labeling and legibility, since at the time of writing there is no international agreement of the term.

PRODUCT INFORMATION WITHIN A FOOD CHAIN

It is recognized that product information is necessary not only for the final consumer, but also for anyone in the food chain in order to provide for a safe use of products and for the

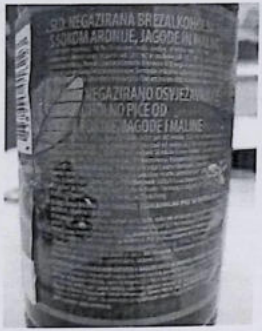

FIGURE 39.1 Example of poor legibility due to a small font size and poor contrast.

purpose of tracing and traceability. Codex Alimentarius General Principles of food hygiene state that product should bear appropriate information to ensure that adequate and accessible information is available to the next person in the food chain, to enable them to handle, store, process, prepare and display the product safely and correctly. The lot or batch can be easily identified and recalled if necessary. Information for industry or trade (business to business or customer) users should be clearly distinguishable from consumer information, particularly on food labels.

Insufficient product information and/or inadequate knowledge of general food hygiene in any stage of the food chain can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness or products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.

It is generally recognized that in the catering business, where foods are used in restaurants, canteens, schools, hospitals and similar institutions and offered for immediate consumption, information to consumers about food is not customarily available. It must be recognized that caterers must be able to provide the same information to consumers as if it were a pre-packaged product.

Information about a food item, either via labeling or other means of communication, is a communication tool not only between the trader (producer, seller, caterer, etc., in short, a food business operator) and consumer, but also between producer and seller, in short, between food operators and any of the food stages within a food chain. This necessity is important in order to conduct a hazard analysis according to Codex Alimentarius Food Hygiene (General principles of food hygiene CAC/RCP 1-1969, 2013). In the process of

hazard analysis, the first step of HACCP analysis requires a product description and the second step a product's intended use. These two steps can only be implemented if proper information is provided by and in between food operators in the appropriate food step.

Food chain information flow must be continuous, from farmer or food producer at the beginning of the food chain to consumer:

Farmer→distributor→processor→wholesaler→seller/caterer→consumer

CONSUMER AND RISK

A consumer addresses the hazard or risk differently from the professional or scientist. The following examples are consumer complaints received by the Slovene Consumer Association and depict certain situations and consumer understanding of food.

Example 1

A 10-year-old boy drank 1.5 to 2 liters of "ACE drink" (vitamin A, C and E-enriched drink) every day and after 2 months was admitted to hospital – he will, and most probably his family, will never consume vitamin-enriched drink again. No legal action was taken.

The producer should consider the highest possible food consumption level by a consumer of a product when designing a product and conducting HACCP, taking into consideration all groups of consumers the product might be used by (for example, small children). As an example, sugar-sweetened beverages (not juices) contributed 9 and 10% to the daily energy intake in Slovenian children (12–16 years old), respectively, which translates to an average of 650 ml of sugary drinks (not juice) consumed per day, therefore a consumption of 1.5 liters per day is possible for a boy (Fidler Mis, 2012).

Example 2

Many pre-packed products make a claim, on a front panel of a package, stating "no preservatives." A consumer with an allergy to sulfates suffered an allergic reaction, since sulfate was added as an antioxidant and not as a preservative (additives can have different functions) to this food. Although sulfate was listed in the ingredients, the consumer considered it safe to use, due to a general belief that "no preservatives" means "no additives." The consumer also stated that the ingredient list was written with such small letters that it was impossible to read the list in the store.

The producer should not have used the claim, written in large type on the front panel of the package, without putting a statement regarding allergens in the same field of vision as the claim, or should choose to omit the claim.

Example 3

A consumer bought pre-packed fresh chicken and kept it refrigerated till the end of its shelf-life (5 days). When the package was opened, the chicken had a foul smell and the

consumer discarded the product. The consumer then made a complaint and sought advice from a consumer association food expert, since this was the second chicken from the same producer, bought in the same store, that had to be discarded in spite of the fact that the product was refrigerated.

The producer/packer should consider consumer behavior (for example, time and temperature of domestic refrigeration or the term "keep refrigerated") in determining the shelf-life of a microbiologically sensitive product. This may also be done by consumer behavior survey at the home. Establishing product shelf-life is the responsibility of the manufacturer or producer who needs to ensure that the safety and suitability of the food product can be retained throughout the maximum period specified, taking into consideration the potential for reasonably anticipated temperature abuse during handling by the consumer. Reasonably anticipated temperature abuse can be integrated into the shelf-life or challenge study or be taken into account by applying an appropriate safety factor. A survey or research of consumer domestic fridge temperatures and consumer practices regarding temperature and time for the food left in the fridge may be also beneficial in predicting or establishing a product shelf-life.

Example 4

A family visits a certain restaurant frequently. On one occasion, a member of the family became ill within 20 minutes after eating. When the owner/cook was asked if any ingredients had changed it was confirmed that peanut oil was now being used. The member of the family was allergic to peanuts.

The food producer, processor or provider/caterer should inform consumers of any allergens present. This example shows the importance of changing the information/label if and when there is any ingredient change.

LABELING OF ALLERGENS

The only way to avoid risks of allergic and intolerance reaction inherent in food is clear and understandable information on all ingredients present in food, either pre-packaged or served, in order for the consumer to make a safe choice.

Codex General Standard for the Labelling of Pre-packaged Foods clearly states that, when it is not possible to provide adequate information on the presence of an allergen through labeling, the food containing the allergen should not be marketed.

For example, EU Regulation (Official Journal of the European Union (25 October 2011), Regulation (EU) No 1169/2011, 2013) requires that labeling of certain substances or products causing allergies or intolerances shall meet the following requirements:

- They shall be indicated in the list of ingredients with clear reference to the name of the substance or product as listed and shall be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example, by means of the font, style or background colour.

  Some of the listed allergens are:
- Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof;

- Crustaceans and products thereof;
- Eggs and products thereof;
- Fish and products thereof;
- Peanuts and products thereof;
- Soybeans and products thereof;
- Milk and products thereof (including lactose);
- Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis* [Wangenh.] K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*) and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;
- Celery and products thereof;
- Mustard and products thereof;
- Sesame seeds and products thereof;
- Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter in terms of the total SO_2, which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;
- Lupin and products thereof;
- Mollusks and products thereof.

Consider an example from a consumer suffering from peanut allergy, who had had several trips to hospital (due to threatening anaphylactic shock) because of eating a food product containing "vegetable oil." Vegetable oil, although declared but not specified, was used and the consumer assumed that the food bought did not contain peanut oil. It had been a costly experience to learn which prepared foods contain peanut oil and which do not, when the label specifies "vegetable oil." It is clear that hazard analysis (in the process of HACCP) for allergen risk is a must for the producer/seller/caterer to market a safe product.

The following are applicable to the labeling of allergens:

- They should be clear, readable and understandable by any consumer;
- They should be emphasized on the label; an alert may be also used;
- Ingredients like lecithin, vegetable oil, starch, flour, whey, casein, etc. should be also labeled by the food source, to be understood by consumer;
- Formula/recipe change of a food product should be clearly indicated on the package;
- Restaurants should label allergens on the menu;
- Industry and business should take into consideration that consumers/families with hypersensitivities will avoid buying new products poorly labelled.

PRECAUTION

It is still not proven whether food colors (either azo dyes, synthetic colors or natural colors) have an effect on hyperactivity and ADHD; however, it has also not been proven that there is no effect, and effects on certain sensitive groups of children cannot be excluded. In many studies the azo dyes themselves had no effect, but the strongest effects were observed

in children receiving azo dyes and benzoic acid combinations. Due to scientific uncertainty, in EU the precautionary principle was exercised by a risk manager (i.e. legislator) and the following legislative requirement is now a part of a Regulation (EC) on food additives (Official Journal of the Europe (31 December 2008). Regulation (EC) No 1333/2008, 2013) requiring, in the Annex V, that the labeling of foods include additional information, stating: *may have an adverse effect on activity and attention in children*, on foods containing one or more of the following food colors:

Sunset yellow (E 110) [*]
Quinoline yellow (E 104) [*]
Carmoisine (E 122) [*]
Allura red (E 129) [*]
Tartrazine (E 102) [*]
Ponceau 4R (E 124) [*]

[*] With the exception of foods where the color(s) has been used for the purposes of health or other marking on meat products or for stamping or decorative coloring on eggshells.

LABELING "MAY CONTAIN"

Labeling that states "may contain…an allergen" is not a precaution and should not be a substitute for good manufacturing policy or risk of legal action, but must be applied and used only if it is truthful and cannot be reasonably avoided. The statement "produced in a facility that also uses…allergen" is a statement seldom understood by the consumer and should be avoided.

CONSUMER FEEDBACK

Consumers can be information providers through a consumer complaint system. The system should not only include the process of redress in the case of a foul or non-edible food item (unsafe food or damaged product) but should also be a means of complaining by placing, for example, information on an internet page. Also, some consumer NGOs gather complaints and give advice as well as legal advice in case of damage (consumer redress procedure) to consumers. Consumer associations also, through their media, publish some consumer complaint cases in addition to publishing the results of consumer product testing. All these complaints or redress procedures can be useful to producers in evaluating the effectiveness of their food hygiene and HACCP procedures and approach to risk assessment and risk management.

This feedback information should be taken in the HACCP plan and when there are consumer complaints that indicate unsatisfactory conditions, implementation of the HACCP plan or validation of the control measures (e.g. formulation, processing, product shelf-life, etc.) needs to be re-examined.

DISCUSSION FOR THE FUTURE

Unfortunately food scandals still occur, and contaminated food can have adverse effects on consumers' health. Despite new technologies being used in food, e.g. nanotechnologies, which may also present risks, food safety will always be a key concern for consumers.

The future challenges lie in the evolving nature of risks as well as emerging risks sustainable management, taking into account climate change (ecosystems, biodiversity) and increasing global trade.

Sustainable production and consumption must become part of our lives, our decisions, our choice and behavior, the society as a whole and all stakeholders, from field to fork, in the food chain. Sustainability not only means adherence to laws and standards, it also means sustainment of four main goals: achieving a sustainable economy, ensuring a healthy and just society, living within the limits of our natural environmental and safeguarding natural resources (Our Common or Brundtland Report, 1987). In the Brundtland Report sustainability is explained as meeting the needs of the present without compromising the ability of future generations to meet their own needs.

Food chain representatives, from field to fork, need to support and manage, and strive for sustainability through improving *corporate social responsibility* and promoting *good governance* at the local, national and international level so that sustainable decisions and actions are implemented.

Corporate social responsibility and good governance should be the guiding principles used by food chain operators/businesses in order to protect consumer rights to safe food and a healthy environment as well as protecting the economy and society as a whole.

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CHAPTER

40

Incident Management and Root Cause Analysis

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INTRODUCTION

There are times when in spite of all efforts, some products do not meet the set standards for quality, safety or regulatory compliance. Clearly when this happens we need to take appropriate actions to protect the consumer and the brands. With proficient investigation and management of incidents, the negative consequences of these can be minimized. Over and above determining responsibilities for the mishap, it is also important to analyze incidents, investigate and understand their root cause and use the lessons learned to strengthen the food safety assurance system.

As for management of crises, management of incidents is composed of different phases (see Chapter 41):

- Prevention of incidents;
- Reporting of incidents;
- Investigation; and
- Root cause analysis.

However, note that in this book, the terms "incident" and "crisis" are used in different manners. For the purposes of this book, an "incident" is defined as an episode resulting from:

- A deviation from the standard practice or a norm and leading to a substandard product; or
- Dissatisfaction of customers/consumers or regulatory authorities, e.g. due to injury, perceived food safety problems non-compliance with regulatory norms or sensory issues.

This compares with the definition of crisis in Chapter 41, i.e. a "crisis" is a predicted or unpredicted event that represents an immediate or future significant threat to an organization, its employees, consumers and the public at large.[1]

Incidents are often limited in time, unpredictable and lead to the need for a settlement and/or corrective actions. They are often (but not always) specific to one or several specific manufacturing sites, as opposed to wider industry crises such as avian influenza or BSE. As per the above definition, a good example of an incident is when a product is found not to meet the company or regulatory standards, or have caused injury to a consumer. What differentiates an incident from a crisis is the magnitude of the event, its consequences and the possible media attention. Frequently, incidents which are poorly managed can lead to a crisis.

Some of the principles and guidance presented in Chapter 41 also apply to the management of incidents, and the reader is invited to look into that chapter. In this chapter, the management of incidents and their root cause analysis are discussed in further detail.

PREVENTION OF INCIDENTS

Understandably, the prevention of incidents relies on a good food safety assurance system and this is addressed throughout this book. The specific focus here is the handling of non-compliances and/or *near misses* to prevent incidents. Near misses refer to situations or adverse events with the potential to cause damage and/or an injury, illness in consumers, without this actually taking place. Thus, as part of prevention, over and above a well-functioning food safety system, it is important to:

- Monitor near misses, or any unsatisfactory situation;
- Analyze their trends and their consequences; and most importantly
- Investigate their root causes so that appropriate action can be taken to prevent their recurrence.

[1]Adapted from Bartlett (1999).

Different types of data provide an indication of a potential food safety problem; these are:

- Violation of critical limits (CL). The violation of the critical limits in the HACCP system is a notorious example of a near-miss situation where the food safety standard is not met, but, with appropriate corrective actions, incidents are prevented. Monitoring unacceptable deviations of the CL and conducting a root cause analysis of the deviations is an important means for strengthening the food safety assurance system and preventing fully fledged incidents.
- Deviations in verification measures. Over and above monitoring at the critical control point (CCP), the HACCP system requires a number of verification activities. Data collected through verifications can be used as indicators to verify if the control measures at CCPs, or as part of prerequisites, are implemented as planned and are effective. Again, should verification data show an unacceptable deviation from set standards, its cause should be promptly investigated and corrected.

  Examples of verification data are:

  - Audit reports of the establishment and/or of suppliers. The reason for non-compliances reported in the audit reports must be investigated and the root cause determined.
  - Results of monitoring raw materials. These can show weaknesses in the food safety assurance system of the supplier. A non-compliance should prompt a notification to the supplier, an inquiry on the cause, and in case of repetition, possibly changing the supplier. In addition, depending on the severity of the monitoring results and status of the raw material batch concerned, there may be a need to locate and hold raw materials and/or to quarantine/withdraw/recall affected product (see "Managing an Incident," below). The scale of response needed will indicate whether the near miss is really an incident or is even progressing towards being a crisis.
  - Results of environmental monitoring. These can be an indicator that the products have been exposed to potential environmental contamination. Unsatisfactory results need to be examined and their root cause determined and followed up.
  - Results of end-product testing. Provided that substandard products have not been marketed and consumers have not been exposed, the situation can be considered as a near-miss situation. Clearly if product has been released, e.g. in the case of short shelf-life products, then an incident management or crisis response will be needed (see "Managing an Incident," below and Chapter 41).
- Reports of employees. Food establishments should be sensitive to employees' grievances or complaints about their conditions of work; they should encourage the reporting of problems, investigate these impartially, and address them in a fair manner. The importance of this point cannot be overemphasized: managing food safety is a very complex and challenging task; periodic audits and testing of products will not be sufficient to prevent incidents. Management of food safety requires the continuous vigilance of employees. Therefore, the real prevention lies in the ability to appreciate risks and to implement the control measures in a rigorous manner. The involvement and active participation of all employees in meeting this challenge is central to food safety management and this is strongly influenced by the organizational culture. A culture that intimidates or promotes fear will inevitably discourage staff from reporting problems and create an environment favorable for incidents.

BOX 40.1

In an industry context, incidents are categorized under different terms:

- Food safety incident is where consumers' health is at risk or the food safety standard has been breached.
- Regulatory incident is when a regulatory requirement is not met, without this jeopardizing the safety of the product; for instance, if there has been a mislabeling with regard to the amount of the product in the package.
- Quality incident refers to a quality defect that does not jeopardize the safety of the product, for instance when there is an agglomeration of the product.

REPORTING AN INCIDENT

The term incident refers to a situation where a non-complying product has reached the market and consumers have been exposed (Box 40.1). Not always do incidents lead to illness or injury in consumers. For instance, in some cases regulatory norms may be exceeded, but the short-term exposure of consumers to a contaminant or an ingredient may not present a significant risk for their health; nevertheless, the food safety standard has been breached and the food business has to recall its products. Over and above the economic loss, such an event can damage the reputation of the company and call into question the ability of the company to manage the safety of its products. Also, some non-compliances or defective products may not present any safety issue, but the consumers may perceive the issue otherwise. This is often the case with the spoilage issues or foreign bodies that would not meet the definition of a food safety hazard.

To prevent any adverse health effects and/or damage to consumer confidence, it is important that the business sets up a sensitive method for reporting incidents and investigating them. Examples are:

- A hotline service, preferably on a 24-hour basis.
- Information on the website on how the consumer and/or customer (e.g. retail) should contact the business.
- A clear in-house reporting system with emergency telephone numbers and a responsible person to contact in case of an incident.
- Lot coding and a traceability system are essential for the investigations and the more specific the lot coding is, i.e. providing information on the time of production, the smaller the product loss will be in case of recall.

MANAGING AN INCIDENT

Following the report of an incident, a number of measures need to be taken as first actions. These of course depend on the nature of the incident. Some of the guidance

measures described below may seem self-evident to a trained or experienced food safety manager. However, experience from past incidents has shown that failures in implementing these measures have turned simple non-compliances into major crises. Therefore it is important that all relevant personnel have appropriate knowledge and training on what to do in the event of an incident. Some key measures are as follows.

The managers in charge should:

- Consider the need for blocking products; this depends on the nature of the defects and whether there is a suspicion or confirmation that the product in question is possibly implicated.
- Inquire about their eventual injury or illness in case a consumer has complained, whether directly or through a third party, e.g. regulatory authorities. In this eventuality, the manager should show empathy with the consumer's problem, whether this is an emotional affectation or an actual health injury; inform them that a thorough investigation will be initiated and that in due course the cause of the incident will be determined. Should the product be implicated, naturally consumers should be compensated and apologies be presented. As seen below, investigation and understanding the cause of the incident are also important for deciding on the follow-up actions, e.g. extension and type of recall or corrective actions.
- In case of any report by regulatory authorities or by a third party, e.g. a customer or retailers, the manager should acknowledge as soon as possible (within 24–48 hours) the receipt of the report and should assure the complainant that the issue will be investigated at once.
- Where applicable, e.g. in case of doubts on the implication of the product, reconfirm the test with an independent and accredited laboratory.
- Initiate an evaluation of the risks of the product for consumers and other consequences of the incident (regulatory violation, image).
- Depending on the nature of an incident, its consequences, e.g. an outbreak of foodborne illness, or a substantial recall[2] or a withdrawal,[3] consider the need for communicating with media (see Chapter 41).
- Decide jointly with the authorities whether a decision should be made to recall a product and whether it should be communicated internally and externally according to the circumstances (Box 40.2). Products should also be disposed of according to the regulation and in such a way that they are not at the reach of general public or employees.

In any case, a swift reaction is needed to address any ill-feelings and maintain trust. At all times, consumers' health and regulatory or customers' concerns should be the first priority, and in further discussions with the complainant, honesty, openness and transparency should be the rule of thumb. To this point, regulatory authorities or third parties should be

[2]Recall means any measure aimed at achieving the return of a product that has already been supplied or made available to consumers by the producer or distributor (adapted from EC, 2002).

[3]Withdrawal means any measure aimed at preventing the distribution, display and offer of a product to the consumer (adapted from EC, 2002).

BOX 40.2

THE DIFFERENT TYPES OF RECALLS DEPENDING ON THE TYPES OF INCIDENTS

There are different levels of recall:

- *Internal level*: products that have to be withdrawn are still within the control of the food operator, either in the factory, in transit or in company warehouses, but not at trade/retail level.
- *Trade level*: the suspected product is in the retail trade; the product is removed from the warehouses and often also from the retail shelves. This is typically done in case of regulatory (e.g. error in the name of product) or quality incidents; it is also referred to as withdrawal.
- *Public level*: recall down to the consumer level; a public recall is required when the incident is assessed to be a safety incident, whether people have been injured or not, and the public must be notified to prevent consumption or use.

provided with all the necessary data to support the findings of the investigation, if different from their report on product non-compliance.

It goes without saying that incident management, as part of food safety assurance, requires competent and well-trained and disciplined staff, as in several historical incidents blocked products were released by mistake. To this end, traceability and product recall should be part of training, yearly review and verification.

INVESTIGATION

Upon the report of non-compliance, whether or not consumers were injured or became ill, an immediate investigation should be launched. This should include:

- Examining the product for the defect and possible implication of the business. There are times when the defect may arise at another point in the food chain, e.g. at the retailer or consumer itself; for instance, many reports of glass complaints may be related to events that occurred in the home environment. The possibility of tampering should also be considered. If such is the case, over and above regulatory authorities, the police may need to be informed.
- Tracing the product to the location and time of production, processing and investigating the conditions of production, processing, transport and distribution. Depending on the nature of the incident, data on the practices of customers or consumers should also be collected.
- Examining whether the hazard was considered in the HACCP study, i.e. the hazard analysis was correctly carried out and whether the HACCP plan was accurately elaborated.

- Examining the records for any deviation in the implementation, i.e. CCP monitoring, environmental monitoring, raw material and end-product testing.
- Identifying and interviewing the operators and managers responsible for the production, eventual third parties working on the site, e.g. subcontractor for cleaning or maintenance.

The scope, method and approach for investigation can vary according to the nature of hazards. For instance, for physical hazards, an examination of the nature of the hazard can determine from which production area or equipment the agent may originate. For biological hazards, over and above the above-mentioned data, possible contamination of products by an infected or carrier employee needs to be considered. For nutritional hazards, e.g. excess or lack of vitamins, in addition to operational errors, error in product formulation needs to be considered. Chemical hazards may originate from the raw material or surface contacts (e.g. packaging, conveyor belt), and sometimes leaks from equipment (e.g. lubricants, cleaning agent residues). In case of suspicion that the raw materials may be implicated, an analysis of these will be required.

Understanding the cause of an incident is essential for determining the range and extent of products affected and the type of corrective measures that are necessary. The Perrier water crisis presented in Chapter 41 is a case in point. The fact that Perrier attributed the contamination of the mineral water to a human error in their North American facility led to a limited recall of water whereas the contamination was at the source, and a broader recall was needed. The delay in recalling the product and communicating an invalid explanation of the incident were the major reasons for the crisis. A similar situation took place with the Coca-Cola crisis in which there were many controversies regarding the cause of the problem. The faulty implication of products in the *E. coli* O104:H4 outbreak due to contaminated fenugreek in Germany in 2011, and *Salmonella* Saintpaul associated with jalapeño peppers and serrano peppers in the USA in 2008 both led to major economic losses for producers of cucumbers and tomatoes.

In case of an incident implying microbial hazards, the decision for segregating safe from unsafe products cannot be based on the testing of the product, as microbial testing alone cannot provide assurance of safety due to the likelihood of both trapping and detecting the hazard in the specific sample tested. This is of particular importance if the nature of the product or organism is such that low doses can cause a serious health effect. In a nationwide outbreak of *Salmonella* Typhimurium associated with peanut butter in 2009, the implicate company retested its products until it found negative results. Judgment of safety should based on the confirmation that the conditions of production and processing are appropri microbial testing can be a further proof but should not be relied on solely. In the same line thought, in the investigation of an outbreak, epidemiological investigation may be sufficie to render a product suspect and initiate precautionary measures, even if the microbiologica testing fails to implicate the product.

ROOT CAUSE ANALYSIS

After a near-miss situation, an incident or a fully fledged crisis, a root cause analysis needs to be done and measures need to be taken to prevent recurrence of the event. While the general public may tolerate incidents caused by an unexpected event or a human error,

it may not accept negligence or the repetition of incidents of the same kind, which is indicative of complacency. Most importantly, in case of an incident, it is essential to be able to demonstrate that the principle of *due diligence* has been respected and all measures have been taken to prevent future cases. In an incident where a company was implicated in a case of *E. sakazakii* in Belgium (March 2002), authorities inquired about the measures that the company had taken since a previous case to prevent recurrence.

The root cause analysis should not be confused with the investigation of the primary cause of an incident, which should be identified in the first place as part of the management of an incident. The root cause analysis is a postmortem exercise for better understanding of the underlying factors leading to the cause of the incident.

To understand the concept of root cause analysis, examining the way an incident occurs is important. This has been described by James Reason (Reason, 1997) and his approach to organizational incidents is used here.

In food safety assurance, a series of measures are foreseen to control hazards. As mentioned in Chapters 29 and 36 these can be grouped under basic good practices, HACCP and verification measures. When an incident occurs, usually it is the result of a, or rather a series of, gaps or failures in these measures. A gap or failure in any of the above-mentioned measures creates a weakness in the food safety management system and causes a threat situation which, if investigated and corrected immediately, prevents an incident from recurring. However, if a gap is not addressed, with time, combined with other gaps, it may potentially lead to an incident and, if this incident is not managed effectively, it may escalate to a crisis situation. An example of the additive effect of gaps in systems is an incident caused by vitamin B1 (thiamine)-deficient infant formula (Israel, 2003). In this incident, a reported 15 babies suffered damage to the nervous system and two died. The cause of the incident was an error in product formulation, but a second failure was in the verification of the composition of the product before its release. Similarly, in the incident of isopropylthioxanthone mentioned in Chapter 41, a combination of gaps in the regulatory requirements, suppliers' tests and practices as well as customers' awareness of risks were the origin of the problem. Such a situation where gaps of different levels and nature can combine to cause an incident is referred to as the "Swiss cheese model" (Figure 40.1).

A second concept that must be understood is the concept of active and latent failures relating to people and management (Figure 40.2). Behind any control measure, there are people who have to implement the control measures or verify that they are correctly implemented. These can be a worker on the line or in the farm, an operator monitoring the temperature recorder, a truck driver who has to manage the temperature during transportation, a food handler who has to wash his hands before preparing food, etc. Their failure to perform their work is referred to as active failures since their actions will have a direct and immediate bearing on the safety of products (Figures 40.2 and 40.3a and b). These are the types of failures that are typically investigated in case of an incident or near miss. Often, as a result of the investigation, the employee receives the blame, and may even be fired, and then the investigation ends at this point. The same process and relationship also exist between regulatory authorities and food establishments that are caught up in an incident.

However, in a root cause analysis the task is to go deeper in the investigation and understand the conditions that have led to the non-compliance of the person implicated in the incident, i.e. committing the so-called active failure. Worldwide, studies indicate that factors

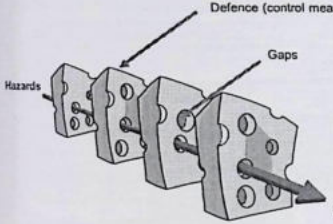

FIGURE 40.1 Swiss cheese model according to James Reason (1997).

