Food Safety Management II

A Practical Guide for the Food Industry

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TABLE 14.1 Microbiological Monitoring and Verification of Various Water Types within a Factory

Water	Target Organisms	Method	Guideline Value	Frequency of Monitoring
Potable, municipal drinking water at intake point.	Coliforms presence/ absence test using membrane filtration	ISO 9308	ND[a] in 100 ml	As determined by HACCP
Water (municipal or well) after treatment	*Escherichia coli*	ISO 9308	ND in 100 ml	
	Enterococci	ISO 7899	ND in 100 ml	
	Total plate count 22°C	ISO 6222	≤100/ml	
	Total plate count 37°C	ISO 6222	≤10/ml	
Product make up water	Depended on processing	–	–	As determined by HACCP
Chilled water circuits (closed), unpreserved	Coliforms plate count	ISO 9308	≤1/ml	As determined by HACCP
	Total plate count 22°C	ISO 6222	≤1000/ml	
Chilled water circuits (closed), preserved	Coliforms plate count	ISO 9308	≤1/ml	As determined by HACCP Check preservative concentration continuous or weekly
	Total plate count 22°C	ISO 6222	≤1000/ml	
Hot water circuits	None	–	–	Check temperature storage (60°C) and distribution (56°C) continuously
Final rinse water	Depended on processing	–	For aseptic processes sterility is required	As determined by HACCP
Cooling water for canning	Coliforms plate count.	ISO 9308	≤1/ml	As determined by HACCP Check chlorine concentration continuous or daily
	Total plate count 22°C	ISO 6222	≤100/ml	
	Chlorination	ISO 7393	2–10 mg/l	
Bottled water	*Escherichia coli*	ISO 9308	ND in 250 ml	As determined by HACCP
	Enterococci	ISO 7899	ND in 250 ml	
	Pseudomonas aeruginosa	ISO 16266	ND in 250 ml	
	Total plate count 22°C	ISO 6222	≤100/ml	
	Total plate count 37°C	ISO 6222	≤20/ml	

Adapted from IISI, 2008, WHO, 2011 and EC 2012
[a]*ND = Not detectable in the defined volumes.*

Groundwater

Groundwater is water contained beneath the surface in rocks and soil, and which accumulates underground in aquifers (WHO, 2006). Groundwater constitutes 30% of the global freshwater pool (Figure 14.1). In many parts of the world groundwater sources are the

TABLE 14.2 Estimation of the Global Water Distribution (Gleick, 1996)

Water Source	Water Volume, in Cubic Miles	Water Volume, in Cubic Kilometers	Fresh Water Percentage	Total Water Percentage
Oceans, seas, and bays	321,000,000	1,338,000,000	–	96.5
Ice caps, glaciers and permanent snow	5,773,000	24,064,000	68.7	1.74
Groundwater	5,614,000	23,400,000	–	1.7
Fresh	2,526,000	10,530,000	30.1	0.76
Saline	3,088,000	12,870,000	–	0.94
Soil moisture	3959	16,500	0.05	0.001
Ground ice and permafrost	71,970	300,000	0.86	0.022
Lakes	42,320	176,400	–	0.013
Fresh	21,830	91,000	0.26	0.007
Saline	20,490	85,400	–	0.006
Atmosphere	3095	12,900	0.04	0.001
Swamp water	2752	11,470	0.03	0.0008
Rivers	509	2120	0.006	0.0002
Biological water	269	1120	0.003	0.0001
Total	332,500,000	1,386,000,000	–	100

single most important supply for the production of drinking water, particularly in areas with limited or polluted surface water sources. Groundwater is typically of more stable quality and better microbial quality than surface waters. Groundwater quality from small suppliers suffers more from a lack of information, risk assessment and risk management. Groundwater often requires little or no treatment to be suitable for drinking. There are many examples of groundwater being distributed without treatment. However, groundwater quality may be corrupted by nearby sources of hazards if the groundwater well is insufficiently confined and/or well integrity is compromised. Viruses are considered to be the most critical pathogens for groundwater contamination, because of their ability to travel through the subsurface and their high infectivity (Schijven et al., 2010). Flooding of groundwater wells due to extreme precipitation and unnatural threats to its quality should be recognized (Schijven and de Roda Husman, 2005). It is vital therefore that the quality of groundwater is protected if public health is not to be compromised.

Surface Water

Surface water may consist of fresh or saline water, or a combination of semi-saline water called brackish water. Brackish and saline waters are present in our oceans, seas and river

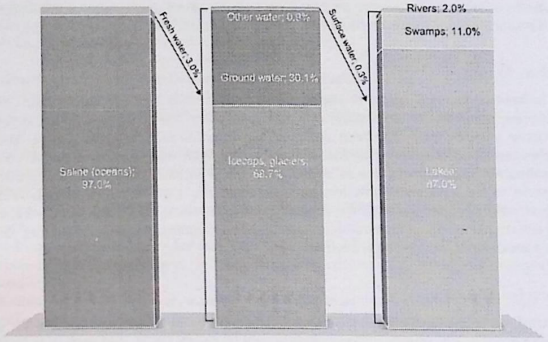

FIGURE 14.1 Freshwater sources.

delta areas. Fresh surface waters include rivers, lakes, swamps and groundwater (Figure 14.1). The larger part of fresh water (two-thirds) is, however, frozen and encapsulated in ice-caps and glaciers. Groundwater also constitutes a large part: one-third. Of the remaining part, fresh water mostly includes lakes, swamps and rivers. Surface waters are largely under the influence of contamination from human and animal activities but also from the environment itself, which may compromise public health. The range of human activities in the catchment that may cause pollution of surface waters with microbiological, chemical and radiological hazards includes agricultural activities, sanitation practices, industry, mining, military sites, waste disposal and traffic. As compared with groundwater, surface waters generally need to be treated, often extensively.

Rainwater

Rainwater is initially free of contamination, except for air pollutants (Lye, 2009; Schets et al., 2010; WHO, 2011). However, the quality of rainwater may subsequently deteriorate during harvesting, storage and household use. When collected from rooftops or otherwise, it may become contaminated by animals and humans directly or indirectly from their waste or, alternatively, chemicals may dissolve from collecting and storage devices and human pathogens may grow in stored rainwater. Well-designed rainwater harvesting systems with clean catchments, covered cisterns and storage tanks, and treatment, as appropriate, supported by good hygiene at point of use, can offer drinking water with very low health risks. Rainwater can provide an important source of drinking water in some circumstances as well

as be a useful source of water for blending with other sources to reduce the levels of contaminants that may cause health concerns, such as arsenic and fluoride.

Saline Water

In light of climate issues and population growth, it may be difficult to provide sufficient water supply to the world including meeting industry needs. In this respect, desalination of ocean and sea water has been explored. Desalination facilities exist all over the world, particularly in the eastern Mediterranean region, with use increasing on all continents. Desalination is used to remove salts from brackish or saline surface water and groundwater in order to render it acceptable for human consumption or other uses such as in the food industry. Some of the desalination processes used (especially distillation and reverse osmosis) are highly effective in removing microbial and chemical hazards facilitating the use of these processes as single-stage treatments.

Recycled Water

After use in the food industry (ILSI, 2012), water may be of sufficient quality for use in a similar process, e.g. washing. Depending on the contact, both in time and surface, between the water and food ingredient or end product, the recycled water needs to meet quality requirements. If these are not met, there is a range of available treatment options to improve water quality (WHO, 2011). See also "Water Reuse in Food Processing," on page 372.

DRINKING-WATER APPLICATIONS IN THE FOOD INDUSTRY

Water is used widely in the food industry. It is used to move products, to produce and/or wash vegetables, fruits, fish and poultry, and to clean and refresh raw vegetables after harvesting and during distribution. Water, or steam made from it, is used for cleaning, disinfection and heating purposes. Finally, water can be a consumer end product and/or an ingredient in food. Virtually all frozen foods carry a glaze of ice which is often derived from process water, and for certain frozen foods (such as fish and shellfish) a glaze is added as a protective measure.

The amount of water used to produce food commodities is sometimes impressive. The so-called water footprint is defined as the total volume of fresh water that is used to produce the goods and services consumed by an individual or community or produced by a business. The production of 1 kilogram of beef requires 15,415 liters of water, an average of 1,600 liters are needed for 1 kg of bread and 27 liters are needed for a cup of tea (250 ml). (www.waterfootprint.org, accessed June 2013).

Water as End Product

Water is delivered to the consumer either as tap water from a piped distribution system or packaged in bottles, cartons or other containers. The food industry delivers packaged water only.

The following types of water are produced as an end product, packaged in plastic or glass bottles, cartons, water coolers, water dispensers and so on. Sizes range from small single serving PET bottles to large carboys for water coolers.