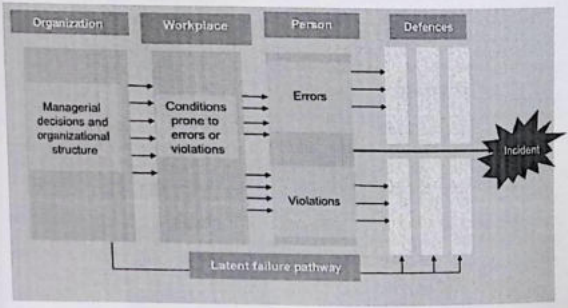

FIGURE 40.2 Levels and types of failures leading to an incident (Reason 1995).

that lead to active failures are often related to the working conditions, e.g. time constraint, lack of clear instructions, failure in defining the responsibility or authority of the person or providing adequate training and coaching, or creating a culture of fear or demonization, etc. Such situations are latent conditions which result from management decisions (Table 40.1). Thus, failures of the management in creating conditions that are optimal for managing food safety are referred to as *latent failures* (Figures 40.2, 40.3a and b). Latent failures may not have an immediate impact, but they weaken the food safety management and increase the probability of active failures, and thus of incidents. Latent failures have been the cause of numerous accidents in the petrochemical, transport and food industries and in financial institutions.

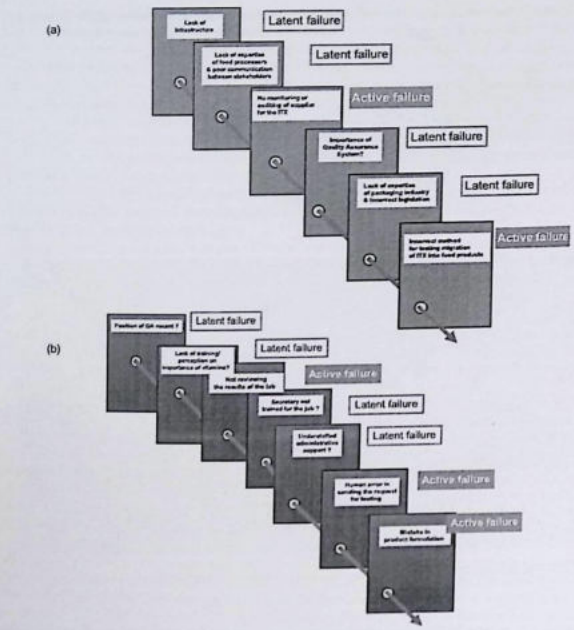

FIGURE 40.3 (a) Root cause analysis of the food safety crisis associated with infant formula contaminated with isopropylthioxantone (ITX). (b) An analysis of the root cause of an incident related to thiamine-deficient infant formula (Israel, 2003) based on information reported from unofficial sources. Some failures are hypothetical mentioned for educational purposes.

To recapitulate, a root cause analysis requires a truthful investigation of an incident at several levels, i.e. understanding:

- The primary cause of the incident: often a technical mistake, equipment failure or human error/violation. Examples are errors in the technical parameters of a product or processing, a broken sieve, or staff using a wrong thermocouple;

TABLE 40.1 Ranking of Latent Failures Preventing Efficient Implementation of HACCP

Barriers to Implementation of HACCP	Frequency of Reported Cases
Time	7
Human resources (staff)	2
Resources	5
Expertise/Knowledge in food safety and hygiene	5
Management commitment and perception of HACCP	4
Understanding of HACCP principles and systems	3
Employee motivation and attitude	3
Training	3
Weakness in regulation or enforcement	3
Lack of policies and procedures	2

(Adapted from Jevsnik, Hlebec and Raspor 2006).

- The conditions leading to the non-compliance of the person in charge of implementing the control measures, such as lack of training, time constraint, difficulty in understanding an instruction; and
- The managerial decisions that have led to those working conditions, e.g. failing to provide the necessary policies, to appoint a competent manager or personnel, to plan an optimum reporting and organizational structure, to provide adequate financial or human resources or adequate equipment, and a management behavior in contradiction or in violation with instructions, or requiring impossible tasks and forcing staff to take risky shortcuts or violate the rules. Worst would be a management that violates its own policies. This will have repercussions on the entire company.

Tools for Root Cause Analysis

Root cause analysis is used quite widely in healthcare and business settings but, as yet, it has not really been adopted by the food industry to any great extent, although the concept is identified as necessary in some food safety and quality certification standards, e.g. BRC Global Standard for Food Safety Issue 6 (BRC 2011). However, some of the tools of root cause analysis, notably structured Failure Mode and Effect Analysis (FMEA), have been used for some time in food companies for various applications. For example, Mortimore and Wallace (1994, 1998 and 2013) advocate the use of FMEA to challenge the controls within a HACCP plan before it is implemented within a food operation, the idea being that by understanding the likely causes of failure in the control systems then the controls can be strengthened further, delivering additional confidence of food safety assurance.

As discussed previously, root cause analysis needs to investigate an incident in depth to gain an understanding of all the conditions that have led to the incident occurring. It is necessary to consider all possible contributing factors and this requires both a structured approach and the ability to "think the unthinkable."

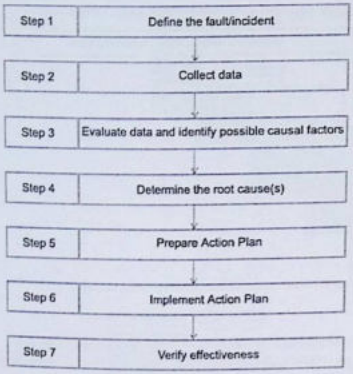

FIGURE 40.4 Root cause analysis – seven step process.

Root Cause Analysis Teams

Like many aspects of food safety management systems, root cause analysis is best performed using a team approach rather than by an individual or individuals working alone. The team needs to include personnel from within the business who have knowledge of key areas of investigation. As such, a multidisciplinary team similar to the approach used in HACCP will likely be most effective. Team members will include personnel who have knowledge and responsibility within technical/quality, manufacturing and engineering functions plus additional relevant personnel, e.g. human resources, purchasing, warehouse and transport managers and so on, depending on the nature of the incident. While the number of team members is likely to be small (four to six personnel), the team will be able to call on other personnel within the business structure to help understand what has happened and the likely contributing factors.

Structuring the Root Cause Analysis

To perform an effective route cause analysis it is important to use a stepwise approach and take the time to gain a detailed understanding at each stage before moving on. Figure 40.4 shows the steps of the structured approach to root cause analysis. Although there is general agreement on the necessary actions, various texts on root cause analysis use different numbers of steps within their route cause analysis models. We will use a seven-step process here since this covers both the analysis and the implementation and verification of corrective actions.

STEP 1 DEFINE THE FAULT/INCIDENT

Members of the root cause analysis team first need to understand what has gone wrong. At this stage it is helpful to compile as much information as possible about the fault or incident, i.e. a summary of what has gone wrong, including as much as possible on the sequence of events and what has been done so far in terms of immediate corrective action and incident management. This information is useful as background to the team allowing everyone to gain an appreciation of the incident situation.

STEP 2 COLLECT DATA

Next, it is important to collect further, more detailed information that will assist in evaluating the problem. For example, this might include:

- Product test results
- Lists of implicated products or processes
- Lists of raw materials associated with implicated products and processes
- Lists of packaging materials
- Monitoring results covering dates and times thought to be implicated. The results sample(s) should be large enough to capture all relevant data around the suspect dates, i.e. building in a margin of error.
- Corrective action records covering the dates and times thought to be implicated
- Engineering and maintenance records
- Pest management records
- Complaints records and customer contact information
- Any other relevant information, e.g. interview information from staff, etc.

Brainstorming will be a useful tool to make sure that all the necessary information sources can be identified and then members of the team can be allocated particular records to obtain and review on a preliminary basis.

STEP 3 EVALUATE DATA AND IDENTIFY POSSIBLE CAUSAL FACTORS

In order to identify the possible causal factors all the data collected so far need to be evaluated and discussed; in addition any further information required will also need to be identified. This is best done by the team working together to discuss the information found and by bringing in additional personnel as necessary to help understand the situation, e.g. factory floor staff who are familiar with the ongoing processing situation and additional experts (possibly external) who can advise on specific issues. Further discussion and brainstorming will help to elucidate the possible causal factors and these all need to be recorded by the group or its appointed secretary/scribe.

STEP 4 DETERMINE THE ROOT CAUSE(S)

The list of possible causes needs to be considered further by the team, evaluating how each one may have contributed to the problem. The use of tools from the root cause analysis toolkit (see below) will help the team understand how the possible causes may be interrelated and will assist in tracking backwards to the root cause(s). Grouping techniques such as Ishikawa Cause and Effect Analysis and questioning techniques such as the 5-Whys are

particularly helpful in this context, although teams may also find some of the other tools helpful in prioritizing possible causes from their list.

The team should agree on the root cause or root causes (likely if there are distinctly different gaps or causal factors involved in an incident). The discussion can then progress onto what needs to be done to address the root cause(s). Additional tools from the root cause analysis toolkit can be helpful at this stage, such as FMEA, which considers the current controls and then identifies recommended new controls for each cause of failure.

STEP 5 PREPARE ACTION PLAN WITH TIMESCALES AND RESPONSIBILITIES

The team's recommendations for new controls, systems, personnel and infrastructure actions need to be built into an action plan with appropriate timescales for completion/implementation. Appropriate responsibility from the management hierarchy should be defined for each action point and personnel should be advised accordingly.

STEP 6 IMPLEMENT ACTION PLAN

The individual actions on the action plan all need to be implemented and signed off as complete. Depending on the nature of the actions and the timescales involved, this will need close management to make sure the plan stays on track; this can be led by members of the root cause analysis team.

STEP 7 VERIFY EFFECTIVENESS

Verification of effectiveness is the final step in the root cause analysis process and this is done to check that the necessary changes identified in the action plan are actually working in practice and are effective at addressing the root cause of the problem. It is also important to check at this stage that the changes have not introduced any other problems that were not foreseen. Verification can be done using audit techniques, and following verification it is likely that the business will wish to implement additional monitoring around the changes within the normal scheduled monitoring activities.

Root Cause Analysis Toolbox

A wide range of management problem-solving tools may be used in root cause analysis and companies will find their own preferences with the experience of trying different approaches. There are no precise rules for this; it is all about getting to understand all the possible contributing factors to gain an understanding of the likely chain(s) of events leading to the incident. This will allow prioritization of necessary changes to control systems, infrastructure and/or management practices. The following short notes are intended to help businesses understand the strengths of a selection of tools used in root cause analysis within different industries. Further, more detailed discussions on the different tools can be found in other management and problem-solving handbooks. Trial of some of these techniques within the business outside of an incident situation, perhaps as part of a business improvement project, will allow identification of preferred tools that can be used when an incident occurs.

A menu of possible tools:

- Brainstorming

  Brainstorming is an established management tool used to capture ideas from the individuals within a group. It is particularly useful because it allows for a large number

of ideas to be generated in a short time and the lateral thinking involved means that initial ideas spark off other ideas and contributions from other group members. Ideas are never criticized or commented on during the brainstorming session because this may influence or even stifle subsequent suggestions. The key point is to get as many solutions down as possible for later evaluation and it is normally necessary to allocate the role of scribe to one team member in order to record the ideas effectively.

- Failure Mode and Effect Analysis

  FMEA is well known as one of the systems that helped to originate the HACCP approach to food safety management. Its method of considering the causes and potential effects of failure is useful in looking at prevention of problems but it can also be employed when investigating all the potential causes of an issue in an incident. Table 40.2 shows an example of FMEA being used to explore the causes of metal complaints due to metal detection failure.

  Some FMEA methods include a risk scoring approach although this is not often used in food manufacturing. However, it can be seen from the example in Table 40.2 that the sheer number of possible causes might mean that there is a need for prioritization of the recommended solutions/controls. This can be done using a simple likelihood of occurrence scheme, e.g. high, medium and low likelihood. Severity may also be considered, although it is likely that severity may be relatively similar in some cases, e.g. in Table 40.2 the possible causes may all result in undetected metal in product.

- 5-Whys

  The 5-Whys is a simple problem-solving technique that helps users to get to the root of the problem quickly. Made popular in the 1970s by the Toyota Production System, the strategy involves looking at any problem and asking: "Why?" and "What caused this problem?" Normally the answer to the first "why" will prompt another "why" and the answer to the second "why" will prompt another and so on. It is thought that at least five questions need to be asked to track back to the root cause, hence the name the 5-Whys strategy. In reality, there may need to be more than five questions asked depending on the complexity of the situation.

  5-Whys helps the root cause analysis team to start at the end result and work backward toward the cause by continually asking "why?" until the underlying cause of the problem becomes clear. In addition to its use in root cause analysis, it is useful at the start of a remodeling or change process and is a recognized lean manufacturing technique, challenging those working on an issue to analyze any problematic situation in a logical manner, thus enhancing change and continuous improvement.

  A number of benefits of the 5-Whys approach have been recorded:
  - Simplicity. It is easy to use and requires no advanced mathematics or tools.
  - Effectiveness. It helps to quickly separate symptoms from causes and identify the root cause of a problem.
  - Comprehensiveness. It aids in determining the relationships between various problem causes.
  - Flexibility. It works well alone and when combined with other quality improvement and troubleshooting techniques.
  - Engaging. It fosters and aids teamwork and teaming within and without the organization.
  - Inexpensive. It is a guided, team-focused exercise. There are no additional costs.

TABLE 40.2 Challenging Metal Detection Failure using Failure Mode and Effect Analysis

Issue (Outcome of Failure)	Failure	Current Control	Possible Causes of Failure[a]	Recommended Controls
Complaints of metal in product from customers. This could result in lost credibility, lost customers and bad publicity. Worse still, metal in product could cause customer injury and may result in prosecution	Failure to detect metal in products[b]	Check metal detector hourly with test pieces and record result	Metal detector breakdown	A range of controls will need to be considered around: – Appropriate sensitivity and calibration – Set up verification at start-up – correct sensitivity – Maintenance systems
			Metal detector not properly calibrated	
			Wrong sensitivity – check pieces	
			Incorrect metal detector in use – wrong sensitivity	
			Metal detector in wrong place in line	
			Rejection mechanism faulty	
			Rejection system not synchronized with detector	
			Rejects not controlled	Lockable receptacle needed that will accommodate all rejects
			Metal detector checks not done	A range of controls will need to be considered around: – Appropriateness and coverage of training – are enough people trained and can they actually do the checks? – How can training effectiveness be verified? – What supervision is needed? – Are the checks allocated within appropriate job roles and instructions? – Management systems and commitment issues need to be investigated
			Metal detector checks done incorrectly	
			Metal detector check reveals failure but this is not recorded	
			Metal detector check reveals failure but no corrective action taken	
			Staff not trained to perform metal detector checks	
			Effectiveness of training not verified in terms of practice	
			Workplace culture issues result in staff not taking responsibility for necessary checks	

[a]This will be a brainstormed list of ideas from the root cause analysis team.
[b]This is likely only one failure mode associated with the issue. Other failure modes to consider will include how the metal got into the product, e.g. consideration of raw material streams and processing/equipment maintenance issues on site or possible damage of the products in distribution.
(Adapted from Mortimore and Wallace 1998)

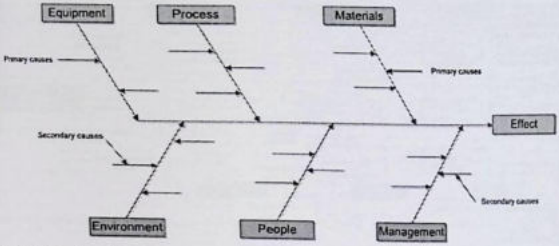

FIGURE 40.5 Example Ishikawa Cause and Effect diagram.

- Ishikawa Cause and Effect Analysis

  Ishikawa Cause and Effect Analysis (also known as fishbone diagrams) is a pictorial method (Figure 40.5) of organizing information about causes and understanding the relationships between cause and effect. It is a widely used technique in problem-solving, and seeks to understand the possible causes by asking questions such as "What happened?", "When?", "Where?", "Why?", "How?" and "What was the impact?" Ishikawa is useful in evaluating complex situations where there may be many potential causes.

  In Figure 40.5 it can be seen that causes are grouped into six categories of Equipment, Process, Materials, Environment, People and Management. These are commonly used category groupings in manufacturing situations; however, the categories in Ishikawa are not predetermined so it is possible to choose your own groupings. The diagram also shows how primary and secondary causes are portrayed and in this way the causes and causes of the causes can be identified, helping to work back to the root cause. Figure 40.6 shows how this method can be applied to an incident, based on the metal complaints issue from Table 40.2.

  This example (Figure 40.6) shows one way of grouping the possible causes identified; however, it is important to note that some causes could be grouped under more than one heading. Also in this case only the primary causes are shown; these would need to be followed up with consideration of the secondary causes and it is possible that, with further consideration, some of the points listed under the "Management" grouping might be the secondary causes affecting other groups within the diagram. There is no right or wrong way here – it is up to the team to decide how best to portray the data in their unique situation.

- HAZOP

  Hazard and Operability Studies (HAZOP) is another structured and systematic technique for examining potential faults in systems. Like HACCP, HAZOP is often

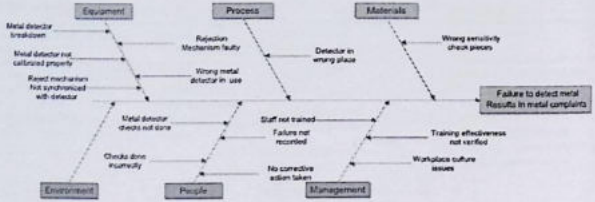

FIGURE 40.6 Ishikawa Cause and Effect diagram for metal contamination example (*after Mortimore and Wallace 1998*).

used as a technique for identifying potential hazards in a system but it also focuses on identifying operability problems that are likely to lead to nonconforming products. In HAZOP, faults or incidents are thought to be caused by deviations from design or operating intentions.

In HAZOP, The identification of deviations from the design intent is achieved by a questioning process using predetermined "guide words." The role of the guide word is to stimulate imaginative thinking, to focus the study and elicit ideas and discussion, thereby maximizing the chances of study completeness (BS IEC 2001). Further detailed guidance on how to use HAZOP, including lists of typical "guide words," can be found in the International Electro-technical Commission's guideline: Hazard and Operability Studies (HAZOP Studies) Application Guide (BS IEC 61882:2001).

- Influence diagrams

  The influence diagram approach is a further technique for visual portrayal of causal factors involved in an incident. The outcome diagram is derived in similar ways to the other tools already discussed, in that expert input, group discussion and brainstorming techniques are used. The technique differs in that it considers the possible causal factors occurring at different levels in the organization. According to Reason (1997), the levels to be considered are:
  - Influencing factor level – this includes the unsafe acts or technical failures immediately responsible for the event.
  - Performance-influencing factor level – the immediate workplace conditions that shape the occurrence of human or technical failures.
  - Implementation level – the underlying organizational factors that create the workplace performance-influencing factors.
  - Policy level – policy and regulatory factors that determine organizational processes occurring at the implementation level.
- An example influence diagram is shown in Figure 40.7. In this diagram the levels and types of failures that can result in an incident that were previously outlined in Figure 40.2 (Reason, 1995) are also highlighted on the right-hand side, indicating the practicality of application of the influence diagram approach to food safety incidents.

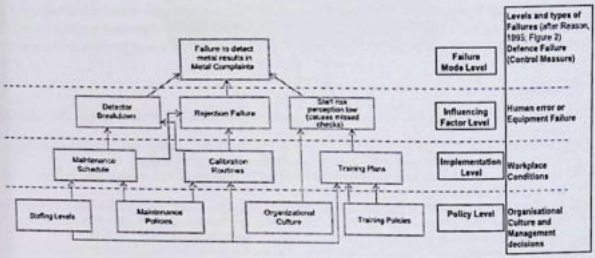

FIGURE 40.7 Example influence diagram for metal complaints (selected causes only).

- Additional specialist tools

A variety of other tools are used for problem-solving in different industries. Root cause analysis teams may wish to consult the problem-solving, risk management and error avoidance literature to identify techniques that could be trialed for suitability in the analysis of incidents. Some of these examples are more quantitative and involve risk rating categories, which might be more difficult to apply in a food manufacturing scenario. Further tools used in other sectors include Fault Tree Analysis, the Human Error Assessment and Reduction Technique (HEART) and the Maintenance Error Decision Aid (MEDA).

As can be seen from the above, the root cause analysis toolbox contains a plethora of techniques that will assist when faced with an incident to investigate. Using any of these tools does require practice so there is no substitute for trialing chosen tools when not in the middle of an incident; the majority of these tools are also useful in preventive improvement projects, which would be a much more suitable time to try them out. A further important point is that there is no substitute for involving the correct people in root cause analysis so it is important to consider carefully who can contribute to the understanding of the incident and its causes.

CONCLUSIONS

The management of a company bears the ultimate responsibility for incidents. They are responsible for creating an organizational culture that allows employees to openly report issues and provides them with the opportunity to see that their constraints are adequately addressed. An open and fair organizational culture is fundamental for the motivation of staff and is at the core of food safety management. In case of an incident, they have not only to follow best practice in managing the ongoing incident but also be candid with analyzing the root cause of the incident, such that they can redress the situation in a fundamental way to prevent recurrence of incidents in a long-lasting manner.

As for crisis management, the lessons learned from incidents need to be reported in a final report and disseminated both internally in the organization and externally with the food safety community at large in order to prevent the recurrence of incidents in society.

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CHAPTER

41

Crisis Management

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INTRODUCTION

In any organization dealing with a risk-prone subject such as food, chemicals, drugs, health, transport or finance, a crisis is an almost unavoidable situation, and any organization with a professional management should be prepared for it.

Food represents a vulnerable sector, both in terms of food safety risks and food security. Therefore, organizations operating in the food sector, whether they are food businesses or agencies responsible for overseeing food businesses, are by nature of their work exposed to such an eventuality and should have a crisis management procedure in place.

WHAT IS A CRISIS?

In food safety, a crisis is defined as a predicted or unpredicted event that represents an immediate or future significant threat to an organization, its employees, consumers and the public at large.[1]

We also know that in most crises, if not all, the media play a central role. As stated by C. Doeg (1995), "What makes a problem into a crisis is the media, or in some instances, the likelihood of media attention. Also, if a disaster strikes, it is the media's treatment of that event which determines to a great extent whether a corporation has a problem or a full-blown crisis."

Generally, a crisis reflects an acute situation requiring real-time and strategic decisions taken at high level, under harsh conditions created by time pressure, media scrutiny and often incomplete or unreliable information about the facts. A crisis is *per se* never a positive event, as it is an indication of failure in food safety management; however, a crisis which is well managed can be an opportunity for the affected organization or society to demonstrate its values and management capabilities, and for the crisis manager to demonstrate his/her leadership. It can also lead to fundamental improvement in food safety management, provided that the food safety situation and crisis management are critically reviewed, the root causes are analyzed and the gaps identified are followed up with corrective actions. In the modern history of food safety, crises have been the origin of many changes or improvements in the management of food safety, particularly in industrialized countries. Among these, the advance of the risk analysis approach to governmental decision-making processes, the restructuring of governmental organizations (e.g. creation of the European Food Safety Authority) and the strengthening of traceability are noteworthy. These developments are described in Chapter 1 of this book as well as other reference material (Motarjemi, 2014).

A crisis may occur for various reasons (Table 41.1):

- Advances in science and new scientific development or findings.
- Emergence of new hazards.
- Human error, be it scientific, managerial or operational.
- Fraud or malicious acts of sabotage, e.g. tampering, terrorism.

While the exact nature and impact of a crisis are often unpredictable, its occurrence at some point in time, in spite of all preventive measures, is to be reckoned with. However, with good management of food safety, we can minimize the likelihood of occurrence and/or impact of crises, but we cannot entirely prevent them as some of the factors leading to a crisis situation are out of the control of managers and are inherent to the nature of the subject.

[1]Adapted from Bartlett R (1999).

TABLE 41.1 Examples of Crises and their Cause

Triggered by	Examples of Crises
Advances in science and new scientific development or findings	Acrylamide, Worldwide 2002 Semicarbazide, Worldwide 2003
Emergence of new hazards	Bovine spongiform encephalopathy (BSE) and emergence of prions Worldwide, 1986 *E. coli* O157 (USA, Japan, UK, etc. 1990s) *Vibrio cholerae* (Latin America, 1993) Avian influenza (2004)
Human error: scientific, technical, managerial, operational error or violation	Bovine spongiform encephalopathy (BSE), Worldwide, 1986 *Salmonella* in chocolate (UK, 2006) *Staphylococcus aureus* (Japan, 2000) Vitamin B1-deficient infant formula, ex Germany, Israel, 2003 Isopropylthioxantone (Worldwide, 2005) *Salmonella saint paul* (USA, 2008) *Salmonella typhimurium* (USA, 2008–2009) *E. coli* O104:H4 (Germany, France, 2011)
Fraud or malicious acts of sabotage, e.g. tampering, terrorism	Lead oxide in paprika (Hungary, 1994) Dioxin in animal feed (Belgium, 1999) Sudan red in chili peppers (Europe, 2003) Wheat gluten in pet food adulterated with melamine, ex China (North America, 2007) Adulterated sunflower oil ex Ukraine (Europe, 2008) Infant formula adulterated with melamine (China, 2008)

The consequences of a crisis can be disastrous for an organisation as well as for the society. For consumers, a food safety crisis situation means that they may potentially be exposed to unsafe products, and despite risks to their health, they may also lose their trust in the food supply. For businesses, the consequences are economic and can affect their image, i.e. product recall and waste of produced food, loss of reputation, loss of market shares and loss of trust of their customers and the regulatory authorities. Additionally, they may be subject to further or more stringent regulatory measures. Loss of trust by customers may also trigger more stringent requirements, e.g. provision of a certificate of analysis. Trust of consumers, customers and the general public is one of the most important assets of a business. It takes many years to build trust, but it can be destroyed with one single incident, particularly if it is poorly managed. When lost, its impact is often long term and will take many years to rebuild.

For public health and regulatory authorities, even when a crisis is initiated in the industry, the good management of a crisis is crucial, because consumers consider their government as the guardian of the safety of the food supply and ultimately responsible for food safety.

Where governments fail to manage a food safety crisis, they may also lose their image, reputation and the trust of the general public in their capabilities to ensure safety of the food supply. In such a scenario, the trade in food can collapse. Such situations were experienced with meat and meat products in the BSE crisis in the UK and other European countries,

and with fruits and vegetables in the case of *E. coli* O104: H4 in Germany (Motarjemi, 2011). Failures in managing an incident or a crisis have also been the cause of political turmoil. Following the 1999 dioxin crisis in Belgium, the Belgian Ministers of Agriculture and Health had to resign. The ruling Christian Democratic government was also voted out of office (Donal et al., 2010). In China, following the melamine crisis, the governmental officer in charge of food safety was executed!

The loss of trust of consumers in their authorities following the BSE crisis and a plethora of small- or large-scale incidents which occurred is one of the factors leading to the mistrust of consumers for new technologies like genetically modified food, food irradiation and application of agrochemicals in food production. In Europe, many consumers turned towards organically produced food.

The consequences of a crisis for an organization or a society depend on how well the organization or society is prepared for a crisis situation. As for a boat whose survival through a storm depends on its solidity, the training of the sailors and the skills of the captain, the outcome of a crisis depends on the infrastructure in place, the training of the staff and the skills of the manager.

WHAT DID WE LEARN FROM OUR CRISES?

The recent history of food safety has been interspersed with food safety crises of varying scale or degree of importance. With the globalization of the food supply and the development of rapid means of communication, many of the crises tend to take a global dimension and require fast action and, frequently, international coordination. In the following pages, a selected number of crises will be analyzed and discussed.