- **Spring water:** Bottled water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water must be collected only at the spring or through a borehole tapping the underground formation feeding the spring.
- **Purified water:** Water that has been produced by distillation, deionization, reverse osmosis or other suitable processes while meeting the definition of purified water in the United States Pharmacopoeia.
- **Mineral water:** Bottled water containing not less than 250 parts per million total dissolved solids.
- **Sparkling bottled water:** Water that, after treatment and possible replacement with carbon dioxide, contains the same amount of carbon dioxide that it had as it emerged from the source.
- **Artesian water/Artesian well water:** Bottled water from a well that taps a confined aquifer (a water-bearing underground layer of rock or sand) in which the water level stands at some height above the top of the aquifer.
- **Well water:** Bottled water from a hole bored, drilled or otherwise constructed in the ground, which taps the water aquifer.

The amount of bottled water consumed per year was estimated in 2011 to be 262 billion liters worldwide. This represents an average of 37 liters per capita. (http://www.zenithinternational.com/accessed june 2013). However, some countries show extremely higher figures. Table 14.3 shows the 20 countries where most bottled water is consumed, compared to the average global consumption.

The market is forecasted to grow to over 400 billion liters in 2020.

Bottled water has come under criticism in recent years for the environmental impacts of groundwater extraction, the energy and environmental costs of the plastic packaging and transportation costs and concerns about water quality and the validity of some marketing claims. One criticism of bottled water concerns the packaging. Bottled water commonly is packaged in polyethylene terephthalate (PET), which requires a significant amount of energy to produce. While PET is recyclable, only a fraction of plastic bottles made from PET are actually recycled. For example, in the United States, according to a NAPCOR (National Association for PET Container Resources) study, water bottles account for 50% of all the PET bottles and containers collected by curb side recycling, and the recycling rate for water bottles was 28% in 2009. However, bales of PET collected for recycling often contain materials such as polypropylene caps, labels and glue, and other contaminants, which are then weighed and included in the PET recycling rate. The percentage of "clean PET flake" yielded once the contaminants have been removed was 21% in 2009 and is a more accurate depiction of how much PET actually gets recycled. European recycling rates tend to be somewhat higher. In the United States, plastic used to create bottles uses an estimated 15 million barrels of oil annually (data on recycling from http://www.container-recycling.org, accessed September 2012).

TABLE 14.3 Per Capita Bottled Water Consumption by Top Countries 2000 to 2010

	Per Capita Bottled Water Consumption (liters)		
Countries	2000	2005	2010
Mexico	124	179	243
Italy	160	191	187
United Arab Emirates	114	181	153
Belgium–Luxembourg	118	160	148
Germany	102	128	134
France	126	139	132
Spain	105	146	124
Lebanon	77	107	121
Thailand	70	76	114
Hungary	39	70	111
Switzerland	90	104	108
United States	67	99	107
Slovenia	56	81	107
Croatia	47	78	101
Cyprus	72	98	98
Qatar	–	79	95
Saudi Arabia	80	93	95
China, Hong Kong SAR	–	68	95
Czech Republic	68	90	92
Austria	75	81	91

Data from Beverage Marketing Corporation and http://www.worldwater.org – accessed September 2012.

Water as Ingredient

The importance of water quality cannot be underestimated by food manufacturers. It plays a vital role, both as a critical ingredient in ensuring food quality and as a key to efficient production. It provides appropriate water content in the final product. For example, canned soups and vegetables contain a high percentage of added water once they have been cooked and packaged. Another important function of water is to dissolve ingredients. Especially when used as ingredient, it is important that the water produces no hazards, flavors or smells which might affect the quality or consistency of the final product. "Determination of Water

Safety," on page 367, presents a simple safety classification of water "fit for purpose" and an easy-to-use decision tree for assessing the suitability of water for its intended use.

Producers of food products that need to be rehydrated before consumption should be aware of the safety of water used for this purpose. In particular products that will not, or will not sufficiently, be reheated need attention from both the water supplier as well as the supplier of the dried food. The water supplier obviously needs to provide safe water, either bottled or tap. The food supplier is responsible for pathogen-free products, maximal intrinsic security (like water content or capacity, acidity, temperature, packaging) and shall instruct customers in how to safely rehydrate the product – in particular if they sell their products to areas where safe water is not commonly available.