Perrier Mineral Water (1990)

One of the well-known and first food safety crises with international impact was the one related to Perrier (Box 41.1), which today has become a classic case study for crisis management. The Source Perrier Company tried to minimize the impact of the incident by explaining its cause before all the facts were known to them (McKoy, 2006). This led to erroneous managerial decisions, i.e. delay in worldwide recall and inconsistent communication to the general public and the media. An underlying factor for errors in the management of the crisis was weakness in international coordination and lack of leadership in an environment of global supply. Although the level of benzene present in the product did not endanger the health of consumers, it did damage the image of a product that was appreciated by consumers who perceived it as a pure product.

Animal Feed Contaminated with Dioxin (Belgium, 1999)

The first major crisis of dioxin related to animal feed occurred in Belgium. For numerous reasons, it caused tremendous outrage. First, there was a perception of an unacceptably long delay in reacting and in informing the public (Box 41.2). The difficulty in establishing a coherent list, or developing an understanding, of the range of affected products hampered

BOX 41.1

CASE OF PERRIER MINERAL WATER (1990)

In February 1990, state regulators in North Carolina found traces of benzene (at levels of 12.3–19.9 ppb) in Perrier mineral water, until that time reputed for its purity. In North America, i.e. the USA and Canada, the company immediately recalled 70 million bottles. Within 2 days, the Source Perrier Company announced that the problem was limited to North America and was caused by an employee's mistaken use of fluid containing benzene to clean the machinery in the North American bottling plant. However, further investigation revealed traces of benzene in Perrier water in other parts of the world. It was later discovered that the presence of benzene in the final product was due to failures in filtering benzene naturally present in the carbonated gas. A worldwide public recall was made. Overall, 280 million bottles were recalled and destroyed. In 1992, Nestlé bought Source Perrier Company.

the management of the crisis. For instance, despite measures taken by Belgian authorities, contaminated chicken and eggs were still on the market in late May while the incident started in late January/early February 1999. Throughout the incident, the list of affected products was constantly amended and, consequently, the decisions for product recall were haphazard, giving the impression that the government was not in control of the situation. Failures in communication and coordination with the European authorities and the European Rapid Alert System, and conflicting opinion and decisions between the European Commission and the Belgian authorities on what needed to be recalled, added to the confusion. The lack of precise scientific information or regulatory standards for the management of dioxin exacerbated the situation.

Over and above the need for strengthening the procedure for crisis management a communication, the crisis highlighted the complexity of the food chain and the need fo better traceability system, foreseeing needs for analytical capabilities and considering th farm-to-fork approach in food safety management.

Animal Feed Contaminated with Dioxin (Ireland, 2007)

A second dioxin crisis occurred in Ireland (Box 41.3). In managing this crisis, naturally the Irish authorities benefited from the experience from the previous outbreak in Belgium and the measures that had been taken since that time. In this incident, as regard to pork meat, the Irish authorities had to take drastic measures and recall all pork products as there was no traceability system for these; for beef products, because of the existing traceability system, the recall was limited to contaminated products. The rapid recall and precautionary measure increased the trust of the European Commission and consumers in the authorities and in the safety of the food supply, and it avoided conflicts with the European Commission and imposition of restrictions, as experienced in the previous incident of dioxin.

BOX 41.2

CASE OF ANIMAL FEED CONTAMINATED WITH DIOXIN (BELGIUM, 1999)

In spring 1999, it was found that some 500 tons of feed contaminated with polychlorinated biphenyls (PCBs) and dioxins were fed to farm animals in Belgium and to a lesser extent in the Netherlands, France and Germany. The source of contamination was a fat-rendering company, where transformer oil with high levels of polychlorinated biphenyls (PCBs) and dioxins was used to manufacture animal foods. Hundreds of farms were affected.

The first pathological symptoms were reported in poultry farms in February 1999. When alerted on 26 April of that year, public health authorities first took some measures to protect public health, but they omitted to inform the public. A month later, i.e. end of May, the public learned about the issue from a television report on the incident.

On 28 May, Belgian authorities ordered the withdrawal from sale of Belgian poultry and eggs from affected farms; other European countries followed. Products from farms not affected by the incident were required to be accompanied with documentation from the authorities. On 2 June, the European Community widened the ban and ordered the destruction of all food items containing >2% egg product and food containing chicken produced from 15 January to 1 June from infected farms. On 4 June, the Belgian government issued a commerce embargo of meat products (pork and beef) with a minimum of 25% fat content, not applicable for dairy products, while the European Commission extended the prohibition order to Belgian beef, pork, milk and milk products from affected holdings. Products from non-affected farms had to be specifically certified by the Belgian authorities. Belgian authorities objected to the EU restriction posed on milk, which had consequences for a large number of products, such as chocolate. A confusing situation prevailed throughout the incident. A political consequence of this incident was that the Belgian Ministers of Agriculture and Health as well as the Minister of Agriculture of the Netherlands resigned. The ruling Christian Democratic government was also voted out of office (Donal et al., 2010; Corie and Powell, 2000; Van Larebeke et al., 2001).

Another factor in the perceived successes of the management of the dioxin crisis was attributed to the leadership and transparency of the Irish authorities. Teamwork was demonstrated through open communication with the European Commission, other national food regulatory agencies and the European Food Safety Authority (EFSA).

Finally, the incident proved the importance and benefit of having a good traceability system.

Coca-Cola (1999)

In some respects, the Coca-Cola crisis in June 1999 (Box 41.4) followed the same pattern as that of the Perrier Source water mentioned above. Although the company provided a

BOX 41.3

CASE OF ANIMAL FEED CONTAMINATED WITH DIOXIN (IRELAND, 2007)

In November 2008, in the context of routine monitoring, the Irish Department of Agriculture, Fisheries and Food (DAFF) detected the presence of marker PCBs in pork meat.

Further investigation indicated that dried bread, used as an ingredient in animal feed, was also positive for marker PCBs. Considering the link between presence of PCBs and possible contamination with dioxin, further tests were carried out. They confirmed the presence of dioxin.

The source of the contaminated dried bread was identified as Millstream Power Ltd., a food recycling plant. Subsequent investigation showed that the contamination of the feed was due to recycled mineral oil used as fuel in flame drying during the processing of animal feed. In total, 10 pig farms and 38 beef farms had received the contaminated feed. In Northern Ireland, seven beef farms had also received contaminated feed.

Soon after, DAFF impounded all potentially contaminated feed on these farms, imposed restrictions on the movement of livestock and reported the problem to the Rapid Alert System for Food and Feed (RASFF) and DG SANCO.

Although the level of contamination of pork meat was in violation of the European norms, the authorities indicated that a shorter exposure did not constitute a cause of alarm or concern and would not result in adverse health effects. Nevertheless, the authorities required a full recall of pork products because the traceability system in operation for processed pork products was not capable of linking products to specific farms. For beef, the estimated exposure to dioxin was viewed as 300 times lower than that posed by pork meat and considering that as a follow-up to the BSE problem, there was a traceability system in place for bovine animals and products, it was possible to track and trace contaminated products and this allowed a partial and selective trade recall of suspected products.

public statement a week after the report of the incident and presented its regrets for the incident, its first reaction caused outrage. The company was perceived as denying responsibility and playing down the importance of the incident. It minimized the severity of the illness and claimed that the products were safe, while at the time the statement was made, the true cause of the problem was not fully known.

Besides the important role played by the media in this case, the scale of the problem was amplified by the radical measures of authorities who banned the product from the market to counteract allegations of mismanagement in the preceding crisis of animal feed contaminated with dioxin feed. This, combined with deficient communication from the company, played badly against the product, indicating to consumers that the company was not taking adequate measures. According to some analysts, the company failed to appreciate the sensitive environment and political unrest caused by the preceding dioxin crisis as well as the general climate of public mistrust created by the BSE issue.

BOX 41.4

CASE OF COCA-COLA (EUROPE, 1999)

In 1999, over 100 persons, including many children, reported feeling unwell, i.e. suffering from headache, dizziness, nausea and trembling, after drinking Coca-Cola in France and Belgium. The incident occurred right after the dioxin contamination of animal feed in Belgium. The French and Belgian governments banned the product. The company recalled some 30 million cans. Investigation of the incident revealed two unrelated failures in production: (1) contamination of carbon dioxide with carbonyl sulfide (COS) which may hydrolyze to hydrogen sulfide (H_2S) and (2) contamination of cans with a fungicide used for treating the wooden pallets. However, tests conducted of the product showed that the product could not be the cause of the illness and the symptoms – at least in most cases – were psychosomatic. Despite an aggressive marketing campaign to regain the trust of consumers, the incident caused substantial losses (an estimated $200 million) and damaged the reputation of the company (Nemery et al., 1999, 2002).

BSE I and II (Europe, 1996–2000)

The tendency for denial or playing down is often a first reflex. Such a practice can mislead decisions, i.e. allowing wishful thinking to guide decisions. It can also convey an arrogant, uncaring and unsympathetic image of an organization. This type of error was also the cause of the bovine spongiform encephalopathy (BSE) crisis, one of the most notorious crises in the history of public health and food safety (Box 41.5).

This crisis revealed various types of expectations among the general public:

- The need for transparency in decision-making and for communication of uncertainty to the general public.
- The importance of prioritizing public health over economic considerations.
- It also highlighted the importance of public perception, as the reaction of most consumers was not proportionate to the risk that they were exposed to.
- Social dimension of a food safety problem; many farmers suffered enormous economic losses and emotional distress.
- The need for better traceability and information of consumers on the source of food.
- The need for considering a farm-to-fork approach in food safety management.
- The need for functional separation between risk assessment and risk management, while maintaining an interactive communication between risk managers and risk assessors.

Many of the lessons learned from the BSE crisis were later supported by the experience in other crises. Together with other food safety concerns, BSE crises led to fundamental changes in the approach to food safety management, including the restructuring of the European institutions involved in managing food safety, as well as to the revision of the decision-making process and the rise of the risk analysis process.

BOX 41.5

CASE OF BSE (EUROPE, 1996, 2000)

In 1986, the first cases of a mysterious degenerative brain disease referred to as bovine spongiform encephalopathy (BSE), or mad cow disease, were reported in the cattle population in the United Kingdom. However, it is believed that cases may have occurred as early as the 1970s. The disease was linked to ruminant-derived meat and bone meal (MBM) fed to cattle. The disease was viewed as without risk to human health until a new variant of Creutzfeldt–Jakob disease (vCJD) was detected in 1996 in humans and was linked to the BSE epidemic in cattle. Consumption of contaminated meat and other food products from cattle was presumed to be the cause of the vCJD. In 2004, it was discovered that the disease was also transmissible to small ruminants.

In Europe, BSE caused two waves of crises. The first occurred in 1996, when the public learned about the fact that BSE may be transmissible to humans and perceived that the risk of BSE to cross the species barrier was downplayed. The second, in 2000, resulted from the mistrust of the general public in the ability of governments to contain the BSE epidemic and from the finding that the export of contaminated feed had spread BSE to other countries in the world.

To date, in the UK, which was the most severely affected by the epidemic, BSE has led to over 180,000 cases in the cattle population and to some 163 definite or probable cases of vCJD, from which 163 persons died (WHO, 2002).

Packaging Contaminants (Semicarbazide, 2003 and Isopropylthioxanthone, 2005)

In 2003 and 2005, the food industry experienced two major crises related to packaging contaminants (Box 41.6). In both cases, products were contaminated with undesirable substances, but without significant danger to health. Although the nature and source of the incident were similar, their management followed a different path.

In the case of semicarbazide (SEM), the early and transparent communication of the food industry to authorities and speedy actions on both sides increased the mutual trust and led to the smooth resolution of the crisis. A rapid risk assessment and communication by EFSA also ensured that European member states took coherent and coordinated action across Europe.

On the contrary, in the case of 2-isopropylthioxanthone (ITX), due to a conflict of opinion between different governmental agencies on the risk of the agent and the actions required, the crisis escalated in one of the European countries. This led to confiscation of Nestlé infant formula products by the police. Subsequently, to safeguard the trust of the consumers and ensure a consistent approach, Nestlé had to voluntarily recall its products from other European countries, even though an earlier decision at the European level had allowed the marketing of the product. The product recall was heavily reported in the media, who also inflated the monetary value of the recall. A succession of conflicts followed. An early risk

BOX 41.6

CASES OF SEMICARBAZIDE (EUROPE 2003) AND ITX (EUROPE 2005)

In May 2003, in the context of monitoring its products for nitrofurazone, a prohibited veterinary antibiotic in Europe, a baby food company found traces of semicarbazide (SEM), which until that time was known as a metabolite, and thus an indicator of nitrofurazone. However, in this case, it was found out that the agent originated from the breakdown of azodicarbonamide.

Azodicarbonamide is also used as a blanching agent in flour in some countries other than Europe. In this case, azodicarbonamide was used as a foaming agent in the plastic gaskets that are used to seal metal lids to glass jars. The agent had decomposed under heat treatment of the product. As azodicarbonamide was used by most of the cap manufacturers, the great majority of the baby jar products on the market worldwide were affected by this incident.

Soon after the discovery of this incident, the industry reported the case to the European and national authorities and informed them that they would take measures to change azodicarbonamide for alternative foaming agents. The European Commission requested EFSA to conduct a risk assessment and advise the commission on the risk of the agent. EFSA conducted a first evaluation in 2003, and in July 2003 stated that the risk to consumers, if any, was very small. It recognized that SEM was a very weak carcinogen in mice and had weak genotoxic activity. While it acknowledged the low safety concern, it recommended that SEM be removed from baby foods as swiftly as technological progress allowed (EFSA, 2003a, b). The European Commission banned the use of azodicarbonamide in food contact material as of August 2005, giving the industry the time to replace it. EFSA also reassured the general public that in view of the low level of SEM and low safety risk, consumers did not need to change their dietary habits and may continue to utilize all foods concerned, including baby foods.

In September 2005, a government scientist discovered traces of a 2-isopropylthioxanthone (ITX) in ready-to-feed infant formula in Nestlé products. ITX is a photo-initiator of ink used for printing on the carton packaging, contaminating the inner side of packaging during its processing, and thereafter migrating into products. Similar to semicarbazide, ITX was utilized worldwide in packaging used by Tetra Pak and other packaging companies; thus a broad range of products (e.g. milk and milk-based products, infant formula, soy beverages, fruit juices, fruit nectars and other drinks) were potentially affected on a global basis.

First on the 24 November and then on 7 December 2005, 3 months after the report of the incident and a month after the heat of the crisis, EFSA provided an opinion on the possible health risks of ITX. EFSA advised that while the presence of ITX in foods was undesirable, it did not give cause for health concern at the levels reported (EFSA, 2005).

Nestlé, the first company to be alerted by the incident, conducted a first recall of its affected products on a precautionary principle. Later, when it received confirmation of the nature of the agent, its low degree of risk and the extent of the problem, through the food industry association, it reported the

BOX 41.6 (Contd)

issue to the European authorities. In October 2005, a plan of action for removing ITX was agreed with the EU and communicated to the European member states through the Rapid Alert System of Food and Feed (RAPSS). Thus, contaminated products continued to stay on the market until they could be gradually replaced by other products. In November 2005, the Italian government, not agreeing with the decisions taken at the European level and the risk evaluation, seized infant formula products of Nestlé, including those in its warehouses. To maintain the trust of the consumers, the company had to remove all affected products from the European markets where the products were on sale. The seizure of the product by the police and the massive recall in Europe reflected badly on the company, who in addition to explaining the incident, had also to respond to the financial analysts about the financial consequences. Within 3 months, the food safety incident escalated first to a food safety crisis, then to a financial crisis, and thereafter to a communication crisis between the CEO of Nestlé and the Minister of Health of Italy.

assessment and risk communication on the subject by the European authorities, as in the case of SEM, could have prevented disparate and drastic measures by governments. The crisis demonstrated that an early communication by trusted sources on the nature of the event and its health implications, if any, was essential to ensure coherent measures and prevent media misreporting. It also showed the importance of coordination and clear procedures for communication among the various authorities.

The ITX incident also demonstrated a number of gaps in food safety management, which became conspicuous in the management of the crisis. First, there was an error on the part of the packaging supplier in the testing method and validation of the extent of migration of the chemical into fatty products. Regulatory standards with regard to inks were also deficient, and the official method of testing was not valid as it did not consider the fat content of some food products. Food manufacturers lacked knowledge of the risks associated with the ink. Packaging suppliers were aware of the risk but did not relay the information to food manufacturers. Subsequently, products were not monitored for this agent and the supplier was not audited for this point. Generally, a lack of expertise and infrastructure in managing this risk at all levels were the root cause of the problem. Fortunately, the chemical agent did not present a public health risk, although it was undesirable.

Melamine I and II (2007–2010)

A critical review of the two melamine incidents revealed the following weaknesses in the management of the crises (Box 41.7).

BOX 41.7

CASE OF MELAMINE (USA, 2007 AND CHINA, 2008)

At least two major incidents have occurred with regard to melamine. The first incident occurred during the period of February to March 2007, when reports of kidney failure and death were reported in pets in the United States.

Investigation traced the source of the outbreak to the pet food company Menu Foods; some other pet food companies were also implicated. Overall, more than 100 brands of wet pet food were affected. As a result, Menu Foods and other pet food companies had to recall their products. The economic impact on the pet food market has been extensive, with Menu Foods alone losing at least $42 million from the recall, not taking into account the reduced sales (Reuters, 2007).

Investigation attributed the outbreak to an adulterated wheat gluten ingredient imported from China. The investigation showed that wheat gluten was mixed with melamine, itself contaminated with cyanuric acid, to swindle buyers out of the protein content and the grade of the product.

Following this incident, it was realized that addition of melamine to animal feed was a common practice in China. Later investigation showed that rice protein concentrates were also adulterated. In the United States, the crisis culminated with the finding that the adulterated wheat gluten was recycled in feed of food animals and subsequently entered the human food chain.

A second incident of melamine occurred in July 2008, in the People's Republic of China, involving milk, infant formula and some other products. By November 2008, China reported an estimated 300,000 victims, mainly babies. As reported, six infants died from kidney stones and others suffered kidney damage; a further 860 babies were hospitalized. In this incident, the dairy company Sanlu and several other food companies were implicated. According to some sources, the issue was known a long time before the incident was revealed. However, according to some unknown sources, the regional authorities were afraid to report the problem during the Olympic Games period. The incident damaged the reputation of China and its export market. A number of criminal prosecutions occurred, and two people were executed!

Adulteration of food with melamine continued after this incident, and during the following years, Chinese authorities continued to sporadically seize contaminated food products.

Melamine 2007

- Delay of Menu Foods in reporting the potential problem: the incident was detected on 20 February, but was not reported to the USFDA until 15 March. An immediate reporting could have spared the lives of many pets.
- Lack of coordination and consistent communication between authorities and the public. This resulted on the one hand in erroneous information as to the cause of the problem

(the New York State Laboratory reported that a rodenticide was the culprit), and on the other hand a situation of a lack of information leading to various speculations and hypotheses.

- Shortcomings in the supervision of food safety. According to some sources, the Menu Foods company had never been inspected by the competent authorities. The agency was relying on local authorities to conduct inspections, whereas the central authorities had jurisdiction over all pet food manufacturing facilities. The incident showed weaknesses in procedures, regulations and inspection requirements. Having said this, it is not sure that an inspection or stronger regulation would have prevented the incident, unless there was more insight into the practices in China.
- Overlooking the disposal of adulterated wheat gluten. This resulted in some companies salvaging the adulterated wheat gluten and recycling it into animal feed, which was used for food animals.

Melamine 2008

- Shortcomings in corrective actions by the Chinese authorities and local food companies. Although few companies were implicated in the fraud, in general there was no oversight by other food companies or authorities for the prevention of such practice or of possible contamination of raw material with melamine. As a result, a number of other food companies were also marginally affected by this incident.
- The fear and the delay in reporting the incident resulted in a larger exposure of the young population and were indicative of the irresponsible and unscrupulous behavior of the companies implicated and of the local authorities.

Shiga Toxin-Producing E. coli (STEC) O104:H4 (Germany and France, 2011)

In the outbreak of *E. coli* O104:H4, the German authorities came under mounting criticism for their handling of the outbreak (Box 41.8). They were blamed for slow reaction and bad coordination between the states and the federal entities. Consequently, it took several weeks to contain the outbreak and identify its source. Yet hasty and invalid conclusions, which they later had to retract, and false information as to the source of the outbreak created a sense of panic in the general population (*Financial Times*, 2011c). Sale of produce, particularly that imported from Spain, was severely affected. Once again, the crisis demonstrated the importance of rapid action, coordination among authorities and the importance of giving validated information. It also showed the health and economic dimension of failures in food safety and crisis management.

Horsemeat Scandal (2013)

As this book goes to production, a new crisis is ongoing in Europe. In January 2013, the Food Safety Authority of Ireland tested a range of inexpensive frozen beef burgers in supermarkets in Ireland for the presence of DNA from other species. The test found undeclared horse DNA in over 33% of the beef burger samples and pig in 85% of them. Further investigation unraveled a huge pan-European scandal involving a vast and entangled network

BOX 41.8

CASE OF STEC O104:H4 (GERMANY AND FRANCE, 2011)

On 21 May 2011, Germany reported a dramatic outbreak of Shiga toxin-producing *Escherichia coli* bacteria (STEC), serotype O104:H4. On 24 June, France also reported a similar outbreak of *E. coli* O104:H4 in patients that participated in an event.

The investigation of the outbreak in Germany first pointed to cucumbers imported from Spain. Later, as the outbreak continued, this proved to be false and the likely source of the outbreak was attributed to sprouts of fenugreek, grown from seeds imported from Egypt (EFSA 2011). An examination of the outbreaks in France and Germany by EFSA indicated that the two outbreaks were likely to be linked. In Germany, 4321 outbreak cases, including 3469 cases of Shiga toxin-producing *E. coli* and 852 cases of the hemolytic–uremic syndrome, had been reported by 26 July 2011, when the outbreak was declared (Buchholz et al., 2011). By that time, 50 persons had died (WHO, 2011). The outbreak in Germany caused huge economic losses in many European countries.

Spain's export of cucumbers and vegetables was badly hit and export of some 150,000 tonnes of produce was affected (*Financial Times*, 2011a and 2011b).

of traders, slaughterhouses and renowned food producers. Fraudulent products have been discovered in many countries, e.g. France, Germany, Ireland, Italy, the Netherlands, Spain, Sweden, Switzerland and the UK. Additional products, e.g. frozen lasagna and spaghetti with bolognese sauce, beef ravioli and beef tortellini, as well as other abattoirs, producers, traders and supermarkets are being implicated in the scandal. There are reports indicating that in the light of the scandal, one-third of British consumers will not buy pre-prepared food products.

Although, at this stage of investigation the scandal seems not to involve a food safety issue, it revealed:

- The very complex food chain where meat sourced in one country (in the current case Romania) changed hands several times before reaching supermarkets in Europe.
- Renown brand name companies subcontract the acquisition of their raw material to other firms and who in turn subcontract to others and so on, making the present system of traceability of little value for ensuring safety, integrity and wholesomeness of food.
- Lack of ethics of managers of food businesses who would deceive consumers for whom the consumption of horsemeat is culturally and emotionally not acceptable.
- Where there are no ethics, the range of problems that can affect the food supply will be endless, unpredictable and beyond our imagination. Although the horsemeat crisis is probably not a safety issue, other cases of fraud can have food safety consequences (e.g. melamine in USA (2007) and China (2008)).

WHAT LESSONS FOR THE FUTURE?

Far from being an exhaustive list of all learnings from the various crises, the experience in the management of various crises points to the following principles:

- Speed of action and communication are vital.
- Prioritizing public health, or consumer health, over economic aspects.
- Validity of information and understanding the degree of uncertainty and/or variability, i.e. getting the facts right.
- Considering public perception, underlying science and other determinants of trust.
- Transparency, i.e. giving the full truth.
- Functional separation between risk assessment and risk management.
- Coordination between different authorities/organizations involved and consistency in communication.
- A rapid risk assessment and communication of risks by public health authorities is fundamental for preventing disparate actions.
- Maintaining the flow of communication to the general public, particularly through a trusted source.
- Monitoring the situation and consideration of the social and political context of an incident.
- Being aware of the global nature of the food supply and food safety, and of the need for international coordination.
- Analyzing other incidents and taking measures to prevent their repetition, as an incident that happens a first time can be considered a mishap; whereas the second time, it will be viewed as negligence.

A cross-cutting lesson from all crises, be it the food sector or other sectors, shows the importance of management commitment, human resource management and organizational culture in a crisis, both in terms of prevention and management of a crisis. As demonstrated in the accident that befell Concorde, in safety, any detail can be important. In this accident, a piece of another plane fell onto the runway and led to Concorde crashing plane and the demise of the company. Therefore, the collaboration of the staff, exemplary leadership and commitment of the management is needed to prevent any failure, however small this may be. Table 41.2 summarizes the key lessons from the above-mentioned and a number of other incidents and crises.

ESSENTIALS OF CRISIS MANAGEMENT

From the above, it can be understood that the importance of crisis management, and preparation for it, cannot be overemphasized. Provided that crises:

- do not occur too frequently,
- are not a consequence of obvious or gross negligence,
- do not involve unethical or malicious malpractices, and
- health and concerns of the general public are given priority

TABLE 41.2 Summary of Lessons Learned from Various Incidents and Crises

Incidents	Lessons Learned
Mineral water contaminated with benzene (France, 1989)	Rapid product recall increases trust Importance of valid information for decision-making Attempts to downplay the extent of an incident will damage the reputation of a company Importance of consistent communication Importance of international coordination
BSE/vCJD (Worldwide, (Europe 1996–2000))	Importance of transparency and ability to communicate uncertainty to public Importance of prioritizing public health over economic considerations Importance of consumer/public perception (e.g. dreadful nature of disease) Need for separation of risk management from risk assessment The social dimension of food safety Importance of traceability and farm-to-fork approach Role of media Importance of risk communication by a global public health authority
S. aureus intoxication; milk (Japan, 1955)	Importance of rapid action (halt of sale, recall of products, and public apology) increases trust
S. aureus intoxication, milk powder (Japan, 2000)	Speed of action Priority to public health Communication: empathy with the victims Full transparency: any attempt of denial, or minimizing the impact (false or partial information, partial product recall) will damage the reputation more Preparation: clear procedures and training Mechanism for reporting problems to management Beware of culture of fear!
Mislabeling of beef product (January, 2001)	A good crisis management does not always help! Fraud and ethical malpractice will not be forgiven
Animal feed contaminated with dioxin (Belgium, 1999)	Importance of speed of action Demonstration of the complexity of the food chain and the need for traceability The need for farm-to-fork approach Role of media Importance of risk perception The need for resources (e.g. laboratories)
Soft drink allegedly contaminated with pesticides (Belgium, France, 1999)	Importance of communication Importance of considering the context of an incident Voluntary recall can increase trust Role of media
Packaging contaminant: semicarbazide (Worldwide, 2003)	Early and transparent communication of the food industry increases trust A rapid risk assessment and communication by trusted sources prevent escalation of a crisis and ensure coherent actions across Europe

(Continued)

TABLE 41.2 (Continued)

Incidents	Lessons Learned
Packaging contaminant: isopropylthioxanthone (Worldwide, 2005)	Importance of risk assessment and communication by competent authorities Alignment with government views Coordination of government agencies Importance of risk perception Financial consequences can also create a crisis Importance of documentation and records Media plays an immense role
Pet food adulterated with melamine (North America, 2007)	The need for additional resources (e.g. to handle consumer queries) Early reporting to public health authorities to minimize damage Importance of coordination and communication between authorities Importance of considering the fate of disposed products Root cause analysis of incidents and dissemination of our experience can prevent future crises
Sunflower oil adulterated with mineral oil (Europe, 2008)	International coordination to prevent dumping of contaminated food to other countries or food sectors Difference between being allowed to keep a contaminated product already in the market and being allowed to release a contaminated product
Salmonella/Peanut butter (USA, 2006 and 2008/9)	Importance of root cause, corrective actions based on understanding the underlying factors for malpractices
Melamine/Infant formula (China, 2008)	Importance of root cause, corrective actions based on understanding the underlying factors for malpractices Risks associated with fear culture Control of contaminated products and their safe disposal
Enterohemorraghic *E. coli* (EHEC O104:H4) and fenugreek (Germany, France 2011)	Importance of speedy action Validation of information before communication to the general public Coordination among authorities Impact of public fear on food market
Horsemeat (Europe, 2013)	Lack of ethics in food business Complexity of the food chain, limitation of traceability Where there is no ethic, all range of problems can happen and are unpredictable

Good crisis management can to some extent reinforce the trust of consumers and trading partners or improve the reputation of the affected organizations, or at least limit the damage. Consumers who would observe that, in case of any adverse event, the business or the government will take necessary measures to protect them will have increased trust in the businesses and governments. As mentioned above, in a crisis situation both governments and the industry may be implicated and will have to bear the consequence of a crisis; therefore, interactive communication and full transparency between the two parties is essential. Additionally, both may be asked to explain why their preventive measures failed.