Dried foods intended for babies, such as infant formula, require specifically safe water as infants' immune system is not fully developed and they are particularly vulnerable. Of course, the product itself shall be free from any harmful chemical, microbiological or physical hazards; however, consumers should be alerted that dried foods are not sterile. Risks associated with the rehydration of products and their final preparation for consumption, including recontamination during storage, should be considered in the products' HACCP plan, and validated safety instructions should be provided to consumers. The Codex Guidelines on Validation of Control Measures provide guidance on the validation process for preparation of consumer information (see Codex Alimentarius. Guidelines for the Validation of Control Measures).

The World Health Organization has issued guidelines for safe preparation, storage and handling of powdered infant formula (WHO, 2007b). These guidelines are valuable for consumers and producers of infant formula. A few relevant subjects for producers of infant formula are summarized:

- **Formula preparation:** In most cases, it is safe to mix formula using ordinary cold tap water that has been brought to boil and then boiled for 1 minute and cooled. According to the World Health Organization, recent studies suggest that mixing powdered formula with water at a temperature of at least 70°C (158°F) will eliminate the bacterium *Cronobacter sakazakii* (previously *Enterobacter sakazakii*) and other pathogenic (micro) organisms. Remember that formula made with hot water needs to be cooled quickly to body temperature if it is being fed to the baby immediately. If the formula is not being fed immediately, refrigerate it right away and keep refrigerated until feeding.
- **Water:** Use the exact amount of water recommended on the label. Under-diluted formula can cause problems related to dehydration. Over-diluted formula will not provide adequate nutrition, and, if fed for an extended period of time, may result in slower growth.
- **Bottled water:** If consumers use non-sterile bottled water for formula preparation, they should follow the same directions as described for tap water above. If the water is marketed by the manufacturer as sterile and for infants, it must meet general requirements for commercial sterility.
- **"Use by" or "expiry" date:** This is the date after which a package or container of infant formula should not be fed to infants.
- **Storage:** Manufacturers must include instructions on infant formula packaging for before and after the container is opened. They must also include information on the storage and disposal of prepared formula.

Water for Processing

During food production, water is widely used as a processing aid without the aim of serving it as an ingredient. Examples of demands for water during food processing are (not exhaustive):

- Washing or cleaning of (raw) products.
- Transport of products.
- Treatment of the product (e.g. alteration, separation).
- Cooling processes: for example, fish is typically shipped in ice; poultry may be cooled in water and slush ice and transported in ice.
- Steam generation for heating, directly or indirectly.
- Cleaning or rinsing of equipment.
- Abnormal incidents (like fire protection).
- Sanitation.

Increasingly process water is recycled. This subject is discussed in "Water Treatment Technologies for Safe Water Production," on page 367.

Water at Household Level

To obtain and maintain safe water at the household level, integrated planning, combined with effective monitoring and evaluation, is critical. An estimated 780 million people drink water from unimproved sources, and millions more drink contaminated water from improved sources (WHO and Unicef, 2012). Until safe, reliable, piped-in water is available to every household, interim measures, such as household water treatment and safe storage (HWTS) to prevent contamination during collection, transport and use in the home, are needed to reduce the burden of diarrheal disease. While a growing body of evidence demonstrates that the use of HWTS methods improves the microbial quality of household drinking water and reduces the burden of diarrheal disease in users, there is also increasing evidence that inconsistent and/or incorrect use may be a major challenge in realizing the full potential from HWTS. In order to develop effective mechanisms to encourage and sustain correct use of HWTS, there is a need to monitor and evaluate uptake. Recently, WHO (2012) has provided a toolkit including process monitoring to assess program implementation and quantitative analysis through surveys, direct observation and water quality monitoring. As part of this toolkit, a set of indicators pays attention to reported and observed use; correct, consistent use and storage; knowledge and behavior; other environmental health interventions; and water quality.

HAZARDS ASSOCIATED WITH DRINKING WATER

Microbial, chemical and radiological hazards may compromise water quality and confer public health risks by human consumption of food and water. The great majority of evident water-related health problems are the result of microbial (bacterial, viral, protozoan or other biological) contamination.

An appreciable number of serious health concerns may occur as a result of the chemical contamination of drinking water. Adverse health effects due to exposure to microbial hazards will be acute and may be chronic as opposed to exposure to most chemical hazards that are rarely acute.