While collaboration and communication between governments and industry is important to manage a crisis, it is also important that the process of decision and implementation not

be biased. Therefore, the principles for risk management and the process of risk analysis developed for the management of food safety in normal times applies also in a crisis situation, except that decisions have to take place under time constraint, with incomplete data and often under media scrutiny. The more a country's food safety management is solid in terms of organization, e.g. definition of responsibilities, values, standards (existence of legislation and enforcement mechanism) and procedure, and skilled and competent managers, the better it will be prepared for managing a crisis situation. The same applies in a food business. In the dioxin case in Belgium in 1999, the lack of norms for dioxin at the European level and of traceability were gaps that, among others, negatively impacted the management of the crisis. In a similar dioxin crisis a few years later in Ireland, the existence of a norm was one of the factors that eased the decision-making process (Donal et al., 2010).

As for food safety management, crisis management requires a structured, systematic and consistent approach and includes four stages:

1. Crisis prevention
2. Crisis preparedness
3. Crisis management
4. Recovery and rebuilding after a crisis

The following principles and recommended practices for crisis management are formulated in a general manner. With some adaptation to the circumstances, they can be applied both in governments and in industry.

Crisis Prevention

It has to be recognized that a crisis situation starts when food safety management has failed. Therefore, regardless of how well it is managed, a crisis is often an indication of failures in food safety management and will have some negative consequences, particularly if crises occur too frequently or past errors are repeated.

Management of a crisis situation mobilizes many resources within the organization and disrupts the normal operations. Therefore, the repetition of a crisis situation not only will erode the trust of the trading partners, customers and the public at large, but will also undermine the routine of the operations and will wear out the staff. Subsequently, these may be more disposed to human error. A vicious cycle of vulnerability sets in. Hence the importance of preventive measures, as the better we manage food safety, the less likely we are to have a crisis. Thus, paradoxically and ironically, the best crisis management becomes its prevention.

The preventive measures are not any different than those that are necessary for food safety management; crisis management should be seen as a continuum of food safety management. For an overview of food safety management, the reader is referred to Chapter 1 and also elsewhere (Motarjemi, 2008, 2014). However, some aspects of food safety management find particular importance during a crisis situation; these are described below.

During a crisis, trust becomes a very important asset, as people operate under acute conditions requiring real-time and strategic decisions at high level. Due to the urgency of the situation, there is no time for checking the validity and thoroughness of the data as in a normal situation. Many decisions are to be taken based on the trust in the integrity and

competence of staff or experts and on their respect of the values and policies of the organizations. However, trust is not built or achieved in one day; it takes years of good practice and of responsible and transparent behavior and management. Although, as mentioned above, the practices during a crisis management can enhance and reinforce trust, its foundation is to be built during normal periods, i.e. during the day-to-day operations. An organization that behaves responsibly will not have difficulty in transparency and giving the truth about the cause of its incident. Therefore, values such as open culture, transparency, prioritizing the safety of products over economic considerations should be spelled out in the policy of organizations and actively supported by the management. In other words, policies should not be a declaration of good intentions but practiced by the leaders on a daily basis.

As part of management, the definition of policies, processes, responsibilities and the provision of logistic support all are important for good management of food safety. Additionally, in a food business, the food safety assurance system, including the GMP, HACCP system and various verification measures, as well as change management, will need to be implemented in a flawless manner (see also Chapter 31 and its validation and maintenance). Regulatory authorities should also monitor the food supply for safety and have an efficient foodborne disease surveillance program to depict any problem at an early stage.

An important and integral part of the food safety management system is management of human resources, as no matter how many principles, systems and tools are innovated for managing food safety, it is finally the staff who have to implement these (see Chapter 37). Human resource management is often a neglected area in food safety management, while it is fundamental to an efficient food safety management and should be considered at the heart of the system. Experience from various crises shows that very often failures leading to an incident or a crisis are known by the staff, or could have been predicted; however, due to fear for repercussions on their career, they fail to report or do not bother to report as they do not believe in the fair evaluation of their information.

Therefore, over and above their knowledge and skills, staff need to be motivated and encouraged and, most importantly, not fear for their career or potential repercussions when reporting potential gaps or malpractices. Any gap or malpractice which is addressed at an early stage will decrease the risk of an incident and eventually of a crisis. Employees need to believe in the commitment of their management in the true sense of the word. Hence, the importance of credibility of the management and their walking the talk on a consistent and continuous basis, as any non-compliance or complacency at the higher level of management, will set a bad example and have serious repercussions on the entire organization. The importance of management commitment, having an open culture, promoting the reporting of problems, and their investigating and closing the gaps for prevention of crisis cannot be overemphasized. Naturally, governments have the leading role in protecting the right of the staff.

As part of food safety management, but of particular importance to crisis management, are of course traceability, recall procedure and the procedure for crisis management itself. The latter will be described below. With regard to traceability, without such a system, in case of a non-conforming ingredient or product, it will not be possible to make a selective recall of products, and all products suspected to be potentially affected will have to be recalled and destroyed. A case in point is the incident with dioxin in Ireland (1999) where, due to the absence of traceability, all pork products were recalled, whereas for beef, as a traceability

system was established following the BSE incident, a selective recall, i.e. a recall of contaminated products, was possible. The same applies for an incident affecting a food business. The finer the traceability system, the more likely it will be possible to narrow the recall of products that are affected by a contaminant. For instance, a company who can trace a contamination to the precise time of production can limit the recall to those specific products. In absence of such a system, unless the nature of the contamination is such that it is possible to segregate affected products by testing, all the production of a day, a week or of a longer period may need to be blocked and withdrawn.

Many organizations may also benefit from an active early warning system or may even do research on potential emerging issues. Such a system is at the frontier between prevention and preparedness for crisis management. Depending on the nature and size of the organization, the system could include monitoring, surveillance and analysis of:

- Literature and scientific data;
- The regulatory development and alert networks;
- Incidents and experience of other companies and countries;
- Consumer complaints;
- Foodborne diseases, animal diseases and monitoring of contaminants;
- Post-launch of new products;
- Audit and/or inspection reports, reports of compliance of products;
- Internal account of staff reporting non-compliance or mismanagement.

Crisis Preparedness

One of the key principles for crisis management is the speed of action, be it investigation into the case or informing the general public. In all incidents where there has been delay in action, it has caused outrage and hard judgment by the public. In the dioxin incident in Belgium (1999), melamine in China (2008), *S. aureus* in Japan (2000) and *E. coli* O104:H4 in Germany (2011), one of the main failures for which the responsible authorities were severely criticized was the delay in removing products from the market or in informing the public; a similar experience was observed with Toyota (2011) and Sony who were slow to inform the public about their defective cars or their security system that was hacked. Therefore, to ensure a rapid course of action in such a situation, a certain number of actions and activities have to be carried out in advance to actively and specifically prepare for a crisis situation. To this end, it is important to consider:

1. Infrastructure and resources that may be required during a crisis. These include:
   - Developing a network of collaboration and alliance with various stakeholders, as during a crisis there will be a need for a rapid exchange of information. Examples are media, other food companies or industry associations, regulatory authorities, consumer organizations.
   - Being aware of the regulatory requirements in relation to (1) the procedure for reporting an incident (i.e. who should be informed, at which point and what kind of information needs to be provided), (2) legal requirements for withdrawing or recalling products, (3) the eventual disposal of contaminated products in a safe manner, and (4) penalties or penal actions for the responsible person, in case of consumer injuries.

- Being informed of the requirements of the Codex Alimentarius Commission and the International Health Regulation in case an incident or an outbreak takes an international dimension or affects foods entering the international trade.
- Foreseeing the scientific support (e.g. access to experts) and additional logistic support.
- Organizing a database on products and their traceability records, i.e. their destination and/or the source of the ingredients.
- Establishing a contingency plan, e.g. how the work will be delegated or an alternative source of products.
- Definition of roles and responsibilities in times of crisis and the network of people who should be informed.
- Additional administrative support and infrastructure, such as designation of a specific meeting room, extra lines for telephone, mobile phones, etc.
- Good organization (responsibilities, network) and written procedure, e.g. first minute actions.
- Red folder: data needed in case of accidents: organization chart, emergency telephone numbers, phone numbers of key partners, governmental agencies, food companies, customers, scientific experts, specialized laboratories.

2. Principles and procedures. While defining procedures and principles, it is important to also define the specific procedures for crisis management, i.e. how the early warning system should work, who decides, implements and communicates during a crisis situation. Often these may be the same as in normal circumstances; however, each organization has to give this matter specific consideration and take a conscious decision, as the same infrastructure and setup may not be suitable for all types of conditions and organizations. The types of questions that should be considered are:
   - The line of reporting of information.
   - The type of information (consumer complaints, regulatory actions, media, disease surveillance, food ban, etc.) that should be reported as part of early warning.
   - The crisis manager and the skills required for this position.
   - Composition of the core crisis management team, competence needed and responsibilities.
   - Those who should possibly be informed internally and externally (regulatory authorities, medical community, consumers/general public, suppliers, customers, media, food companies, trade organizations or international organizations, police in case of tampering).
   - Define the principles of decision-making and the authority, i.e. who would need to approve a decision.
   - The person who will be responsible for implementing decisions and for following up.
   - The spokesperson.
   - The procedure for preparation of the communication.
   - How the issue will be coordinated nationally or internationally.
3. Defining a crisis manager. It is to be noted that the food safety manager does not always need to be the same as the crisis manager. A crisis manager should have specific skills, such as:
   - Leadership.
   - Good technical knowledge (scientific, product, supply chain, regulatory information).

- Organizational management skills.
- Public relations and communication skills.
- Recognition and trust of stakeholders.
- Experience.
- Emotional intelligence (empathy).
- Pragmatism and common sense.

Finally, as part of crisis preparedness, it is important to communicate to all stakeholders, or all potentially involved parties, the flow of reporting, i.e. the communication plan, and the principles and procedures; it is also important to train the crisis team members in crisis management, and periodically perform a crisis management exercise to ensure that the procedures and principles are correctly understood, feasible and complied with. It is clear that in the light of the outcome of the exercises or in case of any new internal or external experience, the crisis management procedure is to be reviewed and improved. An important element for training is, of course, skills in crisis communication. As will be seen below for this purpose, specific skills are required.

Crisis Management

Then comes the time the house is on fire, i.e. a crisis hits. The procedure, e.g. convening the crisis management team, informing the management, is to be put in place. It is important to act swiftly but calmly. Speedy and timely decisions and actions are key but it is equally important not to take decisions in a panic mode, and as far as possible to take the decisions in consultation with the crisis management team, and/or depending on the case, with the support of the management of the organization. Where applicable, external bodies, e.g. other industries, industry associations, governments of other countries, or international organizations, may need to be consulted.

In the eye of the storm, a number of decisions are to be taken and implemented. To this end, a few principles are to be observed:

1. To get the facts right and be aware of uncertainties. Examples of information which would be required are:
   - What has happened?
   - What level of contaminants was found in the food, which method was used and its validity, sensitivity of the method, possible product variation or limitation of the analytical techniques, or the competence of the laboratory.
   - Range of products that are affected, the time the affected products have been on the market, i.e. how far back a product may need to be recalled if necessary, their expiry date, their distribution, and products which are in the warehouse at the time of the crisis.
   - What was the possible cause of the problem? This information will be essential to determine which products, up to which time, need to be pulled out of the market.
   - Who is aware of the issue?
   - Evaluating risks and possible management options. In evaluating the risks, the health consequences for consumers should be the primary concern and the priority. As part of this, different types of risks need to be considered, e.g. safety risks versus nutritional

risks. Safety risks can also entail microbial versus chemical risks. It is to be born in mind that a rapid change in a product or food consumption pattern without taking the necessary precautions may also lead to exposing consumers to new risks. Other types of factors to consider in the decision-making process are regulatory and legal aspects, potential environmental risks, reputation risk, economic and financial implications, social consequences and perception issues. Decisions are to be taken based on the above consideration and considering the pros and cons of different management options, including feasibility and possible timeframe.

To ensure that the intentions with decisions are understood and the decisions are followed, it is important to explain the basis for decisions and to keep records on the reason for them, those who participated in the decision-making process as well as the data that were considered. The implementation and the outcome of the actions are to be monitored and evaluated at all times. Where necessary, e.g. in the light of new information, the course of action or decisions may require amendments. In taking decisions, it is important to consider both short-term as well as long-term consequences, and also to think globally as today food safety is global and decisions can have broad consequences. Experience in other countries may also be beneficial. Finally, to ensure a rapid course of action, it is important to have a plan of action (including a contingency plan).

Crisis Communication

During the last two to three decades, there has been an increasing recognition of the importance of risk perception and risk communication, in particular during the period of a crisis. It has, among others, been realized that perception of the general public, although not always based on science or in line with the view of scientists, is the main driver in the acceptance of products and/or technologies and influences the food market. A huge amount of research has been carried out in recent years. It has been found that the perception of consumers is influenced by a number of factors such as:

1. Prospects of significant benefit for "me."
2. Whether the risk is voluntary (consent) or involuntary.
3. Whether the risk is familiar.
4. The "dread" factor in the risk.
5. Whether the risk and benefit are "fairly" distributed.
6. Whether the risk is part of an unethical activity.
7. Whether the risk assessor and risk manager are trustworthy.
8. Whether the risk is natural or unnatural.

Consideration of these factors is important, as much in the risk communication as in the decision-making. For instance, in the ITX incident in 2005, where infant formula was contaminated with traces of photo initiator of ink, the affected food companies decided not to recall their products on the grounds that the contamination did not represent a significant risk to health, while many consumers would not buy such a product as the contamination was an unnatural event, involuntary and the risk benefit was not equally distributed. With regard to risk assessment and risk communication, the fact that initially the risk assessment

was carried out by the infant formula manufacturers and not by the authorities undermined the validity of risk assessment and communication. On the other hand, in an incident that occurred 2 years earlier in 2003, where traces of semicarbazide were found in baby food, the rapid risk assessment by the European Food Safety Authority and its communication to the general public led to a more peaceful resolution of the crisis.

Consumers and interested parties get their information in different ways. Therefore, different methods and means of communication need to be used to reach the target audience as widely as possible. These include: press release and/or press conference, TV interview, website, podcast, telephone voice messages and hot line for specific consumer queries, alert networks such as the European Rapid Alert System, WHO/FAO INFOSAN, etc. A rumor hot-line can also help people understand if any erroneous message needing correction or explanation is circulating.

Experience from a few crises shows that in the heat of the management of a crisis, a few groups of people are forgotten in the line of communication; they are mentioned here as an aide-mémoire, as depending on the situation, it is essential to keep them informed. Some may need assistance with a brief, a draft declaration or a question and answer, in case they are contacted by the public or the media. These are:

- The chief executive officer or the director general of the organization.
- Trade associations/regulatory authorities or international organizations.
- Stakeholders of the food chain, e.g. retailers.
- Employees.
- The switchboard or consumer services on possible answers to the general public or consumers.

The exact choice of the method and the mechanisms of communication depend on the case, and the strategy for communication needs to be examined very carefully so as not to create undue panic in the population, yet to inform them as needed. In the 2002 acrylamide crisis, the Swedish authorities decided to hold a press conference. According to communication experts, this method of communication created a big communication crisis and media attention, while the contaminant was not new (humans have been exposed to it as far back as the Palaeolithic period when food was cooked over fire), its risks were not yet known, and its content in food could be reduced only after extensive research, meaning that an alarming communication would only create panic without providing consumers with a solution (Löfstedt, 2003).

A few additional principles need to be considered in crisis communication:

- Speed: a communication should be made within 24 hours.
- All communications should be coordinated through one person.
- Depending on the situation, the communication could include the facts, i.e. what is known and what is not known, the decisions, actions and the basis for the decisions.
- Communications should be made in such a way as to avoid any misunderstanding by the audience, i.e. the potential for being understood in different ways than was intended. This can be done by testing the communication on a focus group or person representing the target audience.
- Confirmation of receipt of important messages.
- Full transparency and consistency, in particular being aware that any attempt to downplay or hide facts will cause more damage to the reputation.

- Having and expressing empathy with the victims and affected people.
- Frequency, mode and content of the communications should be culture specific and effective for the specific target consumers.
- Avoiding terms that would amplify the situation or unduly minimize and mislead the target audience.
- In communicating with the media, any gap in information can lead to misinformation.

Documentation and Records

Documentation and records are important means of communication and these are an equally important task in the management of food safety.

In a crisis, which is often a situation where the safety of products has gone out of control, having records of events, decisions and actions as well as supporting documentation becomes even more important. As part of this, all facts and decisions are to be recorded in a logbook. The logbook should contain records of the events, who decided what and who was informed. When meetings have taken place, it should also include minutes of the meetings. These should also record reservations made by any member of the crisis management team and should also be disseminated to all attendees and other interested parties. The preparation of a case report on the event can help in communicating the event to stakeholders in a consistent and transparent manner, and also facilitate the identification of any discrepancy and/or uncertainty that may be detrimental to the process of decision-making. It can also support the development of consensus and the later evaluation of decisions and of the crisis management.

Recovery and Rebuilding after a Crisis

Management of a crisis is often so exhausting that once the storm is over, members of the crisis team tend to return to their normal duties, without further considering the lessons from the crisis. However, the evaluation of the crisis management and determination of the root cause of the incident, its consequences, lessons learned and corrective actions are very important for preventing future incidents (see also Chapter 40). In a case when an infant had died (Belgium, 2001) where the contamination of infant formula with *Cronobacter sakazakii* (formerly known as *Enterobacter sakazakii*) was considered as a possible cause of the incident, the authorities questioned the manufacturer on the corrective actions that the company had taken since its previous *C. sakazakii* incident. Thus, the outcome of the evaluation can be instrumental in improving the food safety management system or the crisis preparedness and procedures, in order to prevent, or minimize, the impact of future problems. A final report on the case, including the root cause analysis and the lessons learned, needs to be communicated widely to prevent future similar cases. Public health authorities need to also report the results of their investigation. The repetition of several important incidents, e.g. melamine, *Salmonella* in chocolate, *Salmonella* in peanut butter, tends to indicate that the causes of incidents are not always fully investigated and the lessons learned are not widely communicated. Finally, the roles and responsibilities, including those of members of management, in the incidents need to be clarified. A major mistake would be to fire the personnel who *a priori* are viewed as responsible before the investigation is finalized and the root

cause of the incident is identified. A critical review of the root cause of incidents can show that not infrequently, the failures can be traced to the management's decisions and lack of commitment.

CONCLUSIONS

In life, the unthinkable can happen. In food safety, any gap even a detail may be the occasion for an incident or mishap with the potential for causing a crisis. A proactive approach to the management of food safety can minimize the likelihood of an adverse event leading to a crisis. A crisis is never good and will cause damage, and should by all means be prevented; however, when it occurs, how it was managed can be the opportunity for demonstrating the management capabilities and the values of an organization. In the management of a crisis, the objectives should be to maintain the trust of the stakeholders, in particular the public, authorities and trading partners. Decisions should be based on facts, including consideration of the uncertainties, and putting the health of consumers as a priority. The perception of consumers is also an important consideration. Speed of action, a consistent and transparent approach and empathy for the victims are some of the key values for which an organization should be scrutinized. In a crisis situation, the media play an important role and communication with the media, or through the media with the public, is key for the management of a crisis. The values and culture that an organization promotes and actively implements is a determining factor for the early identification and management of potential issues and for the prevention of a crisis.

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CHAPTER

42

The Role of International, Regional and National Organizations

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OUTLINE

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INTRODUCTION

Standards appear to be an innate, hard-wired faculty of a living brain. It is demonstrate repeatedly in even nonhuman subjects by virtue of an animal's ability to make distinction between ripe and unripe foods, which individual will make the most suitable mate, where is the best place to build a nest or den. Creating standards appears to be the brain's preferred method to sort and classify the flood of information that it continuously confronts.

Over the course of evolution, this ability to standardize started to categorize certain sounds to mean specific things; such as food, water, danger or mate. The standardized

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sounds led to the development of language that could be understood by multiple individuals to unify a group into a society. All could learn and understand the meaning of the standardization of the various sounds. In time, the standardized sounds were further standardized into specific symbols or groups of symbols, and written language ensued.

Communication is the basis for civilization and, as such, is the lubricant that allows industry and business to flourish. Communications must include concepts, units and measurements that are commonly understood to be useful to the parties involved. The development of standards as a tool of commerce is hard work. Those actively involved with the development of standards know how difficult it can be to put concepts into words so that every reader will arrive at essentially the same interpretation. As difficult as this effort may be for physical attributes of a product, it becomes immensely more difficult when trying to describe a sensory attribute, such as a flavor or odor, in words.

The world of commerce is awash with standards. An internet search for *Food Standards* will reveal approximately 540 million citations. Every country has its own extensive list of standards for both domestic and imported products. Over time, some of those standards have been codified to become regulations. This chapter will focus on the leading organizations that develop standards that are of significance to the food processing industry. Industry members seeking to do business with a particular country or region are strongly encouraged to become familiar with their standards.

Effective standards and guidelines are developed through what is called the Consensus Process.

Wikipedia (http://wikipedia.org) defines the process as follows: "**Consensus decision-making** is a group decision-making process that seeks the consent, not necessarily the agreement of participants and the resolution of objections." Consensus is defined by Merriam-Webster as, first, general agreement, and second, group solidarity of belief or sentiment. It has its origin in a Latin word meaning literally feel together. It is used to describe both the decision and the process of reaching a decision. Consensus decision-making is thus concerned with the process of reaching a consensus decision, and the social and political effects of using this process.

All standards writing organizations using this process follow these basic principles:

- Openness
- Lack of dominance
- Balance
- Coordination and harmonization
- Notification of standards development
- Consideration of views and objections
- Consensus vote
- A process for appeals

All interested parties taking the opportunity to participate in a standard's development are assured that their comments and objections are heard, and that the work is not duplicating the work of standards already created.

Modern commerce in the food industry is both local and international in nature. Worldwide consumers are used to being able to obtain food products which are not locally grown or are not in season. They are critical of freshness, quality and safety. Even

consumers in underdeveloped or developing countries that are forced to live at subsistence levels are wary of receiving cast-off or substandard products. Safe food is of primary concern to all consumers. Unsafe or low-quality food will cause a long-term loss of confidence in a supplier. This loss of confidence will result, at minimum, in a significant loss of market share and, at worst, cause a company to go out of business.

Everyone benefits from standardization. Standardization reduces production costs thus reducing consumer prices and increases the safety and desirability of products offered for sale.

LEADING INTERNATIONAL STANDARDS ORGANIZATIONS

World Health Organization

At the international level of public health oversight is the World Health Organization (WHO).[1] WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends. WHO provides services in every aspect of public health; however, its program on Food Safety (including its activities for the surveillance of foodborne diseases) is of specific importance to food safety. The Food Safety program is allied with the Consumer Protection program of the Food and Agriculture Organization of the United Nations, the host for the Codex Alimentarius Commission (see below).

WHO, as the leading authority on public health and food safety issues, has the international support and resources to conduct comprehensive risk assessment. Chemical and biological hazards in foods are a worldwide public health concern and can have major impacts on international trade. All interested parties from producers, processors to governments need to have access to reliable risk assessment, but few have the resources, expertise or funds to conduct them on the huge numbers of chemicals used in agriculture and food production. It is through the efforts of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) that the food industry benefits.

JECFA meets twice a year to conduct risk assessment and safety evaluations of food additives (including processing aids and flavorings), contaminants, naturally occurring toxicants and residues of veterinary drugs. JECFA has evaluated more than 2500 food additives, approximately 40 contaminants and naturally occurring toxicants, and residues of approximately 90 veterinary drugs since its inception. The findings of the committee are published and available from online archives:

- The WHO Technical Report Series (TRS) contains concise toxicological and chemical evaluations of each substance evaluated.
- The WHO Food Additives Series (FAS) are toxicological monographs with detailed descriptions of the biological and toxicological data from the evaluations and including intake assessments.

[1] www.who.int

- The Compendium of FAO Food Additive Specifications provides detailed specifications on the identity and purity of food additives and flavoring agents.
- The Database of FAO Veterinary Drug Residue Monographs.

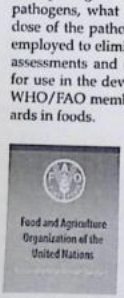
JMPR meets annually to review residue and analytical data on pesticides and other contaminants. Their reviews are focused on the chemicals' rates and by-products of metabolism, effects on the environment, use patterns and to establish maximum residue levels (MRLs) and average daily intake levels (ADIs). As such, JMPR serves as the scientific advisory body for the FAO, WHO, FAO/WHO member governments, and to the Codex Alimentarius Commission via the Codex Commission on Pesticides/Residues (CCPR).

Following the Uruguay Round the World Trade Organization (WTO) succeeded the General Agreement on Tariffs and Trade (GATT) and established that scientific, risk-based standards were to be used under the Sanitary and Phytosanitary (SPS) agreement to address trade practices. This positioned the FAO/WHO, through Codex, to be the preferred source of risk assessment data.

The findings of the committee are published and available from online archives:

- Toxicological monographs summarize the data reviewed.
- Residue monographs containing information on pesticide use patterns, chemistry and composition of pesticides, methods of analysis for residues, and information on MRLs are published in the FAO Plant Production and Protection Paper series.

JEMRA was established to meet the challenges created by the emergence or re-emergence of foodborne pathogens. The risk analyses performed by JEMRA cover the entire food chain. They focus their analyses on detailed review of scientific papers with emphasis on food–pathogen combinations. They are focused on identifying what are the potential risk pathogens, what happens when the pathogen is ingested, what constitutes an infectious dose of the pathogen, who in the population are at most risk, and what measures can be employed to eliminate the chance of foods becoming infected. The primary users of the risk assessments and data they develop are the Codex Committee on Food Hygiene (CCFH) for use in the development of standards, guidelines and recommendations, and directly to WHO/FAO member countries so they can better monitor and control microbiological hazards in foods.



Of significant benefit to the food processing industry and the governmental bodies that monitor its activities are the extensive WHO efforts to develop and disseminate guidance materials on HACCP programs, the strengthening of national food safety programs, consumer education programs and international health regulations.

As noted throughout this chapter, the Food and Agriculture Organization of the United Nations (FAO)[2] is closely aligned with WHO. The two organizations support and complement each other. The mission of FAO is to provide independent scientific advice, data input for risk assessment activities and similar guidance on food safety issues to the Codex Alimentarius Commission and governmental bodies. Decisions that influence international

[2]www.fao.org

trade and food safety requirements must be based on sound, demonstrable science data. To assist this goal, FAO supports the development of member countries' resources to effectively manage food safety and quality programs by providing advice on specific scientific food safety issues. FAO provides additional guidance in food control measures through training and various publications. The following are major topic areas addressed by FAO:

- Assessment of food safety capabilities
- Establishing effective food safety programs
- Encouraging participation in Codex activities
- Development and implementation of HACCP systems
- Development and implementation of food inspection programs
- Product quality assurance programs

All of FAO's efforts are focused on achieving food security while protecting the environment and assuring sustainability of agriculture around the world.

CODEX ALIMENTARIUS
International Food Standards
World Health Organization

The objectives of the Codex Alimentarius Commission (CAC) are to protect the health of consumers and ensure fair practices in the food trade. Through the work of its committees, CAC develops and publishes standards and codes of practice under the auspices of WHO/FAO. Codex Alimentarius international standards, guidelines and codes of practice are recognized by the World Trade Organization's (WTO) *Agreement on Sanitary and Phytosanitary Measures (SPS Agreement)* as the reference for food safety requirements. Codex members represent 99% of the world's population. Participation offers countries a forum in which they can join the international community and assist in the development and harmonization of food standards and encourage their global adoption. Therefore, it plays a major role in international trade and in the resolution of disputes between buyers and sellers.

The WHO/FAO booklet *Understanding the Codex Alimentarius*[3] defines standards and codes of practice as follows:

> Codex standards usually relate to product characteristics and may deal with all government-regulated characteristics appropriate to the commodity, or only one characteristic.
>
> Codex Codes of Practice – including codes of hygienic practices – define the production, processing, manufacturing, transport and storage practices for individual foods or groups of foods that are considered essential to ensure the safety and suitability of food for consumption.

In many cases, Codex standards form the basis for many national standards. This provides the international trading community with a substantial foundation. Above this foundation are many standards writing organizations producing standards and guidelines.

[3]Joint FAO/WHO Food Standards Program, FAO, Rome.

These standards and guidelines are also recognized internationally. They may be specialized in various aspects of food processing and have gained wide recognition for their expertise. As with Codex, the successful organizations produce their documents through the consensus process. The consensus process assures that the documents produced have had input from all of the interested stakeholder groups; all opinions are openly discussed until a consensus is reached; the process has safeguards to protect the due diligence of the procedures; and the decisions are science based rather than on proprietary interests, arbitrary opinion or market protection.

The largest standards writing organization in the world is the International Organization for Standardization (ISO).[4] ISO was founded in 1947 and is based in Geneva, Switzerland. Since its founding, ISO has developed more than 19,000 standards. These standards and those of its partners, the International Electrotechnical Commission (IEC) and the International Telecommunications Union (ITU), encompass the entire scope of all industry activities from agriculture, food, construction, mechanical engineering, electronics, to computer and communications technology.

ISO is a network of the national standards institutes of 164 countries. These national standards institutes may be mandated by their respective governments or they may be industry established and operated. Inclusion of standards writing organizations from both government and non-government sources provides ISO with a superior advantage in assuring that the needs of both government and industry are addressed through the consensus process. While individuals and enterprises cannot become members of ISO, they do have the opportunity to influence ISO standards and decisions by becoming active in their national ISO delegations or the delegations' member organizations. Individuals may be selected to serve on ISO technical committees as recognized subject matter experts designated by their national delegations. A principal regional partner of ISO is the European Committee for Standardization (CEN).

Support of world trade is a major activity of ISO. ISO maintains a close relationship with the World Trade Organization (WTO) which grew out of the deliberations of the Uruguay Round of 1985–94 of the General Agreement on Tariffs and Trade (GATT) as well as the specialized agencies and commissions of the United Nations. ISO has focused their technical committee to assure that all ISO standards are compatible with these international organizations.

To reach the broadest audience as possible, ISO maintains an extensive library of videos to highlight the objectives and goals of the various standards and policies. Of particular interest to the food processing industry within the ISO library are 114 standards specific to food items and processes. ISO has five current publications detailing the creation and management of food safety management systems and the certification of these systems. ISO 22000 is a food safety management system that can be applied to any organization in the food chain, farm to fork. The standard has requirements for food safety management systems processes and procedures, and requires that the organization implement prerequisite programs and HACCP.

[4] WWW.ISO.ORG

LEADING REGIONAL STANDARDS ORGANIZATIONS

European Committee for Standardization
Comité Européen de normalisation
Europäisches Komitee für Normung

The European Committee for Standardization (CEN)[5] is based in Brussels. CEN was created in 1975 with goals to facilitate trade, remove trade barriers for European businesses and consumers, and promote global trading while protecting European citizens and the environment. It accomplishes these goals through the development of standards and publication of technical reports and technical specifications. CEN is the only European standards writing organization recognized by the European Union according to Directive 98/34/EC for all areas of commerce except for electrotechnology and telecommunications.

Thirty-three national members cooperate to develop and maintain European standards signified by the preface EN. The national members solicit the involvement of a vast number of technical experts, business federations, consumers and special interest groups to obtain the best and latest information when developing standards and technical specifications. CEN and ISO have a cooperative association, established by *The Vienna Agreement*, to provide representation in each group's meetings and to adopt the same text in each of their documents when applicable. Approximately 30% of CEN standards are identical to ISO standards. Once developed, the EN standards gain additional importance as they also become national standards for each of the member nations. Any existing national standards that conflict with the EN standards are withdrawn so as to provide uniformity throughout the European market. The adoption of standards and the removal of conflicting documents provide a uniform marketplace where products can travel freely without the cost burden of local or regional requirements.

CEN has established more than 400 standards as well as technical specifications and technical reports of value to the food processing and related industries. These include methods of testing of products for composition, toxins, microorganisms and allergens; materials handling equipment, food technology, metallurgy, packaging materials and systems, machinery safety, and construction materials and building designs. Of particular interest are those food and product standards which have been adopted as national standards and control the flow of products in commerce. Standards are available that also impact the food service industry.

CEN works closely with the European Commission to assure food safety:

- M/315 Standardization, Mandate in the field of method of analysis for animal feeding stuffs
- M/381 Standardization, Mandate in the field of methods of analysis of foodstuffs concerning food hygiene
- M/382 Standardization, Mandate in the field of method of analysis for animal feeding stuffs
- M/383 Standardization, Mandate in the field of method of analysis for mycotoxins in foc
- M/422 Standardization, Mandate in the field of method of analysis for heavy metals and iodine in food
- M/463 Standardization, Mandate in the field of method of analysis for food contaminants

In conjunction with the European Research Center of the European Commission, CEN participates in the organization and planning of workshops for food and feeds. In this regard, CEN *Workshop 18 – Cleanability of commercial foodservice equipment* used in retail and

[5] www.cen.eu

catering sectors was created in March 2004. This workshop developed the document *CWA 15596-2006 Code of practices on cleanability of commercial food equipment used in catering sectors.* Consumers are purchasing greater quantities of ready-to-eat food items and dining away from the home more frequently. The safety of retail deli counters and salad bars in grocery stores, and restaurants ranging from food carts to fast food establishments to high-end restaurants, are all potential sources of food safety issues. Standardization of the equipment designs, processes, food handling procedures and cleanability of the equipment and facilities is of major concern to local authorities.

CEN Technical Reports are developed to complement EN standards by providing information on the technical content of the standards. These reports are informational in nature and do not place any regulatory obligation on the member nations.

Packaging is vital to the food industry. The food industry utilizes approximately 60% of all packaging materials produced. These materials include glass, paper, cardboard, metal cans, metal foils, plastics and specialized laminates. They are of concern to raw material suppliers, food processors, users and consumers, transportation firms and waste management companies. Packaging materials that have direct product contact are a food safety issue. International and smaller, local packaging material manufacturers rely on standardization and regulations to assure them that they will have broad access to food markets around the world. The CEN Technical Committee has produced approximately 200 normative documents or technical reports dealing with packaging materials.

efsa
European Food Safety Authority

The European Food Safety Authority (EFSA)[6] provides independent risk assessment for food industry risk managers. EFSA has a legal obligation mandated by the European Parliament (EU Regulation 178/2002) to provide their services to EU member states. The EFSA goal is to be recognized globally as the European reference body for risk assessment, based on the highest scientific standards, on food and feed safety, animal health and welfare, plant protection and plant health.

The EFSA role is to assess and communicate risks within the entire food chain. They have a significant influence on what is available in the food retail stores and eventually on the consumer's dining table. The risk assessments conducted include adopting or revising EU legislation on food safety, the approval of regulated substances such as pesticide residues and food additives, and the development of nutritional guidelines and policy.

The primary stakeholders within the EFSA structure are the European Parliament, the EU member states, industry groups, consumer groups and non-governmental organizations (NGOs). EFSA conducts risk assessments when requested for scientific advice from any of the stakeholder groups and it may initiate activities on its own. The risk assessments are conducted by reviews of the current scientific research papers and study data available, through web-based public consultations, and may carry out research among its Scientific Panels and Directories for its key target audiences. These activities are conducted through five directories overseen by the EFSA executive director. The directorates are:

- Risk Assessment and Science Assistance
- Scientific Evaluation of Regulated Products

[6] www.efsa.europa.eu

- Science Strategy and Coordination
- Communications
- Resources and Support

LEADING NATIONAL GOVERNMENTAL ORGANIZATIONS

All national governments have regulatory and standards development or implementation programs to protect their consumers. Depending on the national structure of each country the responsibilities for these activities may be centralized or divided between multiple agencies. The following are examples of influential agencies from the United Kingdom and the United States of America.

Food Standards Agency

The Food Standards Agency (FSA)[7] is the primary standards organization for the food industry in the UK. FSA was established by the Food Standards Act of 1999 and, therefore, has a statutory obligation to protect public health and food hygiene across the UK. They accomplish this mission by working closely with local authorities in England, Scotland, Wales and Northern Ireland. FSA can commission research on food safety and hygiene issues when necessary to establish the best regulations and policies. All decisions are based on the best available science available.

FSA as the UK representative to the EU Commission and Codex assure that the concerns of the UK are considered in the policies and standards created by those agencies. The strategy of FSA is to assure:

- Foods produced or sold in the UK are safe to eat;
- Imported food is safe to eat;
- Food producers and caterers give priority to consumer interests in relation to food;
- Consumers have the information and understanding they need to make informed choices about where and what they eat;
- Regulation is effective, risk based and proportionate, is clear about the responsibilities of food business operators, and protects consumers and their interests from fraud and other risks;
- Enforcement is effective, consistent, risk-based and proportionate and is focused on improving public health.

As the primary regulatory agency for the public health aspects of food safety, FSA works with local authorities to implement and enforce the *Food Law Code of Practice*. The Code of Practice sets out instructions and criteria that local and port health authorities (food authorities) should comply with when enforcing food law. Food authorities must follow and implement the provisions of the code as they apply. Included in these regulatory activities are the establishment of a list of Approved Plants, audits of local authorities to assure uniformity of inspections, training, issuing food alerts when necessary and monitoring of food safety.

[7] www.food.gov.uk

The United States, Food and Drug Administration (FDA),[8] Center for Food Safety and Applied Nutrition (CFSAN) is the primary United States food regulatory authority except for red meats and poultry, which are regulated by the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA). FDA has a statutory obligation to protect the public health through the Food, Drug and Cosmetic Act of 1936 as amended. Its regulations are codified under Title 21 of the Code of Federal Regulations (CFR) and thus available to all interested parties.

The *good manufacturing practices* (GMPs) (21 CFR Part 110) and *thermally processed low-acid foods packaged in hermetically sealed containers* (21 CFR 113) are of universal interest to the food industry. CFSAN also publishes, independently from the CFR, the Pasteurized Milk Ordinance (PMO) specifically for the dairy industry, and the Food Code for the retail food industry. In addition to these regulatory and inspection guidelines, FDA also publishes Standards of Identity for most common foods. The Standards of Identity can be obtained from 21 CFR 130 through 169. FDA, like its counterparts in Europe, conducts risk assessments and approves all food additives used in the United States. On 1 January 2011, the Food Safety Management Act (FSMA) was signed into law. This act has a significant impact on both domestic and international trade within the United States.

FDA is the United States representative for interaction with Codex, the EU Commission and other national governments in regard to international food standards and international trade issues affecting food safety issues and quality.

For the food industry, FDA has interest and regulatory authority for:

- Risk assessment
- Biotechnology
- Dietary supplements
- Food defense and emergency response
- Food ingredients
- Food safety
- Retail food protection
- Guidance, compliance and regulatory information
- International activities
- Labeling and nutrition
- Animal drugs and residue monitoring
- Science and research

The United States Environmental Protection Agency (EPA)[9] is not a primary standards setting organization for the food industry. However, the EPA does conduct risk assessments for pesticide use and residues used in agriculture. These pesticide residue limits are used by the American regulatory agency for the protection of consumers. EPA risk assessments and residue limits are commonly referenced worldwide as a source of reliable data for establishing food standards limitations.

[8]www.fda.gov
[9]www.epa.gov

LEADING INDUSTRY ORGANIZATIONS

GFSI

Following a series of food safety incidents, a group of business CEOs banded together to form the Global Food Safety Initiative (GFSI).[12] This program is retailer and food service industry driven in order to maintain control over the safety of their supply chains. GFSI was formed in May 2000 under Belgium law. The stated vision of GFSI is "Safe food for consumers everywhere." Its mission further aims to "Provide continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide."

The Consumer Goods Forum, a global network for retail goods retailers and manufacturers worldwide, provides the direction and day-to-day management of GFSI. They recognized early on that the huge variety of products, processes, plant layouts and delivery systems was not compatible with a "one-size-fits-all" approach. Therefore, GFSI does not:

- Intervene in retailer or supplier policy;
- Make policy for standards developers;
- Undertake certification or accreditation activities of retailers.

The approach GFSI has taken is the development of a program through which the knowledge and expertise of how the various food chain participants manage food safety can be evaluated. The program will:

- Provide a method to benchmark existing food safety standards used from the farm through the processing level to the consumer;
- Compare existing standards against the requirements that have been put together by the participants in the food supply chain.

To accomplish this goal, a technical working group composed of retailers, manufacturers, certification bodies, accreditation bodies, standards developers, food service providers, food safety experts and consultants developed the GPSI Guidance Document. The current volume is the Sixth Edition Issue 3 Version 6.2 and is available for free from the GFSI website. The process outlined in this document is intended to be executed in an independent, unbiased, technically proficient and transparent manner. The Guidance Document is divided into three parts:

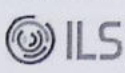
"Part I – The Benchmarking Process" provides the key steps developed by GFSI to rate an existing safety management system according to the key elements identified by GFSI as necessary to ensure food safety. The benchmarking process is to be done by an impartial group with full transparency so that others in the GFSI program can be assured that the benchmarking is accurate and complete. Members of the GFSI Benchmarking Process include Safe Quality Food Institute (SQF), British Retail Consortium (BRC), International Featured Standards (IFS) and Food Safety System Certification (FSSC) 2000.

"Part II – Requirements for the Management of Schemes" provides requirements necessary to the effective management and control of a food scheme. All food safety schemes require validation that they are effective and then continual verification that the scheme is working on a day-to-day basis. This part also provides the requirements for the

[12] www.mygfsi.com

competence of auditors working for the independent third party Certification Bodies that will evaluate the suitability of a food safety scheme for inclusion in the GFSI program. "Part III – Scheme Scope and Key Elements" describes and expands upon the key elements determined by the technical working group as necessary for inclusion in a food safety plan to be eligible for recognition by the GFSI program. These key elements will include the requirements for good practices which may include HACCP or HACVCP-based controls.

Firms that have successfully complied with the requirements and been certified as in conformance with the GFSI program can enjoy significant benefits as a supplier or retailer, with dealings with government agencies, recognition across borders and marketing areas, and reduction in production costs through efficiencies and reduction of duplicate inspections by multiple buyers.



International Life Sciences Institute (ILSI)[11] is based in Washington, DC. The nonprofit organization has the mission "to provide science that improves public health and well-being." They accomplish this mission by supporting and encouraging collaboration among experts, academia, government and industry on the tasks of gathering, summarizing and disseminating science. ILSI focuses its activities primarily on nutrition, health promotion, food safety, risk assessment and the environment. These are important activities that support the goal of a standards writing organization (SDO) to provide science-based standards and regulation recommendations. This, in turn, assists industry and governments to address the risks and issues that are of common concern around the world.

ILSI has identified Four Global Issues that are of common concern at the local, regional and international level, and in which nearly all ILSI entities are involved. They coordinate the scientific efforts of the programs and projects related to each Global Issue, and provide links to additional information to interested parties as available:

- Biotechnology
- Functional Foods
- Obesity
- Risk Assessment

The International Commission on Microbiological Specifications for Foods (ICMSF)[12] is a subsidiary of the International Union of Microbiological Societies (IUMS). Their mission is to be a leading source of independent, impartial scientific microbiological concepts and standards that can be adopted by government agencies and industry to reduce the incidences of pathogens in foods. ICMSF has links to WHO and Codex so its activities have worldwide availability. The commission's goals are to:

- Assemble, correlate, and evaluate data about the microbiological safety of foods;
- Consider if microbiological criteria would improve and assure the safety and quality of particular foods;

[11] www.ilsi.org
[12] www.icmsf.org

- Propose the adoption of such criteria; and
- Recommend methods of sampling and microbiological examination to assure uniformity of results worldwide.

The commission was established in response to the increasing number of foodborne diseases and the need for increased microbiological testing. The demand for international trade in foods is expected to continue to rise. Diseases caused by foodborne pathogens are a worldwide public health concern and impact on a countries' or market's food security. The food standards proposed by ICMSF are based on sound scientific principles of analysis, sampling plans and microbiological limits. Their standard's equivalency between countries is well established.

EUFIC

The European Food Information Council (EUFIC)[13] located in Brussels, Belgium, is a non-profit organization which communicates science-based information on nutrition and health, food safety and quality, to help consumers to be better informed when choosing a well-balanced, safe and healthful diet. EUFIC's publications are based on peer-reviewed science. Information that EUFIC publishes has been subject to a review process by members of its Scientific Advisory Board (SAB). The SAB, comprised of renowned experts from across Europe, advises EUFIC on its information and communication programs, ensuring that all information is based on scientific evidence, relevance and is factually correct. Given the broad range of subjects addressed in EUFIC's popular newsletter, Food Today, a dedicated editorial board provides additional insights and feedback for this publication.

EUFIC is supported by companies of the European food and drinks industries, but also receives some project funding from the European Commission. All members adhere to EUFIC's Transparency Statement. EUFIC's mission is to enhance the public's understanding of credible, science-based information on the nutritional quality and safety of foods and to raise consumers' awareness of the active role they play in safe food handling and choosing a well-balanced and healthy diet.

EUFIC continues to partner with a broad base of stakeholders in numerous research projects funded by the European Union. With financial support from the European Commission's Directorate General for Research, the consortia in which EUFIC participates aim to improve our knowledge about food safety and quality, and health and nutrition. Projects they participate in include CHANCE, DIETS, EATWELL, EURRECA, FLABEL, FOOD4ME, IDEFICS, NU-AGE, CONNECT4ACTION, RECAPT, INPROFOOD, and more. Additional information concerning these various programs can be obtained from the EUFIC website.

IOCU

The International Organization of Consumers (IOCU)[14] is a global federation of consumer advocacy groups. As the world's consumers have become more informed about products, processes, food safety issues and the environment, they have banded together to make their voices heard by national governments and international bodies. IOCU is a non-governmental organization (NGO)

[13] www.eufic.org

[14] www.sagepublications.com

that links the activities of 170 consumer organizations residing in 60 countries. The consumer organizations support the eight following consumer rights:

1. The right to safety;
2. The right to be informed;
3. The right to choose;
4. The right to be heard;
5. The right to the satisfaction of basic needs;
6. The right to redress;
7. The right to consumer education;
8. The right to a healthy environment.

IOCU has standing committees or working groups on education, testing and development, health, transnational corporations, library and documentation, air transport, and information technology to assist their members to organize, lobby and change government regulations and policy. The organization extends the influence of the consumer by having established consultative status on several United Nations bodies. These include the UN Children's Fund (UNICEF), the World Health Organization (WHO), the UN Environment Program (UNEP), the Food and Agriculture Organization (FAO), the UN Conference of Trade and Development (UNCTAD), the UN Education and Science Organization (UNESCO), the UN Industrial Development Organization (UNIDO) and the Economic and Social Council (ECOSOC).

BEUC

The European Consumer Organization (BEUC)[15] is based in Brussels, Belgium. As with other consumer advocacy organizations, their purpose is to lobby the European governments on behalf of consumers' issues. BEUC supports and reinforces the eight consumer rights promoted by the IOCU. The organization acts as an umbrella group representing 40 independent national consumer groups from 30 European countries.

BECU is duly registered with the European Parliament Lobby register which affords its representatives unlimited access to parliament facilities to meet with members of parliament and EU Commission officers. Access to the public policy developers in parliament allows BEUC to vigorously defend consumer rights and has resulted in many favorable policy decisions. Their work is to ensure that consumer policy at the EU level is sustainable for all. In BEUC terms, "sustainability" is not only the protection of the environment, including climate change, but also reduction of negative social and economic impacts. Improving well-being for all, without compromising the needs of vulnerable groups, such as children, the elderly and low income consumers, must be taken into account when designing policy.

GMA

The Grocery Manufacturers Association (GMA)[16] is located in Washington, DC. GMA is an advocate for the leading food, beverage and consumer products companies to facilitate and advance the quality of life for the consumers in the United States and around the world. GMA is active in product safety, health and nutrition, preservation of the environment, global commerce, collaboration among retailers, and providing advice and counsel to governments on consumer

[15] www.beuc.org
[16] www.gmaonline.org

products issues. They pursue their goals through a strong commitment to scientific research, testing and evaluation of consumer products and business practices. GMA assists their members as a central information resource and as a means to collaborate between members, retailers, service providers and consumers to obtain healthy, affordable, safe foods.

NSF International (NSF)[17] is based in Ann Arbor, MI, USA. Their organizational mission is "To make the world a safer place for consumers." They accomplish their mission by developing and publishing internationally recognized standards for food, water and consumer products. NSF has offices in many European countries and other international locations in the Far East, Southeast Asia, South America and Mexico.

One goal of NSF is to offer a knowledge base to support and increase legislators and regulators awareness of public health issues. The NSF Regulatory Affairs office provides information on the interpretation and application of their standards, answers to regulatory code questions, product verification to assure the products meet national standards and other requirements.

NSF offers a wide scope of programs that are of particular importance to the food and beverage industries and in auditing for conformance with international food safety initiatives, such as the Global Food Safety Standards (GFSI) (including SQF (Safe Quality Food), BRC (BRC Global Standards), Global GAP (the Global Partnership for Good Agricultural Practices), FSSC (Foundation for Food Safety Certification) and IFS (International Featured Standards)), HACCP-9000 and ISO 22000.

NSF has developed over 50 American national standards pertaining to food safety and public health under their various programs. Three standards, developed jointly with the 3-A SSI organization, are specific for meat and poultry equipment (14159-1, -2 and -3).

LEADING HYGIENIC DESIGN STANDARDS ORGANIZATIONS

The emphasis on the many product standards writing organizations often overshadows the importance of the equipment and processes used to produce safe foods. The successful conformance to product standards, as well as the reduction of production costs, is significantly enhanced when the equipment and processes are designed and fabricated to standards that will help assure that microbial and physical contamination, and the carry-over of allergens, are prevented. Multiple incidences of poorly designed processing equipment have led to problems with food safety, product quality and massive industry recalls due to an inability to properly clean and sanitize the equipment. These problems of equipment design and fabrication can be prevented by following the standardized criteria readily available.

The European Hygienic Engineering and Design Group (EHEDG),[18] based in Frankfurt, Germany, has regional offices in most European countries and international locations in the Far East, Southeast Asia, South America and Mexico. EHEDG is a consortium of equipment manufacturers, food processors, research institutes and public health authorities. It was

[17] www.NSF.org
[18] www.EHEDG.org

FIGURE 42.1 Sample EHEDG certification mark.

formed in 1989 with the mission to promote hygiene during the processing and packaging of food products. EHEDG as an organization does not develop specific standards. European legislation requires that food be processed and packaged hygienically, with hygienically designed equipment, in a hygienic facility. EHEDG takes the requirements of the legislation and presents them in a series of guidelines which are easily understood and provide guidance for specific classes of equipment and processes. Currently, EHEDG has developed 41 unique guidelines to assist the food processing industry. The scope of these guidelines cover:

- Equipment and building design and cleanability
- Equipment and building element installation
- Industrial services and utilities
- Maintenance of assets

The EHEDG certification program provides purchasers of equipment with a readily recognizable symbol (Figure 42.1) displayed on equipment that meets the guidelines' requirements. This assists purchasers to obtain equipment that will support their production of safe foods.

3-A Sanitary Standards, Inc. (3-A SSI),[17] based in McLean, VA, USA, is the premier standards writing organization for hygienic standards for food processing equipment. Their first standard was published in 1920. The historical basis for 3-A standards development has been the dairy industry. However, it has been shown over time that the fundamental principles of hygienic design and equipment cleanability encompassed by the 3-A Standards and Accepted Practices are universally applicable over most food products. The mission statement of 3-A SSI is:

> It is the mission of 3-A Sanitary Standards, Inc. to enhance product safety for consumers of food, beverages, and pharmaceutical products through the development and use of 3-A Sanitary Standards and 3-A Accepted Practices.

3-A SSI develops two types of documents. The 3-A Sanitary Standards provide criteria for specific types or classes of equipment. The 3-A Accepted Practices provide criteria

[17] www.3-A.org

for specific processing systems. There are 71 3-A Sanitary Standards and 10 3-A Accepted Practices as of 2012.

The 3-A symbol, 3-A, is a copyrighted mark to signify to buyers of the equipment that it conforms to all of the criteria of a covering 3-A Sanitary Standard.

For many years the Baking Industry Sanitation Standards Committee (BISSC) developed standards specific to baking industry equipment. As with other standards writing organizations in the United States they are accredited to develop standards using the ANSI procedures and guidelines. BISSC was formed in 1949 by representatives from six national baking industry organizations. The complete line of BISSC standards was first published as a single booklet in 1977. The current publication is the widely successful *ANSI/BISSC Z50.2-2003 Baking Equipment Sanitation Standard*.

In 2007, the board of directors of BISSC elected to become a wholly owned subsidiary of the American Institute of Baking International (AIB).

AIB International,[20] based in Manhattan, KS, USA, was established in 1919 initially as a research organization. Currently AIB offers a wide range of services to the food industry as well as the baking industry, including:

- AIB Consolidated Standards
- AIB GMP Inspections
- AIB Knowledge Center
- Analytical services
- Consulting and customized training
- Distance learning and training products
- Food defense services
- GFSI certification schemes
- HACCP accreditation
- Resource center
- Seminars, webinars and courses

CONCLUSIONS

Standards are pervasive throughout the food industry. The organizations highlighted in this chapter are a limited sampling of the most recognizable in widespread use. The information provided indicates the extremely complex interaction of all of these organizations as they work towards a common goal – food safety. Participating in standards development and the use of developed standards by manufacturers, processors, distributors and retailers provides them with the ability to assist in the creation of documents that will benefit all users through improved food safety, quality, efficiency, cost reduction and acceptance by consumers.

[20] www.aibonline.org

Further Reading

Allergen Information Manual & Auditor Guidelines, downloadable from www.aibonline.org
ANSI Essential Requirements: Due Process Requirements for American National Standards, 25 West 43rd Street, 4th Floor, New York, New York 10036.
Application of Risk Analysis to Food Standards, downloadable from www.who.int/foodsafety/micro/jemra/en/
CEN Compass: The world of European Standards, downloadable from www.cen.eu
EFSA's approach to identifying emerging risks in food and feed, downloadable from www.efsa.europa.eu/cs/Satellite
Enhancing Food Safety through Third Party Certification, downloadable from www.mygfsi.com
Food Defense Guidelines, downloadable from www.aibonline.org
GFSI Requirements on the Application of ISO/IEC 17011:2004, downloadable from www.mygfsi.com
Understanding the Codex Alimentarius, downloadable from codexalimentarius.org
WHO Global Strategy for Food Safety, downloadable from www.who.org
World Consumer, IOCU, The Hague.

SECTION IV

SUSTAINABILITY AND ETHICS

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CHAPTER

43

Sustainability and Food Production

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INTRODUCTION

The chapter gives an overview of the sustainability issues facing food production today and the challenges for the future. Sustainability is a modern "buzz-word" used in many circumstances without proper consideration of what it really implies. To help amend this situation this chapter will present and discuss the concept of sustainability and its three dimensions. The interpretation of social, economic and environmental sustainability in the area of food production will be discussed with reference both to the present situation and

also to the future. The actions taken in the food industry and by the research establishment to improve sustainability will be reviewed. The important links between food safety and sustainability will be emphasized. And finally, a number of important issues will be considered and acted on for a more sustainable global food production in the future.

SUSTAINABILITY – AN INTRODUCTION

Sustainability was highlighted in the report "Our common future" from the World Commission on Environment and Development (WCED) (Brundtland, 1987). The definition in this report stated: "Development that meets the needs of the present without compromising the ability of future generations to meet their own needs." The report also pointed out the need to assess sustainability along three pillars: Environment, Economy and Society. Sometimes the pillars are called People, Planet and Profit, or the triple P. The WCED had its roots in the 1972 Stockholm UN (United Nations) conference on the Human Environment, which was the first major international activity in the field of environment. The Stockholm meeting resulted in the establishment of many national environmental protection agencies, as well as UNEP, the UN Environmental Programme.

In the 1970s an important contribution towards improving the understanding of the global ecological situation was made by the Club of Rome. The key purpose was to perform technological forecasts taking into account the interconnectivity of ecology, economics, demography and the resource sector. Their report, entitled *The Limits to Growth* (Meadows et al., 1972), made the informed public aware that exponential economic growth has limits, set by the ecological capacity of the earth.

The Earth Summit in Rio de Janeiro in 1992 emphasized that the three pillars of sustainability should be treated in their integrity and the renowned Agenda 21 activities were derived from the principles for sustainability agreed upon during the Rio Summit (UN, 1992). At the Johannesburg World Summit on Sustainable Development in 2002 plans for implementation and sustainable development were important issues, focusing on poverty eradication, health concerns and sustainable production and consumption. From this period the word sustainability is being used extensively in documents, plan and programs, sometimes without proper consideration for what it implies. It is obvious that sustainability has and must have different meanings to different actors, organizations and countries. The consumer might have an understanding that sustainability stands for "green and healthy" with the implication that the food is deriving from production systems with positive attributes for them, like local production, animal welfare or pesticide-free production. On the industrial side the World Business Council for Sustainable Development (WBCSD) is interpreting sustainability as: "ecologically sound, economically viable and socially acceptable."

Food production and consumption is the primary requisite for a decent life and the sustainable well-being of humankind. However, human activity has the single largest global environmental impact (Smil, 2000). The majority of the global concerns for a more sustainable future are strongly related to different aspects of food production. These aspects will be presented and discussed in the following paragraphs with regard to food production and its relation to the three pillars of sustainability. Some of the major issues of sustainability of relevance to food production are outlined in Table 43.1.

TABLE 43.1 Sustainability Issues of Relevance to Food Production

Sustainability Pillar	Category	Issue
Social aspects	Human health and well-being	Food safety and nutrition
		Food security
	Human rights	Child labor
		Right of association
		No discrimination
		Rights of indigenous people
	Labour conditions	Level of wages
		Working hours
		Safety standards
Economic aspects	Corporate	Sustainable return of investment
		Corporate social responsibility and citizenship
	Fairness	Fair distribution of revenues
		Contracts and credit facilities
	Global	Food waste reduction
		Efficient use of natural resources
Environmental aspects	Global	Contribution to climate change
		Loss of biodiversity
		Land use
	Regional	Eutrophication
		Water

SOCIAL ASPECTS OF SUSTAINABILITY AND FOOD PRODUCTION

An obvious social aspect of food production is its contribution to the health and well-being of the consumer of the food. Such aspects may include an assessment of whether the characteristics of produced food are in agreement with dietary recommendations or other societal goals related to, e.g. reducing obesity or preventing cardiovascular disease. Thus, general societal changes such as increasing urbanization and a more sedentary lifestyle will form the background for these social sustainability assessments. Another important aspect will be the biological and chemical safety of food.

Food security is an obvious aspect of global food sustainability. The growing world population will require a growing food production. An often cited figure is the need to increase world food production by 70% to the year 2050 when it is projected that the world

population will have increased to 9 billion from the present 7 billion people (FAO, 2009). Global food production has increased by about 2% annually in the last decades, and this increase will also be needed in the future. However, a number of doubts have cast doubt on this forecast, due the effects of climate change, the lack of arable land and to water scarcity in many regions (World Bank, 2010). In addition the UN Millennium Goal Program points out that the number of hungry people in the world (living on less than US$1 per day) continues to be around 1 billion. The elimination/reduction of poverty and hunger seems to be the goal which is most difficult to reach in the UN Millennium Goal Program (UN, 2011).

The social dimension of sustainability is also addressing the implications of the Universal Declaration of Human Rights (UN, 1948) for the people working in food production as well as others affected by the activities of food production. As an example, this may involve effects on living conditions for indigenous people affected by increased agricultural activities in their traditional living area.

Furthermore the social dimension of sustainability may consider the fairness of the working conditions for the labor force directly involved and affected by food production, assessing whether these are in agreement with international labor agreements such as the "ILO Declaration on Fundamental Principles and Right to Work." Issues such as child labor, minimum wages, working hours, freedom of association, etc. are also assessed.

Corporate social responsibility implies that the company or organization is acting as a good partner or citizen in the community and society where it is active, which is often taken as part of the assessment of social sustainability of the company or organization.

ECONOMIC ASPECTS OF SUSTAINABILITY AND FOOD PRODUCTION

The economic aspect of sustainability is most often interpreted as the ability of a commercial activity to produce a good level of return of investment (ROI) to the owners consistently over time. This assessment of economic sustainability involves looking not just at ROI but also at plans for management of economic and ecological risks and other "good management practices." This interpretation of sustainability often dominates the financial sector, where a number of assessment systems for sustainability exist, e.g. Dow Jones Sustainability Index. However, in the broader interpretation of economic sustainability, factors such as prevention of corruption and bribery are also assessed.

Many economic sustainability activities are related to ensuring fair distribution of revenues to the different actors in the food chain in order to give them the possibility of a sustainable livelihood. The focus is particularly on the small-scale farmer for whom the share of the price paid by the consumer often is less than 10%. A number of actions are taken within Sustainable Agriculture and Fair Trade programs to ensure a higher percentage being paid to the farmers (SAIPlatform, 2011; Fair Trade, 2011). Many labeling schemes among retailing and purchasing organizations also include assessments of these aspects of socio-economic sustainability.

A recent report from FAO and SIK highlights the enormous waste of food in the food chain (Gustavsson et al., 2011). The results of the study suggest that roughly one-third of food produced for human consumption is lost or wasted globally, which amounts to about

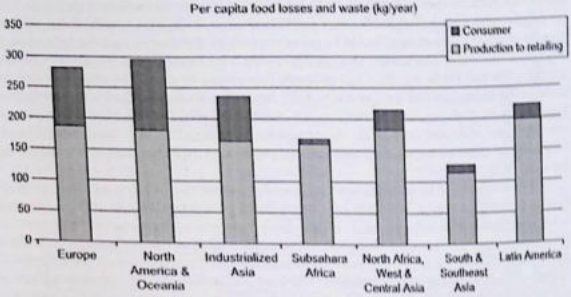

FIGURE 43.1 Per capita food losses and waste, at consumption and pre-consumptions stages, in different regions (Gustavsson et al., 2011).

1.3 billion tons per year. Food is lost or wasted throughout the supply chain, from initial agricultural production through to final household consumption. The most astonishing data come from the consumer sector in medium- and high-income countries where between 95 and 115 kg per capita per year is wasted, meaning that it is discarded even if it is still suitable for human consumption (Figure 43.1). The losses in the chain from production to retailing are substantial too, ranging from 125 to 200 kg food per capita per year. These figures should be compared to the annual production of food which per capita amounts to about 750 kg. These results indicate that a very important step to ensure global food security is to focus on reducing the food lost and wasted in the chain from the primary production to the store and eventually the consumer (Gustavsson et al., 2011).

To improve sustainability in the food sector natural resources will have to be used more efficiently, therefore an important issue on the road to sustainability is waste reduction along the chain from primary production to consumption. Whether by new preservation techniques, packaging, optimizing logistics or otherwise, new innovation must provide sustainable solutions. Furthermore the waste in industrialized countries can be reduced by raising awareness of wasteful behavior among food industries, retailers and particularly among consumers. An example of this is the UK campaign Love Food, Hate Waste.

ENVIRONMENTAL CONCERNS RELATED TO FOOD PRODUCTION

Fifty years ago the publication of Rachel Carson's *Silent Spring* (Carson, 1962) set off an alarm that the food production system used in the USA (and Western Europe) had grave ecological consequences from the spreading of toxic pesticides affecting, among other

things, the birds of spring. Another early reporter on the environmental problems of food production was Georg Borgström who published and discussed much about the risk of scarcity of water for food production in many regions of the world and the related conflicts regarding freshwater availability (Borgström, 1969). The reports and books published during the 1970s and 1980s, e.g. the Club of Rome (Meadows et al., 1972), did raise awareness, both among politicians and the general public, about the ecological limits to growth including growth of food production. Among the most influential publications from this time was the series of annual *State of the World* reports published by the Worldwatch Institute, which included contributions on the environmental issues on food production (Worldwatch Institute, 2011).

A hotly debated and very visible environmental problem caused by modern food production in Western Europe in the 1980s was the leakage into lakes, rivers and seas in coastal areas of nutrients from effluents and sewage from food production causing degradation of the water quality. The most evident problem was and still is nitrogen leakage from the use of fertilizers in agriculture, which leads to eutrophication. To some extent phosphorus also contributes to the eutrophication problem. The food production system (mainly agriculture) is responsible for between 60 and 75% of the eutrophication in many industrialized countries. Eutrophication fertilizes water bodies resulting in unnaturally high rates of plant and algae production and accumulation of organic matter that degrade water and habitat quality with risks of total depletion of oxygen at the bottom of the water body. Large areas in the Baltic Sea and the Mexican Gulf, for example, are witness to this problem.

The problem of the presence of toxic compounds remains an environmental problem of food production, such as pesticides in fruits and vegetables, heavy metals (cadmium, mercury, etc.) in grains and dioxins in fish. Many of these compounds show very persistent toxicity with low rates of decline even many years after the actual source of contamination has been eliminated.

Today, awareness is growing regarding the impact on climate change from food production. It has been estimated that global food production uses about 20% of all energy used in society (Sonesson et al., 2009). It is the human activity which uses the highest amount of energy. Modern food production has an extensive dependence on fossil fuels for fertilizer manufacturing and fuel for tractors and transportation. The contribution to global warming is higher, however, estimated at about 25%. The major reason for this is the contribution to global warming of methane and nitrogen compounds from the digestive tracts of animals in meat production. About half of the global warming potential emanates from meat production according to a much discussed report from FAO (2006). The dramatic differences in global warming potential between meat and vegetable products are shown in Figure 43.2.

From a biological point of view the accelerating loss of biodiversity is a major problem caused by the methods used in food production such as mono-culture agriculture, but also many other activities in society. These losses of biodiversity will jeopardize food availability and security by reducing the "safety net" provided by the availability of alternative plants for future food production and other factors affecting human well-being. Another major impact on biodiversity comes from modern industrialized fish trawling which has led to the near depletion of a number of important fish species (UNEP, 2011). The problem of loss of biodiversity is complicated by the lack of "ownership" of the problem.

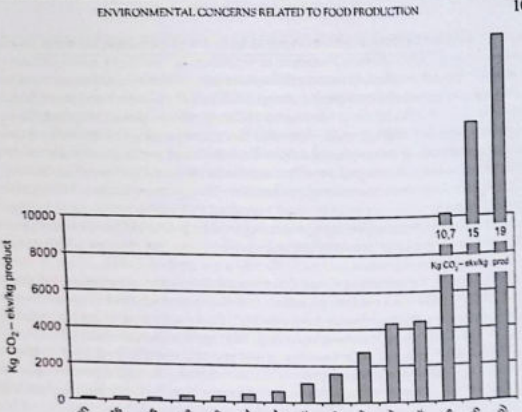

FIGURE 43.2 Global warming potential (CO_2 equivalents) for a range of foods (Sonesson, 2011).

The growing production of biofuels in many countries has brought about a debate on the most appropriate use of arable land in the world. A number of studies have pointed out that there is not much additional land available for crop production use. The need to increase food production to meet the needs of the increasing population is giving fuel to a debate on how available productive land should be used; for food, feed, fuel or forestry? The demand for more land causes more rainforests to be cut down at an alarming rate with devastating impacts on biodiversity and often limited added benefits to agricultural production (Alkimi et al., 2006).

The food sector is using about 70% of the available freshwater in the world, correspon ing to about 3 tons of water per capita per day. There are many problems with the pres use of water in the food sector, e.g. poor water management and deteriorating water quali Furthermore, in many parts of the world water availability is becoming an increasing pro lem with dropping water tables and an influx of salt into groundwater and freshwater (V and Van Ranst, 2009). The prediction for future climate change clearly points to the prob lems of availability of water, which will be much aggravated in the coming years particu larly in the regions of the world where water already is a scarce resource (IPCC, 2007).

IMPROVING SUSTAINABILITY IN THE FOOD SECTOR

The first impact on the food sector of the increased concern for the environment was the requirement to reduce the biological material (BOD) in the wastewater from farms and food industries. After the Stockholm conference in 1972 many countries established "Environmental Protection Agencies" (EPAs), which often had the cleaning of effluents from industries (and municipalities) as their major plan of action. Thus the food sector started to invest in sewage treatment operations, cleaning up the effluents emanating from food production.

The food industry was also strongly affected by the new environmentally driven legislation on packaging waste imposed in many countries in Europe and Japan during the 1990s. The costs involved in these packaging waste systems (e.g. Die Grüne Punkte) drove a development to lower packaging weights and thus lower packing volumes without reducing the performance of the packaging.

In response to the growing interest and awareness in environmental and sustainability issues after the Rio 1992 conference, many countries started environmental and sustainability activities under the name of "Agenda 21." These activities often included initiatives taken by the industry and their organizations. During this period the UN Global Compact was started with partners from industry, governments, unions and NGOs committed to aligning their operations and strategies with 10 universally accepted principles in the areas of human rights, labor, the environment and anti-corruption (UN Global Compact, 2011).

After the Rio conference in 1992, the industry started the "World Business Council for Sustainable Development" (WBCSD, 2010) with the aim of providing business leadership for change toward sustainable development. Gradually the food industries also identified the importance of the issues related to sustainability, realizing the advantages of reducing the use of input resources such as energy, water and ingredients, possibly with the experiences from the reductions in packaging use as a guide. In order to demonstrate their efforts to reduce the use (and the costs) of energy, water and waste many food industries and retailers today present sustainability reports. These reports also demonstrate the companies' contribution to social and economic sustainability. This might encompass sourcing the agricultural raw materials from sustainable agriculture in developing countries with fair payment to the farmers as one of the goals, as well as better control of the use of pesticides, e.g. as demonstrated by the Roundtable on Sustainable Palm Oil (RSPO, 2011). Other food operators are participating and/or supporting sustainability related labeling schemes such as "Rainforest Alliance" or "Fairtrade," where a limited number of sustainability-related factors are assessed in order for the grower to receive the "Label."

To the general public and consumers the most obvious effort by the food and retail industry to "go green" is the marketing of "organic" or "biodynamic" food products, using a myriad of labels. However, the market segment often only captures a few percent of the total market, so the impact on global sustainability is rather limited. The advantages in terms of environmental performance of organic foods over traditionally produced foods have been much discussed and quite a number of research studies have been presented, e.g. Mattsson (1999).

In the last few decades, research on Life Cycle Assessment (LCA) of food production within the national and international research programs has provided an important

contribution towards assessing the environmental sustainability of a range of food production chains and food products, particularly in Europe. Generally, LCA employs a range of environmental indicators related to the major environmental problems coupled to emissions and resource use, but the LCA method disregards the effects of temporal and spatial variation, by evaluating emissions rather than impacts.

The assessment of total sustainability of a food product or production system is not easy. A major complication is how to achieve trade-offs, where aspects of one pillar are improving at the cost of those from another pillar. Furthermore, there are dependencies through the impacts of social and economic processes on the environment, such as the ecological footprints left by international trade, which may have impacts on both ecological aspects and on fair trade relations. Therefore, it is important to continually strive for improved assessment methods for sustainability. A number of initiatives have been taken to include some of the factors of social and economic sustainability into environmental assessment methods in order to develop improved methods for assessing sustainability (UNEP, 2009).

Many other quantification methods for environmental or sustainable performance of a food product focus on one or a small number of issues, such as food miles (on transport of products) or carbon footprints (Tesco, 2007). A number of food retail companies announced in 2007–2008 that they planned to introduce carbon footprint labels on most of their food products. However, this has not materialized to any greater extent, probably due to the difficulties and complexities of how to perform the environmental analysis and the question of how to present the information in an easy-to-understand way.

FOOD SAFETY AND SUSTAINABILITY

Food production systems that lack sustainability will often also demonstrate deficiencies in food safety. The social dimension of sustainability concerns both the social conditions for the people involved in food production and the people affected by the food production. If basic human rights are not met for the workers it is likely that other basic food safety considerations are not taken into account. Moreover, there is an obvious connection between ensuring that food safety standards are met and the health and well-being aspects of social sustainability for the consumers of the food.

Inadequate risk management by food production operators has been demonstrated to jeopardize food safety with often very dramatic effects on the economic sustainability of the food production operation. Also, without adequate revenues from the operations there is risk that the operators in the chain will shortcut the necessary food safety measures. In parts of the world where food security is a major issue, food safety might often be overlooked the pressure on the other aspects of food security are emphasized – the availability of and access to food.

The impact on food safety from poor industrial practices resulting in persistent chemical toxins in the environment is still a major problem in many countries. Where this happens, such as fallout from nuclear power failures, the food safety risks rise dramatically and adequate risk management must be in place to minimize the effects. In natural disasters the situation may rapidly develop into a food security crisis with deteriorating food safety as

a consequence. Thus environmental sustainability will require both long-term measures to reduce food safety risks and adequate risk management plans to handle sudden and unforeseen events.

SUSTAINABILITY AND FOOD PRODUCTION IN THE FUTURE

It is obvious that the dramatic climate changes predicted by the UN International Panel for Climate Change (IPCC, 2007) will greatly challenge food production in the future. The absence of effective policies to reduce emissions of carbon dioxide and other greenhouse gases is predicted to lead to significant increases in global warming and changes in precipitation patterns over the next 20–40 years (FAO, 2009). Developments of the environmental future of the world, e.g. "UN Millennium Ecosystem Assessment" and "UNEP Global Environmental Outlook," predict that the degradation of ecosystem services could grow significantly worse during the first half of the 21st century. The IPCC report also predicts decreasing agricultural production as a result of climate change. In the tropical and subtropical parts of the world temperatures will be higher and already dry areas will become even dryer, which will restrict food production. In contrast, food production in the more temperate areas of the world might benefit from a warmer and wetter climate. Furthermore, there is a risk of collapse of ecosystems due to land degradation particularly in the tropical parts of the world. The increasing frequency of extreme weather events will also negatively affect the agricultural production and the resilience of the ecosystem. Growing populations and increased food production will lead to increased demand for freshwater. Water withdrawals are expected to increase in all sectors, leading to an expansion of areas with severe water stress (IPCC, 2007; UNEP, 2011).

It is evident that food production will face many major challenges in the future to meet sustainability demands. By 2050, a world with 2 billion more people will need 70% more food (FAO, 2009). This will require enormous efforts on improving the efficiency of the food production and supply system. And this must be done with less energy and fewer water inputs than today. To reduce the contribution to global warming from food production the overall energy consumption must be reduced considerably. This will demand major contributions from all levels of society, business and individuals on all scales from local to global level. Changes will be needed all the way from more sustainable agricultural practices, better post-harvest handling and preservation, improved distribution and a less wasteful food chain including the consumption end of the chain.

Smil (2000) calculated that before large-scale application of fertilizers, the global population was effectively capped at ca. 3 billion people, less than half the present number, by nitrogen limitation. Thus we need to take advantage of man-made fertilizers in the future but they need to be used much more efficiently, as with inputs of other natural resources, not least energy and phosphorus.

On the social dimension of sustainability the UN Millennium Goal (UN, 2011) of reducing by 50% the number of really poor (and thus hungry) people in the world (those living on less than US$1 per day) has not progressed recently, due to the dramatic increase in world food prices since 2008 and the ensuing economic crisis. These "Millennium Goals" will continue to form an important part of the future demands on a sustainable future

as part of human solidarity, formulated within the "Universal Declaration of Human Responsibilities," where Article 9 reads: "All people have a responsibility to make serious efforts to overcome poverty, malnutrition, ignorance, and inequality. They should promote sustainable development all over the world..." (Inter Action Council, 1997).

Scenarios for the future of food production in Europe, a part of the world not so severely affected by the climate change, predict that the changed conditions for food production in the coming 30–40 years will also have impacts on many other societal factors, related to – but not part of – food production. Climate change will induce migration to move north, away from the dry and hot parts of Europe and North Africa toward more temperate parts as quality of life deteriorates in the south (SCAR, 2007). This will also lead to strong competition for land use (and probably to more inequality). In most of the scenarios local and regional markets dominate over the global market (OECD, 2009). These scenarios predict stronger legislation to support measures to improve sustainability with more concerned and active consumers and societies as drivers (SCAR, 2007).

Animal protein products such as meat are taking an increasing share of the resources used in food production. In animals 6 kg of plant protein is required to yield 1 kg of meat protein, on average (Smil, 2000; Pimentel and Pimentel, 2003). Consequently, only 15% of protein and energy in these crops will ever reach human mouths and 85% are wasted. The inherently inefficient conversion of plant protein into animal protein makes animal protein responsible for a disproportionate share of environmental pressure of the food production system. In addition to 40% of the grain harvest, some 75% of soy is fed to livestock. The production of animal protein products accounts for over half of the global warming contribution of the overall food production (FAO, 2006).

Meat consumption has increased fivefold in the last 50 years and the increasing number of grazing animals is degrading already impoverished grassland in many parts of the world (UNEP, 2011). Globally, demand for meat and fish products is still on the rise and the projection is for a doubling of animal food products, including both meat and dairy products, until 2050 (FAO, 2006). But inevitably, the prices of meat, fish, soy and cereals will also rise and a trend towards diets containing less animal protein and more plant protein seem inevitable. Notwithstanding the environmental benefits of this move from animal to vegetable protein diets, according to many scientists, including the UK National Health Servic this would also be a trend towards a healthier human diet (NHS, 2009). As pointed out b Aiking et al. (2006), if consumers were to reduce their overall protein intake and replace animal protein products with plant-derived protein products, the majority (87–94%) of prime agricultural land currently used for feed crops might be released, with additional benefits to animal welfare and human health. Moreover, this diet transition would result in a tremendous reduction of the pressure on land and freshwater resources, and – last but most certainly not least – on biodiversity. As already pointed out, there is not much additional land that can be transferred to agriculture, in a business-as-usual scenario, without severe consequences for climate change from deforestation.

In the present situation of global economic crisis it is clear that the economic issues are at the heart of a transition towards a more sustainable future. A number of economists are questioning the possibility of reaching a more sustainable future if the present economic system based on the need for constant growth continues (Jackson, 2009). As almost all human activities mean extraction of natural resources as well as dispersing the wastes back into

nature it is obvious that there is a limit to how far the growth of these activities can continue. The growth in the economy must be decoupled from the growth in the extraction of natural resources (UNEP, 2010), many of which already are past their global boundaries as discussed by Rockström et al. (2009). A number of alternative economic systems have been presented and the debate is very active among environmental economists, but the political interest in a common solution is surprisingly low. The momentum in the transition to a more sustainable development is lacking, but unity and speed are urgently required, in order to safeguard a future sustainable world with adequate, healthy and safe food for everyone. Lelieveld (2012), in his expose of the historic development of security and safety of food, also point out the importance of fair and reasonable food regulations for improving the availability of safe food globally.

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CHAPTER

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Climatic Changes[1]

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OUTLINE

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INTRODUCTION

Our society is subject to constant changes and these will not be without consequences on the safety of the food supply. Various factors such as

- urbanization
- demographic changes, such as population growth, migration, increase in life expectancy
- emergence of new hazards as a consequence of advances in science and technologies or biological changes
- changes in lifestyle and consumer expectations
- economic crises

will all pose new challenges to the food industry. However, perhaps, one of the most important factors that will impact food supply worldwide is climatic changes.

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IMPACT OF CLIMATE CHANGE ON FOOD SAFETY

Climatic changes can affect the safety of the food supply in a number of ways. Subsequent changes in environmental, social and economic factors may influence agricultural and livestock production, and may have a direct or indirect and unforeseeable impact on food safety and on the incidence of foodborne diseases. For instance, it is a well-known fact that certain microorganisms thrive in warmer climates and that their incidence increases during summer months. Several reports have also indicated that the incidence of cholera and diarrhea has increased under the effects of El Niño and other climatic conditions. With the increase in ambient average temperatures, it is likely that certain foodborne infections such as salmonellosis will show a longer annual peak and that their annual incidence increases.

Similarly, infections in food animals and seafood may escalate, and with this the raw material derived from these animals may be more at risk of contamination. In addition to food animals, intermediary hosts to foodborne parasites such as snails may increase in number and cause an increased contamination with parasites. Likewise, there is a heightened possibility of mycotoxin formation in plants as a consequence of the growth of fungi. A possible consequence of the above may be the excessive use of agrochemicals in animal production and agriculture. While the latter do not present a safety concern *per se* if properly carried out, the potential abuse of these chemicals to fight animal and plant diseases needs to be considered by the food industry. Climatic changes can engender extreme weather events, such as heavy rainfall, floods and droughts which may exacerbate the situation. These will contribute to the contamination of food, environment and water resources, with, among others, fecal matter; they will also stress plants and their susceptibility to diseases.

Other possible consequences of climatic disasters such as heavy rainfall or floods may be the collapse of infrastructures such as power supply, or the breakdown of water and sewage systems. These may in turn have adverse consequences on the food safety system. Several reported outbreaks of cryptosporidiosis, giardiasis and other infections have been associated with heavy rainfall. During 1997–1998, excessive flooding also caused cholera epidemics in several African countries.

Climate warming also increases coastal water temperatures and provides ideal conditions for the proliferation of microorganisms, such as *Vibrio* spp., and of planktons. Certain phytoplanktons, e.g. dinoflagellates, produce toxins and may produce biotoxin, and with algae bloom, there is a risk of increased marine biotoxin intoxications such as ciguatera. Zooplanktons are also a reservoir for *Vibrio cholerae* and facilitate the long-term survival of organisms in estuaries. A number of studies suggest a link between cholera epidemics and environmental factors such as warmer seawater and climate in general.

Weather pattern fluctuation can also lead to an increase in rodent and/or insect populations and subsequently contamination of food and water supply. For instance, it is known that rodent breeding increases during mild weather conditions whereas drought or heat may have an inverse effect. However, drought may drive rodents to seek indoor sources of water. An increase in the size of the rodent population, combined with heavy rains or floods, might lead to contamination of food with vectorborne pathogens such as *Leptospira* spp. and proliferation of infectious diseases. Several reported outbreaks of leptospirosis have attributed to such climatic conditions.

CONCLUSION

Professionals in the food industry should be vigilant with raw materials. In the context of the HACCP study of raw materials, the consequences of changes in society and climatic warming in particular should be considered in their hazard analysis, and their control and monitoring procedures adapted accordingly.

More in-depth information on climate changes and their impact on food safety can be found in the FAO report entitled "Climate change: implications for food safety" (2008).

Further Reading

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CHAPTER

45

Nutritional Trends and Health Claims

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OUTLINE

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INTRODUCTION

Consumers are expecting the food industry to deliver products that fulfill four main expectations. Two are based on immediate practical criteria: sensory characteristics, from taste, flavor and smell, to texture, noise and appearance; and services and practicality, from handling, storability, easiness to prepare and clear labeling. Two others are based on experience and intellectual criteria: safety and satisfaction of nutritional needs (see Figure 45.1).

Food is our only source of energy, and satisfaction of nutritional needs has been driving food choice for a long time. Thanks to an increase in food availability, it is becoming a stronger determinant for a growing number of consumers all over the world. Modern human nutrition science emerged in the 1950s, when it was shown that malnutrition in African children increased the risk of infectious diseases, and reciprocally that protein and energy renutrition improved some immune functions. At the same time children's malnutrition was reported in the USA and nutrition entered the political agenda. In 1968, Senator George McGovern took the lead of the first United States Committee on Nutrition and

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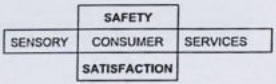

FIGURE 45.1 Assessment of food by the consumer. Two practical criteria: sensory and service. Two intellectual criteria: safety and satisfaction of nutritional needs.

Human Needs. Six years later he expanded the scope of the committee from reducing malnutrition to health risks associated with overeating, starting with the effect of an excess of dietary cholesterol on cardiovascular diseases, a complex relationship not yet completely deciphered after 60 years of intense research. This illustrates on the one hand the complexity of interactions between nutrition and health, the difficulty to combine observational epidemiology and experimental nutrition, and on the other hand the scientific dilemma: when is there enough scientific evidence to support a claimed benefit of a food, or a diet, on health? This is still a matter of debate today.

Diet is one of the major components of our lifestyle that we can individually control in our own environment to manage our present and future health, including the health of future generations. The double challenge is to limit the risks and to improve the benefits. Both components of this ratio are changing: foods and diets are more abundant and more energy dense, the environment and lifestyles are less demanding in terms of energy, and the world and our expectations are also changing. Our knowledge of technology and science has increased dramatically, and during the last couple of decades our focus on diet and nutrition has also changed.

HISTORICAL PERSPECTIVE

Dietary challenges have evolved during the short history of human species on earth. The first of these challenges was to select from Nature foods that can provide adequate energy and nutrients. Collecting raw foods from the environment meant ingesting a variety of foods that often contained insects and microbes; it was also essential to select foods that were first not poisonous and second nutritious. A number of explorers died during this exploratory phase of acquiring the basic knowledge of edible foods. A large part of food education was to learn which foods were safe and to train the taste buds to distinguish between edible foods and hazardous ones. This hard training may explain our fear of eating new foods – neophobia. It may explain why our reptilian brain remembers the old days when trying a new food may end in death! But how do we overcome this phobia? It is still a common practice when traveling abroad to see how local people approach their food, and then follow their example to overcome our anxieties. It transpires that people have been able either to select or to adapt and adopt certain foods. Safety was the critical point, and taste was a first warning signal: bitterness is often associated with poison in Nature, and sweetness with edibility.

The second challenge was to develop ways to store and preserve foods. Food processing must have been a key step in civilization. It dramatically improved shelf-life and storage capacity of food over a few days. Humans were able to overcome natural seasonal shortages of foods, and to explore and colonize some countries where winter reduces drastically the availability of foods. Humans have adapted the processing of local foods to local conditions and invented ways to survive in every part of the planet. Strikingly, our normal body fat contains enough energy to survive during a winter – 3 months. Increasing food storage capacity also changed the size of human groups living together: it was possible to feed a family all year around, then a larger group of people, or even a city, and nowadays the whole world benefits from improved storage of foods.

Storage also contributes to the development of agriculture and breeding on large scales. A large production of food also requires a large storage and preservation capacity to handle the harvests. This is still a challenge today as a significant part of food production is lost during storage (Gustavsson FAO, 2001).

It is quite interesting to note that food preservation used two kinds of techniques for safety: (1) killing microbial contaminants with acidic or alcoholic fermentation, and cooking; and (2) reducing the water content of foods to prevent growth of microbial contaminant. Apart from drying in a sunny wind or in a smoky cavern, some specific ingredients were used to preserve foods: salt, sugar and fat. Therefore preserved foods were high in salt, sugar or fat. It is tempting to speculate that only those who were able to cope with the necessary concentrations of salt, sugar or fat in foods survived. We can also speculate that they learned to like those concentrations: they indicated that the food was safe, and therefore survival was assured. Nowadays a too high consumption of salt, sugar or fats is identified as one of the dietary risk factors for many people. We may wonder why those nutrients are now becoming a threat. One explanation is that life expectancy is now longer, allowing metabolic disorders to develop and challenge the health of elderly consumers.

A breakthrough in preservation occurred in 1810 when Nicolas Appert published in Paris his work on the art of preserving animal and vegetable substances. He reported more than 15 years of experiments of putting foods in glass jars and boiling them in water. The same year British inventor Peter Durand patented the use of the tin can, and started a long history of canned food. The final touch came with the invention of the can opener in the USA by William Lyman using a rolling cutting wheel. Preservation can be industrialized without the constraints of salt, fats and sugars.

The third challenge was to produce enough food to feed everyone. The twentieth century was the century of industrialization of agriculture and breeding. Food production capacity increased dramatically and is still increasing. A first step in processing is the need to store this large production of raw food for very long periods of time and also during transportation all over the world to local producers. But there is still room for improvement: it is estimated that one-third of crop production is lost during storage. Obviously this huge increase in production was associated with the industrialization of preservation and storage, as well as packaging techniques to handle and distribute processed food around the globe. Packaging started another revolution: labeling can convey information for the consumer. Selecting and buying a food requires the consumer to read and understand packing information, and no longer to rely on practical experience as was the case before.

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The benefit of this increase in production is associated with two consequences: (1) seasonality is potentially redundant and it is common to find milk, apples, tomatoes, lambs, chicken, etc., all the year round in both hemispheres. Diversity of diet is diminishing accordingly, and most seasonal consumption has almost disappeared in westernized countries. On the other hand, the monotony of seasonal diet is easily diversified: the choice of processed foods in the supermarket is larger than at the local raw food market. (2) Diversity of crops is diminishing: the same cultivar is used more widely than before. For example, more and more consumers are eating the same flour: the statistical probability to have one consumer less adapted than the average population is increasing. On the other hand, a variety of cultivars are being used to make our daily bread, and we will have to adapt to new ones on a regular basis, which means that our long-term nutritional epidemiology has to deal with evolving food composition. Epidemiological correlations are stimulating but never truly demonstrative. Globally this increase in food quality and production (and improvement in politics) decreases world hunger and improves life expectancy. However, producing enough food for a still rapidly growing population remains a challenge.

With abundance and availability average dietary intakes are changing at two levels: (1) there is a reported increase in proteins, sugars and saturated fats. Spontaneously adults are not able to select a diet that fits their dietary or nutrient recommendations, when 7 years old French children were able to do so (Debry, 1980) on a 3-week basis. Simultaneously the human workload to produce food is reduced due to mechanization: far fewer human calories are required to produce food. Farmers increase their weight according to the level of mechanization (Vardavas, 2009). Man is facing a totally new challenge: how to eat less than the previous generation, when foods have never been so abundant and cheap from an energetic point of view. (2) Dietary practices are changing: surprisingly this large increase in production is correlated with a significant increase in wasted foods. A recent US survey reported that one-third of foods are thrown away: 17% of dairy products, 20% of vegetables, 15% of fruit, 33% of meat, 35% of fish and 18% of grain (NDRC, 2012). This increase in waste is a consequence of the increase of food production (Hall, 2009).

A drastic change in dietary habits and practices is happening: the tradition of eating meals at home as a family is no longer relevant: we seem now to be either eating alone or at work. Furthermore portion sizes and the composition of dishes are changing, and a re-education of our eating habits is needed.

Finally, modern times generate a brand new challenge: access to drinkable water. The amount of water on our planet is fixed and water is indefinitely recyclable. We are drinking the same water that the dinosaurs drank. In the past two processes were used to have access to drinkable water: alcohol disinfection (combining wines with water, or brewing beers), or boiling water for beverages, for example. A century ago modern technology discovered the use of chloride to reduce the microbial risk in water. Tap water became drinkable. We are still facing some challenges from microorganisms, and we also have to encounter new chemical contaminations generated by increasing amount of wastes, including drug residues and industrial processes. Pure water is both a microbial and a chemical challenge and the next dramatic test for the human race in the coming decades.

FOODS FOR HEALTH

Industrialization of food supplies increases the availability of safe food. The fight is no longer to get enough food, but to select the best foods to improve the dietary needs of consumers. Diet is important to improve a healthy lifestyle. This is more important than ever because the human species is experiencing an unprecedented event: life expectancy is increasing, from 45 years a century ago to currently 75 years. The percentage of the elderly population is increasing (e.g. from 8% in China and 12% in USA in 2005 to a projected 16% and 19% in 2030).

Due to progresses in hygiene and medicine the number of people living with diseases is increasing, generating an economic burden. And as we get older there is a physiological decrease of the different functions of the body, generating costs and/or opening new challenges for nutrition.

We are also discovering the long-term consequences of different earlier lifestyles, mainly on cardiovascular and cancer risks, and also the burgeoning epidemic of obesity.

DIET AND HEALTH

Historically, diet was one of the four elements given by the gods to humans. In Greek mythology Aesculapius had four children: two sons, Machaon (surgeon) and Podalirios (physician), and two daughters, Hygia and Panacea. Hygia used cleaning and washing to take care of health, while Panacea was in charge of identifying beneficial herbs, plants and ingredients among all the products Nature was offering. It is amazing that food risk (hygiene) and food benefits (panacea) were already under the control of women, men being physician and surgeon.

The synergism between diet and health began with the discovery that certain foods were able to cure diseases: the Andeans learned that grinding corn with lime and alkali prevented a devastating cutaneous disease, pellagra was recognized as due to a lack of vitamin B and Hippocrates used liver to prevent blindness induced by a lack of vitamin A.

The first human nutritional study was conducted by Lindt in 1747: this was a pilot study on 12 sick sailors split into six groups of two "volunteers," which suggested that lime was better than cider, vinegar, horseradish, diluted sulfuric acid and salted water to cure them. The Royal Navy was interested enough to conduct a confirmatory study on HMS *Suffolk* in 1794 during a trip from England to India. Sir Gilbert Blane, Physician Extraordinary to the Prince of Wales, gave lime to half of the crew and used the other half as a "control" group without lime. Lime prevented the experimental crew from suffering from scurvy. The first data were convincing enough for Captain James Cook, the famous explorer. He used lime to prevent the deadly disease. In 1933 vitamin C was identified by Szent-Györgyi, but the exact composition of lime is not fully known today, and lime is still more active on scurvy than its content in vitamin C indicating that some other ingredients have biological properties.

Antoine Lavoisier discovered the energy equation (energy in = energy out) in the 18th century and was used by Liebig in Germany to calculate the amount of energy needed for mine workers to extract a fair amount of coke.

Modern nutrition started after World War II, with the demonstration in the developing world of the role of energy and protein intake in two forms of malnutrition: marasmus and kwashiorkor. Adequate nutrition is also important for an efficient immune system, and adequate water and minerals intake are essential to manage acute diarrhea. These health issues are still a challenge in the developed world: a large proportion of the elderly in Europe are suffering from insufficient intake of energy, protein and water: between 50 and 75% according to a European report (So rensen et al., 2008).

The modern age of dietary science can be schematically split in two phases: the first is the deleterious effect of excessive intake of nutrients and nutritional prescriptions reduce dietary risk factors.

The increase of life expectancy was associated with an increase of new causes of death, namely cardiovascular disease, and when a US senator died of an excess of blood cholesterol, scientists explored the possible links between cholesterol in the diet and risk of cardiovascular disease. A classical correlation was published by Ancel Keys between the intake of fats and saturated fats in seven countries and their rate of cardiovascular mortality. However, changes in consumption of fats and saturated fats are not correlated with similar changes in cardiovascular mortality, and the final conclusion is still a matter of debate, even if everyone agrees on the common sense conclusion that an excess of fat (saturated or not) is not recommended.

For some time now physicians have been aware of what to ban from their patients' diets, adapting the amount of sodium to blood pressure, of protein to creatinine's clearance, of sugars to glycosylated hemoglobin, the ratio of fat to carbohydrates to the respiratory capacities, the amount of alcohol to gamma glutamyl-transferase, and so on.

After this "banning phase" came the second phase: the "recommending" phase where dietary prescriptions are about positive actions. For example, French official guidelines consist of half "reduction" and half positive guidance like: eat five servings of fruits and legumes a day. The benefits are expressed in the reduction of risk factors like high blood pressure and obesity.

Two factors contributed to starting the second phase: dieticians realized that it was necessary and more important to tell patients what to eat than what to avoid, and the majority of consumers are more interested in a healthy lifestyle and a willingness to benefit rather than associate food with diseases, even disease prevention.

The first modern use of specific foods to improve a function mimics an old tradition in Greek Olympic Games: it was a common practice to include in the diet of athletes foods associated with their sports: runners ate horse meat, weightlifters ate bear meat, fighters ate lion meat, and so on.

Modern sportsmen explored this concept and demonstrated that an improved diet was able to improve performance. This was demonstrated by Ron Hill, the Athens' marathon winner in 1969, and was supported by the success of Swedish athletes using the dissociated diet to win during the Winter Olympic Games.

The principle is to starve muscles of glucose to increase their glycogen storing capacity, then to feed them glucose and to benefit from that increased glycogen content to improve physical performance. This has been popularized by Bjorn Borg and Ivan Lendl and is becoming a mandatory habit with pasta parties before a marathon. A specific diet can improve a specific function, e.g. muscular function.

Another classical and sometimes vital specific functional food/nutrient is water: hydration is a key factor in achieving proper performance – an adequate intake of water improves physical as well as intellectual functions.

A new area in nutrition science has recently begun: Which nutrients are more specific to a given function? And equally which function can be improved by a specific nutrient, food or diet? Two European-supported programs (Fufose and Passclaim), under the umbrella of ILSI Europe, explored the concept of improvement of a function by food. This concept is based on two physiological observations:

1. Within a population every physiological function is distributed among individuals, most of the time in a Gaussian manner. Around the average value there are lower and higher functional capacities. There is room for improvement of those under the average and even those higher than average. It is a common observation that adequate training improves a functional capacity: e.g. dissociated diet improved the muscular functions of athletes.
2. Within an individual all functions oscillate around a basal value: this is chronobiology: e.g. we wake in the morning with a high level of blood cortisol and low body temperature, and sleep in the evening with a lower level of cortisol and higher body temperature. Those rhythms can be on a different time basis: day, week, season or shorter. Age is another obvious inevitable source of oscillations and decrease of functionalities. There is a possibility to reduce the duration of the low capacity period, and to prolong the period of higher capacity: e.g. coffee is able to increase the length of awareness, or reduce its evening decrease.

What are the functions that can be improved, or the reduction that can be prevented? Is it possible to prevent or slow down the aging factor? This is a challenge for each of us and our healthcare systems.

The benefit relies on scientific data and Passclaim (Aggett et al., 2005) concluded that such a benefit requires:

- an identified ingredient/food/diet ingested in an adequate amount,
- human data using commonly agreed marker(s), and
- reproducible results based on randomized controlled human trials.

One of the oldest accepted functional ingredients is wheat bran: it has been demonstrated in different human trials that a low intake of bran is associated with a long gut transit time, and that an adequate increase of wheat bran intake normalized gut transit time and increased fecal bulk and weight.

The second benefit came in 1997 from the USA when FDA agreed on the effect of oats to reduce the risk of cardiovascular disease, based on human trials.

In 1980 Japan was the first country to implement a specific regulation for this kind of food: FOod for Specific Health Use FOSHU with the same scientific basis – a demonstration of the benefit through human trials. There a few hundred Japanese foods that hold a FOSHU claim, including a lot of probiotics.

In the late 20th century some European countries started to validate claims, and in 2006 the European Commission asked its European Food Safety Agency to convey scientific panels to give scientific opinions on submitted dossiers for claims related to:

- general function: based on generally accepted scientific evidence;
- new function claim: based on new scientific evidence or use of specific product or substance;

- reduction of risk factors of diseases: based on scientific evidence related to risk factors of diseases and a specific product;
- function claims in children: based on scientific evidence related to the specific children target.

EFSA used three criteria to assess the scientific evidence:

1. The food/constituent is defined and characterized.
2. The claimed effect is defined and beneficial to human health.
3. A cause and effect relationship is established between the consumption of the food and the claimed effect (for the target group under proposed conditions of use).

The scientific opinions are then reviewed by the European Commission in charge of final decision to agree or not with the proposed claim and to disseminate them to the member states.

EFSA's panels first cleared claims related to general functions, selecting those based on generally accepted nutrition science such as the benefit of vitamins and minerals. The panels were more restrictive with new function claims as the Commission asked them to use the best evidence to support their opinions, when nutrition is not the best field for providing very strong evidence due to the complexity of the domain and the variability of human physiologies.

Other panels in different countries are evaluating scientific evidence on the effect of products on health, function and risk factors. It is worth mentioning that by using similar published data different panels made different opinions on similar products.

It is interesting to note that the modern Law does not allow foods to cure nor prevent diseases, when nutrition science started by the demonstration of diseases like pellagra, scurvy or diarrhea cured or prevented by foods. This reflects, at least partly, the misconception of diseases as the consequence of an exogenous pathogenic element, often a microscopic one. This is supported by a discovery like the role of *Helicobacter pylori*, a gastric microbe responsible for gastric ulcer. The modern understanding of human physiology is that a disease is the result of an aggression by a pathogen *plus* the response of the host. Therefore the cure of a disease is based on two pillars: to destroy the pathogen (a role for a drug) and to support or enhance the host's defense (a role for diet). Nutrition is feeding the response of the host and therefore is part of the management of the disease as well as its cure. This was observed at the beginning of modern nutrition in the 1950s when the renutrition of malnourished people was able to restore immune functions and to cure infectious associated diseases.

On the other hand, a number of modern diseases result from a dysfunction of the metabolism and/or overnutrition due to inadequate dietary intake. It is logical to address the cause of a disease – malnutrition – to cure it. Science tells us that some foods and diets help to cure and prevent diseases even if they are illegal!

There is a fascinating new area for nutrition that provides adequate scientific evidence to support these new benefits. However, a difficult ethical question needs to be answered: Does the demonstration of such benefits require extensive studies due to the complexity of the nutrition and health relationship? Costs of such trials will significantly increase the cost of foods, when the consumers who need those foods the most may not have enough money to buy them: one simple human nutrition trial costs the equivalent of a million meals. When

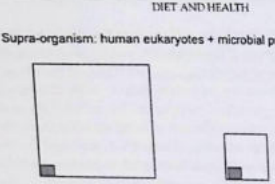

FIGURE 45.2 The ratio of microbes/host. Dark squares are eukaryotes, and the empty squares are prokaryotes.

scientific evidence are enough, they must be assessed according to the expected benefit, the potential risk and the needs of the target population.

Modern tools bring about a revolution in the physiology of nutrition and health: genomics explores the human gut through many large programs in different parts of the world and concludes that we are living with a forgotten organ – the gut microbiota. The following illustrates the importance of that new organ: it contains 10 times more microbes than we have cells in our body, it contains 100 times more genes than our cells, it weighs 1.5 to 2kg, more than the liver, and is far more metabolically active than the liver. Edgar Lederer, a Nobel Prize winner, suggested considering this association as a "super-organism" where the major part will be the microbiota (Figure 45.2).

The importance of the microbiota can be touched upon by two correlations: J. Gordon has reported that transferring the gut microbiota of an obese mouse to a lean mouse results in a fattening of the lean mouse. In another trial he reported that obese men have a different gut microbiota profile than lean men, and when obese men lose overweight, their gut microbiota profile evolves toward a lean profile.

MetaHit reported also that the presence of a specific species, *Faecalibacterium prausnitzii*, is associated with a lower level of inflammation, a lower risk of inflammatory bowel disease and a better chance to lose weight.

Two elements of the diet have a direct impact on the gut microbiota:

1. Prebiotics: mainly indigestible carbohydrates that are fermented by some part of the gut microbiota, changing the composition and some functions of the gut microbiota.
2. Probiotics: living microorganisms that, when ingested in an adequate amount, provide health benefits to the host. Specific strains provide specific benefits. They can act directly on the host: yoghurt is able to digest lactose in the gut of lactose malabsorbers. Therefore anyone can digest yoghurt, supporting the claim "one yoghurt a day" as part of dietary recommendations, change the functioning of gut microbiota, e.g. changing the metabolism of gases and improving gut comfort (Sonnenburg, 2006), or change the functioning of digestive cells (Van Baarlen et al., 2011).

The role of microbiota on host functions within and beyond the gut offers a fascinating potential through the modulation of inflammatory status, including the aging process, or brain functions including mood and autism.

Costs and time of demonstration are not compatible with challenges, and in nutrition knowledge is still a mixture of observations supported by some data and a battlefield where different stakeholders are dependent on industry as well as on academia where the fight for official support requires one to follow the official mind set, and use the trends.

Diet is a key element of an adequate nutrition and a major contributor to health and proper functioning of our body, including gut microbiota. Is it possible to change dietary habits and to improve them?

Many education programs have been implemented in different countries using different channels, with very limited impacts.

The first element was the confusion between nutrition and diet as illustrated by the Recommended Dietary Allowances where all nutrients' needs were listed, without any dietary translation. It is impossible without a computer to build a balanced diet based on nutrient composition of foods.

Then there was the period of ban "the" culprit food, which ended in suppressing bread, or fat, or sugar, or salt, or meat, or whatever. A number of experts used that trick to get a lot of media coverage and money.

In fact it is well known that we are unable to change our diet dramatically over a long period. But we can change the serving size or the frequency of intake.

The following trend was the reverse: invest in a specific beneficial food – carrot juice, pineapple, one apple a day. But there is no perfect food, or magic food.

Moderation is the key word, and the food industry is playing a major role by adapting food contents in a progressive and unnoticed way, like the change from whole milk to half skimmed milk, or the reduction of salt in soup, or the change of fat composition in dressings, and so on.

Labeling is another dead end as there is no simple message: a food is neither good nor bad in itself, it is a matter of including it in a balanced diet – excess or deficiency must be avoided on a long-term basis. Some foods are staples like grains, legumes, fruits, dairy products and meat/fish, and some foods must be added more carefully in the diet, but none can be excluded.

Finally, we have to take into account human diversity, as illustrated by the old concept of Professor Apfelbaum's "Mangeurs inégaux." For the sake of the species we have different individual metabolic capacities and ingesting the same amount of the same fatty acid can improve or worsen blood cholesterol depending on the eater. Some of us have a high metabolic resting rate and we burn a lot of calories while some others are sparing every eaten calorie, without mentioning the role of the gut microbiota that can increase of decrease energy extraction from the diet. Some functions can be improved in some responders and not in others.

Modern tools will help us to integrate the complexity of our super-organism and hopefully identify some major crossroads, or some major clusters of responders and non-responders, and adapted functional foods.

Until we have all the information, we need to progress and use wisely scientific information. It looks like we are still in an exploratory phase where we have to be careful with risk

assessment, and adventurous with benefit testing. We may not have the financial resources to wait until we know everything before incorporating some specific foods for some identified health and functional benefit. The reward of the audacious explorer will be to add years to a healthy life.

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CHAPTER

46

Ethics in Food Safety Management

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INTRODUCTION

Food production is a complex matter, affecting people's lives, organizations' profits and the well-being of the whole planet. It is not always straightforward to say what is right and what is wrong when it comes to the production of food. Many ethical questions can be raised regarding the food supply chain, including agricultural production.

Climate change, animal welfare, fair trade, health and safety of employees as well as consumers, fair treatment of employees and their social rights, economic sustainability and use of natural resources are all important dimensions within the system of production, processing and trade, and where every food item often includes value conflicts. An increasing number of the Western population are becoming overweight and obese. Should the food industry limit their marketing of fat and sweet foods to reduce these problems, or is this the responsibility of consumers as far as they have an informed choice? Maybe the industry's

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aim first of all is to increase profit and secure employment? Tremendous variation in the global food production system exists. People in parts of the world are starving and to secure enough food supply is important. But is it unethical to focus on efficient food production, when this is set up against animal welfare and environmental friendly production? And is it acceptable that multinational companies have a double standard, which means that products rejected in one country can be exported to another country with less stringent safety legislation? If so, what would be the eventual consequences? Would other kinds of non-ethical practices, e.g. dumping of food, increase? The question of how far a single standard for reasons of ethics should be respected in the world was raised in an Asian country where a multinational company was required to produce its products according to the European safety standards. Is it unethical behavior when they, due to environmental contamination and local practices, were unable to have raw material meeting European requirements?

We may also ask if the short-term consequences on people are more important than the long-term consequences on the planet, and if it is all right that what is closest in time and space is most important for us. How the food industry responds to these questions will influence how consumers, citizens and other relevant stakeholders perceive them. A perception of the food industry as a large-scale sustainable production and processing system or as a business with the main purpose of making financial profit will influence consumer trust and thereby their acceptance of novel technologies, novel foods and food science and technology in general.

Food security, food safety and sustainability are considered as first priorities related to the modern developments in agricultural technologies (EGE, 2008a). In this chapter we will discuss the scope of ethics in the food industry in relation to food safety. We start out by defining ethics. Then, ethical dilemmas in food safety cases are discussed. Lastly, the precautionary principle and a framework for ethical decision-making in the food industry are highlighted.

WHAT IS ETHICS?

s is defined as the philosophical study of the moral value of human conduct and of s and principles that ought to govern it (www.thefreedictionary.com/ethics). Simply , ethics refers to standards of behavior that tell us how human beings ought to act in many situations in which they find themselves – as friends, parents, children, citizens, businesspeople, teachers, professional food producers, consumers, and so on.

Ethics is different from following the law. A good system of law incorporates many ethical standards, but law can also deviate from what is ethical. Selling tobacco to children in countries with no laws against it can be perceived as unethical. Ethics is not the same as following culturally accepted norms either. Some cultures are quite ethical, but others become corrupt – or blind to certain ethical concerns: "When in Rome, do as the Romans do" is not a satisfactory ethical standard. Ethics is not science, feelings or religions. Science can provide important data to help us make better ethical choices. But science alone does not tell us what we ought to do. Science may provide an explanation for what humans are like. But ethics provides reasons for how humans ought to act. And just because something is scientifically or technologically feasible, it may not be ethical to do it. Even though science makes

it possible to breed cattle with extreme overdevelopment of muscles, we may question if it is ethical when we take animal welfare into consideration. We cannot trust our feelings either. Some people feel bad when they do something wrong, others do not. While most religions do advocate high ethical standards, they do not always address all kinds of ethical dilemmas (Velasquez et al., 2012; Baumhart, 1961).

If our ethics are not based on feelings, religion, law, accepted social practice or science, what are they based on? Some ethicists emphasize that the ethical action is the one that produces the greatest good and does the least harm for all who are affected – customers, employees, shareholders, the community and the environment (the utilitarian approach). The utilitarian approach deals with consequences: it tries both to increase the good done (e.g. ending hunger) and to reduce the harm done (e.g. environmental and social destructions). Other philosophers and ethicists suggest that the ethical action is the one that best protects and respects the moral rights of those affected (the rights approach). This approach starts from the belief that humans have a dignity based on their human nature *per se* or on their ability to choose freely what they do with their lives. On the basis of such dignity, they have a right to be treated as ends and not merely as means to other ends. They have a right to adequate food and a fundamental right to be free from hunger (FAO, 1996, Rome Declaration). The list of moral rights – including the rights to make one's own choices about what kind of life to lead, to be told the truth, not to be injured, to a degree of privacy, and so on – is widely debated; some now argue that non-humans like animals and plants have rights, too. Also, it is often said that rights imply duties – in particular, the duty to respect others' rights. Aristotle and other Greek philosophers have contributed the idea that all equals should be treated equally (the fairness or justice approach). Today we use this idea to say that ethical actions treat all human beings equally – or if unequally, then fairly based on some standard that is defensible.

The power distribution between retailers and suppliers has led many producers to state that multiple food retailers are abusing their position of power and engaging in practices that adversely affect the competitiveness of suppliers. To address these adverse effects it has been recommended that a code of practice be introduced to govern retailer–supplier relationships (Duffy et al., 2003). The Greek philosophers have also contributed the notion that life in community is a good in itself and our actions should contribute to that life (the common good approach). This approach links ethics to social responsibility and calls attention to the common conditions that are important to the welfare of everyone. Companies have a duty to be good citizens including their own workers and staff and "to do the right things" (Porter and Kramer, 2006). A very ancient approach to ethics is that ethical actions ought to be consistent with certain ideal virtues that provide for the full development of our humanity (the virtue approach). These virtues are dispositions and habits that enable us to act according to the highest potential of our character and on behalf of values like truth and beauty. Honesty, courage, compassion, generosity, tolerance, love, fidelity, integrity, fairness, self-control and prudence are all examples of virtues. Virtue ethics asks of any action, "What kind of person will I become if I do this?" or "Is this action consistent with my acting at my best?"

Each of these approaches mentioned above helps us determine what standards of behavior can be considered ethical. Different actors may not agree on the content of some of these specific approaches. They may not all agree to the same set of human and civil rights or on

what constitutes the common good. They may not even agree on what is a good and what is a harm. Nonetheless, each approach gives us important information with which to determine what is ethical in a particular circumstance. And much more often than not, the different approaches do lead to similar answers (Velasquez et al., 2012).

ETHICAL ISSUES IN FOOD SAFETY

The series of food scandals and scares during the last decade resulted in a melting consumer confidence. Despite the fact that food has never been safer, it seems that consumers are considerably uncertain, anxious and increasingly critical about the safety of their food.

The safety of food products for human consumption as a precondition for their marketing must be guaranteed. But who is responsible for food safety? Are the producers and processors, or the food business operators in general responsible as stated in the European legislation (178/2022/EC), or should this responsibility be shared with consumers? Should consumers having sufficient education and knowledge be able to make informed choices? This might apply to nutrition-related choices but the safety of foods cannot be judged by consumers. Here the operators of the food supply chain are mainly kept being responsible. In food safety, the border between ethic, compliance and responsible behavior, as seen below, is not always clear cut and at times these issues are intertwined.

One of the largest food safety incidents the World Health Organization (WHO) had to deal with recently was the Chinese melamine scandal from 2008 involving milk and infant formula. By November 2008, China reported an estimated 300,000 victims, with six infants dying from kidney stones and other kidney damage, and a further 860 babies hospitalized (Branigan, 2008; see also Chapter 41). The chemical melamine appeared to have been added to milk to cause it to appear to have a higher protein content (McDonald, 2008; Macartney, 2008). A spokesman from WHO said the scale of the problem proved it was "clearly not an isolated accident, [but] a large-scale intentional activity to deceive consumers for simple, basic, short-term profits (VOA, 2008)." The issue raised concerns about food safety and political corruption in mainland China, and damaged the reputation of China's ability to manage the safety of its products. It also affected its export, with at least 11 countries stopping all imports of mainland Chinese dairy products.

This case clearly shows the catastrophic consequences when a firm puts its own goal above others. Adding a potentially fatal chemical compound to a food product is not only unethical, but also illegal and above all a criminal action. The case is not a difficult dilemma to judge in terms of ethics, legality or criminality. What was particularly unethical was that the problem was known for some time at the regional level but not divulged for fear that the scandal may have negative impact on tourism and the upcoming Olympic Games. The incident was brought to the attention of the general public after the games. An even greater negligence and source of outrage was the fact that this event was the second melamine incident; the first occurred in the USA in 2007 and was due to wheat gluten imported from China. Hundreds of dogs and cats were intoxicated (see Chapter 41). No efficient corrective action was put in place after the first incident. The products of a multinational company which had already experienced the problem in the United Stated was affected again in China and had to be recalled. Although a professional food safety management and crisis

management calls for corrective actions after a first incident, it is also a matter of due diligence and ethics to be cautious on emerging risks. Consumers can forgive a first and an unexpected risk but when the same incident happens again for a second or a third time it is a matter of negligence.

Sometimes, issues are clearly illegal and reveal an underlying unethical attitude on the part of managers responsible of companies. For instance, release of a product knowing that it is contaminated or does not meet regulatory requirements, or repeating a microbial test until a negative result is obtained as evidence of safety is a sign of an unethical or immoral attitude of managers.

Other food safety issues are more problematic and less clear cut. The case of unpasteurized cheese is more controversial. Unpasteurized milk is known to be a potential source of foodborne pathogens, including *Listeria monocytogenes* (Todd, 2011). Thus, consumption of soft cheese made from unpasteurized milk is viewed as a medium to high food safety risk. *L. monocytogenes*-contaminated unpasteurized cheese has caused abortion and in a large cheese outbreak in California in 1985 one-third of 142 cases had fertile outcome (Linnan et al., 1988; Hof et al., 2003). Since the first compulsory law requiring milk from cows to be pasteurized, milk pasteurization is credited with dramatically lowering the incidence of typhoid fever, scarlet fever, diphtheria and tuberculosis. In USA today, it is forbidden to sell raw milk cheeses that have been aged for less than 60 months (US Code of Federal Regulations CFR, section 7 CFR 58.439). In Europe, the European Food Safety Authority (EFSA) states that there is a substantial risk of *Campylobacter* with milk and milk products if products are not subjected to a combination of treatments that eliminate the risk (*EFSA Journal*, 2005).

On the other hand, those in favor of unpasteurized cheese state that these cheeses, which have been made for centuries in France (e.g. Roquefort, Brie, Camembert) and other European countries (e.g. Serra da Estrela, Queijo da Ilha, mozzarella) are superior in taste. They are more complex in aroma and flavor, and they have longer lasting tastes. In addition, some believe that raw-milk bacteria and enzymes are helpful digestive aids and argue that lactose-intolerant people are able to digest raw-milk cheeses without their usual difficulty (Sheehan, 2007). Some cheese producers are also concerned with the extended ripening time for pasteurized cheese (Buffa et al., 2001). Up until the early 1900s, all cheese was made from raw milk, and raw-milk cheese defenders state that the unpasteurized cheese problems are related to hygiene problems and lack of knowledge. Raw-milk cheese makers, whether they are making young or aged cheese, must pay extra attention to the type of bacteria that develop in milk at different temperatures, and need to routinely test for bacterial counts. Food hygiene conditions must be held to the highest standards to avoid the introduction of bacteria that can develop in unheated milk. Raw milk needs to be made into cheese immediately to avoid fluctuations in temperature or possible contamination. Because the most likely source of *Campylobacter* in raw milk appears to be the feces of cows or goats, good hygienic practice (GHP) during milking is important (*EFSA Journal*, 2005). An HACCP system in place would serve as an appropriate tool for avoiding food safety outbreaks.

So what are the dilemmas? Is it all right to forbid sales of cheese made with unpasteurized milk? Here food safety is set up against people's pleasure of eating tasty cheese, traditional food cultures and the food industry's economic interest. Is unpasteurized cheese safe enough? In theory, a fully informed consumer might decide which food-related risk to

take and which to avoid. But what does it mean to be fully informed? Can we expect that all consumers are able to collect the detailed information about the wide array of food safety issues and make their own decisions? Are there any good strategies for providing relevant information in such a way that consumers understand the risk? Is the correct thing to do to delegate this responsibility to responsible authorities? And what if the consumers do not trust these authorities?

The issue is even more serious when raw milk itself is sold, or worse, when raw milk is given to children. Other examples are when raw minced meat is served without information to consumers that the product may present a risk. A corollary of this situation is the subject of food irradiation. Application of this technology, evaluated as safe by the World Health Organization, can prevent a range of foodborne illnesses from foods of animal origin such as campylobacteriosis, *E. coli* O157 infection, salmonellosis and infections caused by parasites. However, its application is hampered by the fear of some misinformed consumers. Again, the question is how are consumers informed and how do they voice their view? Is it ethical that some people lose their life because of a powerful lobby against food irradiation? Or is it unethical of food scientists not to understand and pay attention to some consumers' cost of the long-term consequences of irradiation?

Another key example is when a food industry transfers responsibility of safety to consumers without providing proper warnings, crystal clear instructions on safety measures, or even worse market and promote a product in a society when it knows that consumers would not be able or have means to ensure its safety. The latter issue was raised with the question of breast milk substitute in the developing countries, until WHO established the Code of Breast-milk Substitutes that responsible companies comply with. The issue of warnings on food packaging is still not well addressed in most legislation and the clarity with which drug providers or electrical equipment or aviation companies provide information has not yet been established in the food industries. This has made some companies write an ambiguous text that does not raise the concerns of consumers, but where the company in case of an incident can decline any responsibility.

Other emerging areas where the ethics of a company is demonstrated is the validation of health claims, full consideration of safety in development of new technologies and novel foods, and in ensuring that food science and technology is not developed for the sole purpose of business interest but gives priority to consumer health.

As mentioned in Chapter 37, food safety management relies very much on the management of people, including ensuring that employees are competent in their job, have received the proper training and briefing about their responsibilities, are given the means and authority to do a professional job, and also set the right reporting structure to minimize conflict of interest in audits and investigation of incidents. Most of all a company must have a culture that fosters reporting and openly discusses problems, protects and rewards whistleblowers, and has a management that walks the talk and follows its own policies. The company culture is an area which is not legislated and enforced by law but is one of the most important aspects of the ethical practice of a company as it impacts on all aspect of operations, including safety and health and the social right of employees as well as safety of products and health of consumers.

Finally, one of the most fundamental aspects of ethics in the food industry is the commitment and "real will" of the company to build a solid food safety assurance system or just to do the minimum necessary to meet the requirements of legislation and certification bodies.

As safety of food products is the outcome of the food safety assurance system (including the professional management of its staff) of food companies, no matter how comprehensive and strong the regulatory system of a country may be, it cannot replace the everyday vigilance of managers, workers of a company who have to oversee the safety of products.

The Precautionary Principle

The precautionary principle states that if a product, an action or a policy has a suspected risk of causing harm to the public or to the environment, protective action should be supported before there is complete scientific proof of a risk. In the absence of scientific consensus, the principle implies that there is a social responsibility to protect the public from potential harm. This is a "better safe than sorry" or "caution in advance" principle that applies both to human health and to environmental protection.

One of the primary foundations of the precautionary principles, and globally accepted definitions, results from the work of the Rio Conference, or "Earth Summit" in 1992. Principle #15 of the Rio Declaration notes:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The application of the precautionary principle has been made a statutory requirement within the European Union (Recuerda, 2006), and according to an FAO Expert Consultation report on food safety "international food safety organizations must make clear that science, while an important tool, is not sufficient in itself for food risk analysis and that it needs to operate within an ethical framework" (Kaiser, 2003). The problematic cases are the ones where there are disagreements about the value judgments made in the risk assessment. For novel food, new technologies or newly identified hazards, the answer to what is "safe" may not be the subject of a consensus. When both the likelihood of damage and the consequences of damage are unknown, then risk assessment becomes difficult and the assessors face ethical dilemmas (Kaiser, 2003; Almås, 1999). Genetically modified organisms (GMO) are one example of a new technology which has created a lot of debate. The presence of different interest groups and diverse citizens' values in different political arenas triggered a range of policy responses to GMOs in the 1990s (Vázquez-Salat et al., 2012). While GMO was strongly supported by the scientific and biotech industry in the USA and led to a flourish of GM crops, European citizens were strongly opposed to GM plants. Consumers were skeptical and talked about "unnatural Frankenstein's food." They lacked confidence due to their governments' response to a series of food scares in the 1990s (Skogstad, 2003). Today, the GMO regulatory framework in the EU is different from the one in USA and more in line with the public's perception of risk than with the scientific definition of risk. The precautionary principle is applied in the EU and is constantly challenged.

A main ethical question which raised a controversy with regard to GM foods was a few years ago when EU countries would, as part of food aid, propose GM foods to the developing countries (Africa). In 2002 Zambia announced it would not accept GM food aid in any form. So the question was why would a technology and product rejected by the European population be good for the African population? Most African countries approach

GM technology applied to crops with caution. "Why shouldn't we be wary of this technology and its possible long-term health impacts, if the EU [European Union] is. If it is not good for them, why should it be good for us?" said Tewolde Egziabher, Ethiopia's director of the Environmental Protection Agency. Positions were polarized to a great extent after a quote from a US state department official, "Beggars can't be choosers," hit the headlines. It prompted the then president Levy Mwanawasa to say hunger was no reason for feeding his people "poison" (see the link http://www.irinnews.org/report/93991/FOOD-Rumpus-over-GM-food-aid).

The evolutionary aspect of the food system influences risk assessment of food safety and triggers some ethical dilemmas. Although consumers' food variety increases and the food industry potentials for new business grow, there are food safety issues to consider. The food market is becoming more and more global. Not only food but also food pathogens are distributed around the world. In Norway, sugar peas from Kenya led to an outbreak of dysentery in 2009, probably due to consumption of raw products. In Kenya, people boil or fry vegetables before consumption. This is not the case in Norway where unpeeled fruit and raw vegetables are consumed frequently. In many ways Norway is a food safety oasis in Europe, with a livestock population virtually free from *Salmonella* and where only one out of nine national outbreaks of infectious intestinal diseases linked to lettuce, sprouts, sugar peas and basil the last 20 years came from Norwegian produce (Røssvoll et al., 2012). The problem is that consumers' food safety habits and routines, inherited from parents, are not always adapted to handle new food scares from imported products. When food and food pathogens change, while food preparation routines stay the same, then food safety becomes an issue. The solution to this food safety problem raises ethical questions related to freedom of choice, economic prosperities for developing countries, distribution of pathogens into clean areas, etc.

ETHICAL DECISION-MAKING

Making good ethical decisions requires a trained sensitivity to ethical issues, a practiced method for exploring the ethical aspects of a decision and a weighing of the considerations that should impact our choice of a course of action. Having a method for ethical decision-making is absolutely essential. The more novel and difficult the ethical choice we face, the more we need to rely on discussion and dialogue with others about the dilemma. Only by careful exploration of the problem, aided by the insights and different perspectives of others, can we make good ethical choices in such situations.

A framework for ethical decision-making has been developed at the Markkula Center for Applied Ethics at Santa Clara University (www.scu.edu/ethics/decision). This framework for thinking ethically, which is the product of dialogue and debate among Manuel Velasquez, Dennis Moberg, Michael J. Meyer, Thomas Shanks, Margaret R. McLean, David DeCosse, Claire André and Kirk O. Hanson, is a useful method for exploring ethical dilemmas and identifying ethical courses of action. They divide ethical decision making into five blocks:

1. **Recognize an ethical issue:** Could this decision or situation be damaging to someone or to some group?

2. **Get the facts:** What are the relevant facts of the case? What facts are not known? Can I learn more about the situation? Do I know enough to make a decision?
3. **Evaluate alternative actions:** Which option will produce the most good and do the least harm? Which option best respects the rights of all who have a stake? Which option treats people equally or proportionately? Which option best serves the community as a whole, not just some members? Which option leads me to act as the sort of person I want to be?
4. **Make a decision and test it:** If I told someone I respect – or told a television audience – which option I have chosen, what would they say?
5. **Act and reflect on the outcome:** How can my decision be implemented with the greatest care and attention to the concerns of all stakeholders?

How companies respond to these questions when facing a dilemma will impact the companies' ethical image and thereby also the performance of the company. Responsibility for those concerns is shared among the players of the food supply chain, companies, decision-makers and consumers. Production, processing, storage and distribution of food and agricultural products are generally accepted as routine parts of everyday life all around the world. Therefore these activities have rarely been addressed within the realm of ethics. But food and agriculture, and the economic benefits derived from taking part in the associated system, are means to an inherently ethical end: feeding the world's population and preserving the earth's food-producing capacity and natural eco-systems for future generations. The ethical dimension of agriculture is therefore inherent to discussions on modern agricultural technologies (EGE, 2008b).

The ethics of a company and its management becomes conspicuous in times of an incident or a conflict. The ethics of a company is demonstrated by questions such as to what extent the company will:

- voluntarily acknowledge a contamination and/or if necessary recall its products;
- investigate the root cause of incidents up to the management level;
- accept loss of benefits to protect consumers;
- act transparently and reveal information on the incident and its cause; and
- take punitive actions against those who have knowingly and irresponsibly violated the policies (note: errors are different from violations and should be not the subject of punitive actions, see Chapter 37).

In the healthcare or aviation sectors, reporting of non-compliance or problems, and independence in investigations of incidents, is much more advanced and can be a model for the food sector if food safety is to be strengthened.

CONCLUSION

Consumers want a large variety of safe food choices, while producers want safe products to sell, but also less regulation. These ideas are at times in conflict. Exotic and convenience food year round and free choice of organic, raw, local and imported food create value to the producer and benefit to the consumer, but are associated with varied and sometimes serious risk to health (Todd, 2010).

New technology, which made it possible to process the food in advance, transport over long distances, display at retail and at home, made it possible for the pathogens to grow to levels capable of causing infections. Exposure to new pathogens, from imported products or due to new technologies, creates new food safety issues and raises ethical questions. Is zero risk what we aim for, or is there a level of acceptable risk?

The likelihood of becoming sick from the next meal has probably never been less than it is today, but the long-term consequences of today's food production is less known (Almås, 1999). The production process is more complex and less transparent and consumers are no longer in control of the production. They need to trust retailers and producers. Consumers are worried. Some of these worries are directly linked to the risks involved, be they real or perceived. Other worries are more linked to ethical questions related to well-being, free choice (autonomy) and fairness (justice). Availability of safe food needs to be addressed in relation to factors such as: respect for consumer choice, right to information on safety, universally affordable food, adequate income and working conditions for employees and workers, fair practice in trade, animal welfare and sustainability of biotic populations. Also, consumers are worried about new technologies and if these new techniques take into consideration their health and safety, or if they merely are developed for business interests and the benefits of producers. Some consumers wonder to what degree science is being developed impartially, if governments and public health authorities give priority to consumers' health in their opinion on risks and risk management options, and if incidents are investigated independently and transparently.

A dialogue about the ethical implications of food production, processing, policy, supply nd consumption may help involved partners make better decisions. The discussion needs to e lifted to a level above what each company at any given point in time feels is best for them.

Aristotle says that identifying the good with pleasure is to prefer a life suitable for beasts:

> It is better to be a human being dissatisfied than a pig satisfied; better to be *Socrates* dissatisfied than a fool satisfied. And if the fool, or the pig, are of a different opinion, it is because they only know their own side of the question...

Every company has a social responsibility. Not behaving according to accepted norms for ethical behavior may have consequences not only for food safety, but also on a companies' image, reputation and performance. Ethics is not a question of thoughtless and slavish worship of rules, and to scrupulously check every action against a table of dos and don'ts. The fundamental question of ethics is not "What should I do?" but "What kind of person should I be?" For the food industry the question is "What image would we like for our company?" Will we accept compliances, deceive full negligence or non-compliance as long as we are not caught or will we vigilant in any condition?

"Integrity is doing the right thing, even when no one is watching" (Clive Staples Lewis, 1898–1963), and ethics is to the industry what integrity is to a person.

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CHAPTER

47

Training and Education

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At last, few words should be said about education and training in food safety management, the purpose of this book. In this final, short, chapter we would like to draw your attention to some important points on the subject.

1. Often the terms education and training are used interchangeably and in food safety management we often use the term *training* while we may actually mean *education*. Strictly speaking there is a difference. Education is generally defined as the process of learning and acquiring information. It may be carried out for different purposes such as having a profession, a university degree, or more generally, for developing the power of reasoning and judgment. Training is the process of teaching a person (or an animal) a particular skill or type of behavior.
   A key difference between training and education is that in training, the subject may learn to practice behavior without always or necessarily knowing, or thinking of, the reason behind it. In education, the subject receives the knowledge and motivation to make informed decisions and choices. For professionals in food safety and other employees, although for simplicity we often use the term training, both education and training are essential, as managers should have the scientific knowledge and understanding to take sound decisions, but also to have the skills to perform their job.
2. It is a fallacy to automatically attribute failures in food safety management to people's incompetence and/or lack of training. As explained in Chapter 37, a failure can have different reasons, therefore, before deciding to resolve an issue with further training, there is a need for understanding the root cause of the problems and identifying the organization's needs (Figure 47.1).
3. When it has been confirmed that there is a problem with the competence of managers or employees to fulfill their responsibilities and perform their tasks, one should first determine the reasons why this is the case. Although it may be due to a lack of knowledge and skills, it may also be for a range of other reasons, such as lack of time, overload of work, weak infrastructure, lack of clear procedures or instructions, undesirable

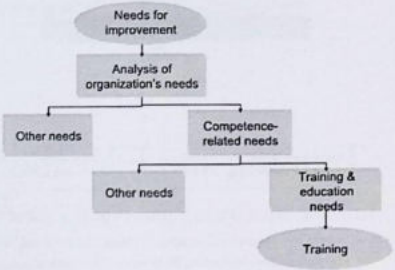

FIGURE 47.1 Decision steps from identification of a company need for improvement to decisions for training. *Adapted from ISO 10015 (1999).*

policies and directives, inconsistency between responsibilities and authority, inadequate resources, lack of motivation or conflicts in values.
The design of a training program must include three types of information:
a. background knowledge and skills of trainees;
b. the work objectives;
c. the tasks that are or will be required to perform (Figure 47.2).

4. As for any management process, following the implementation of a course, the impact of that course needs to be evaluated, and based on the results of evaluation, further improvements need to be brought to its design. As part of this, it is good practice to, sometime after the course, follow up with the trainees and evaluate the impact and relevance of the course on their work performance and identify improvements needed to improve its design.
5. Often, after a course, when trainees return to their job or start their career, they may need further coaching to implement what they learned. Without that, it may be easily forgotten and thus the training will have been in vain. Involvement of a mentor would help to achieve the purpose of the training.
6. At regular times, an entire team (e.g. a department) should be given the same training together. Also, inspectors should receive the same training as professionals in the food industry and if possible also jointly. This then will enhance a common understanding of food safety management and decrease the risks of conflicts and differences in insights, which otherwise will become evident after an incident when it is too late.
7. Often we focus our training on technical people, i.e. on food safety managers or others directly involved in managing food safety, such as food safety scientists, laboratory staff, auditors, operators and line workers. There are, however, other people who may not be involved directly in food safety management but their decisions or actions can

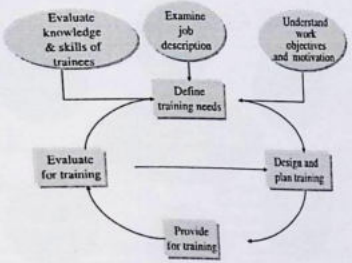

FIGURE 47.2 Steps for planning, designing and improving the training and education process. *Adapted from* ISO 10015 (1999).

have bearings on food safety. This can range from a business director to professionals working in packaging, transportation or administration. Their perception of what is a risk and what are important measures may be different and they may not be aware of the consequences of their decisions or actions for food safety. There have been numerous incidents associated with such situations. In food safety, as in other sectors (e.g. aviation), any detail is important if accidents are to be effectively prevented. The sensitization and education of these people should also be considered in food safety management; they should be made aware of the relevance of their decisions or work to food safety, in particular in an inadvertent adverse event.

8. Finally, but most importantly, the education of decision-makers, particularly the CEO of businesses, needs to be stressed.

This book has been developed with the aim of providing a common basis for training of food safety professionals working in industry and/or those who will assess food operations, to promote a common vision on food safety management and explain the underlying science. Providing training to staff, both managers and employees, is at the heart of any food safety management as without competent, knowledgeable and motivated staff, no system will be functional and effective (Figure 47.3).

Training staff to be competent for their job is not only important for consumer safety but it is also an employee right. An employee, who has not received proper training for his or her job, cannot be held responsible for incidents that are the results of mistakes. The ultimate responsibility and accountability fall on the management of the operation that failed to provide the necessary training.

Finally, a key factor in food safety management is the conscience of the staff themselves. Therefore, as final words to the practicing and future food safety professionals, and all

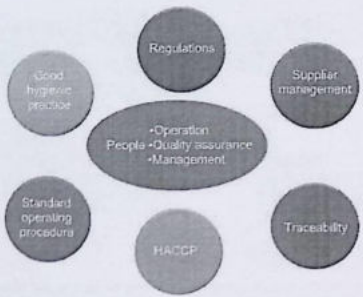

FIGURE 47.3 People are at the heart of food safety management systems and their management including their training and education is elemental in the food safety management system. *Adapted from ISO 10015 (1999).*

users of this book, we recommend that, in case of doubt, they should ask themselves three questions:

1. Would I give the food in question to my children?
2. How can I defend myself in a court of justice?
3. What did I do to prevent or minimize the risk?

Reference

ISO, 1999. ISO Quality management – Guidelines for training. ISO 10015: 1999. International Organization for Standardization, Geneva.

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Note: Page numbers followed by "b," "f," and "t" refer to boxes, figures, and tables, respectively.

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