Microbial Hazards

Bacteria, viruses, protozoan parasites, algae, amoebae and helminths are known microbial hazards associated with drinking water. Some of these organisms, such as a few bacterial species, algae and helminths, can multiply independently in the aquatic environment whereas other, so-called enteric pathogens are completely dependent on their warm-blooded host, animals and/or humans, for their multiplication (Table 14.4). In case the enteric bacteria, viruses or parasites can be transmitted from animals to humans, whether or not waterborne, these are called zoonotic. Examples are the protozoan parasite *Cryptosporidium*, the hepatitis E virus and the bacterium *Campylobacter*. Viruses (20–300 nm) in general are much smaller than bacteria (approx. 1 μm) which are turn smaller than protozoan parasites (10 μm or larger). The different sizes affect their fate and transport in the aquatic environment as well as their removal and inactivation efficacy by treatment.

Infection with waterborne pathogens may pass without symptoms, or lead to mild disease, severe disease or death. Young children are especially vulnerable for contracting water-related infections and diseases mainly involving diarrhea, and if not properly treated these could be life threatening. On a global level, the UN and partners estimate that child mortality has declined by 41% since 1990, from 12 million deaths per year to 6.9 million in 2011 (data from WHO, accessed November 2012). However, many countries, especially in sub-Saharan Africa, are still far off-target in reducing child deaths. Contaminated water is an important cause of the catastrophe (see also Motarjemi et al., 1993, 2012): worldwide, an estimated 780 million people lacked safe drinking water in 2010 involving 1.8 million diarrheal disease deaths, mostly children, every year (WHO, 2011).

In low income regions exposure to *Vibrio* bacteria causes large cholera outbreaks with many thousands becoming ill, resulting in countless deaths (Mandal et al., 2011). These outbreaks may follow natural disasters such as floods, as in Haiti in 2010. However, outbreaks are ongoing in sub-Saharan Africa. Hepatitis E virus has caused numerous outbreaks among displaced people in Chad and Sudan in 2004 resulting in more than 45 deaths, mostly pregnant women (Boccia et al., 2006). In 2007, in northern Uganda, the virus demanded 160 deaths with more than 10,196 persons diseased (Teshale et al., 2010). Although the problem with unsafe drinking water is strongly related to low income countries, high income countries may also suffer from major outbreaks. One of the largest recorded outbreaks of waterborne disease took place in Milwaukee (USA) in 1993. Over 400,000 people were infected with *Cryptosporidium parvum*. This outbreak was probably caused by polluted water from Lake Michigan, the source of the drinking water. In May 2000 approximately 2300 people became seriously ill and seven died from exposure to contaminated drinking water in the town of Walkerton, Ontario (Canada). A combination of extreme weather, lack of appropriate control systems and human failure resulted in water being contaminated with *E. coli* O157:H7 and *Campylobacter jejuni*. These cases illustrate that the complexity of (tap)water systems in developed countries may be alive to technical and/or human failure.

TABLE 14.4 Sources of Water-related Pathogens

Pathogen	Source		
	Human	Animal	Environmental
Acanthamoeba	–	–	+
Adenoviruses	+	+	–
Aeromonas	+	+	+
Campylobacter	+	+	–
Cryptosporidium	+	+	–
Cyanobacteria	–	–	+
Pathogenic *E. coli*	+	+	–
Enteroviruses	+	+	–
Giardia	+	+	–
Hepatitis A virus	+	–	–
Hepatitis E virus	+	+	–
Legionella	–	–	+
Leptospira	–	+	–
Mycobacterium (nontuberculous mycobacteria)	–	–	+
Naegleria fowleri	–	–	+
Noroviruses	+	–	–
Pseudomonas aeruginosa	–	–	+
Rotavirus	+	–	–
Salmonella (para)typhi	+	–	–
Salmonella nontyphi	+	+	–
Shigella	+	+	–
Staphylococcus aureus	+	–	–
Toxoplasma	+	+	+
Vibrio	+	+	+

(Updated from Schets et al., 2010)

Disease outbreaks may be directly associated with drinking-water consumption but also to more indirect exposure. After heavy rainfall, 60% of cruise participants reported gastroenteritis with stools positive for *Shigella sonnei*, *Giardia* and *Cryptosporidium* after consumption of ice produced from potable water contaminated with lake water (Serdarevic et al., 2012).

Chemical Hazards

Water may contain many different chemicals, usually in low to very low concentrations; however, spills may be extensive. An example is the Minamata disease in Japan (1956). It was caused by the release of methyl mercury in the industrial wastewater from the Chisso Corporation's chemical factory, which continued from 1932 to 1968 (Wikipedia, accessed December 2012). In Bangladesh it is estimated that a major part of the population is at risk of poisoning because groundwater used for drinking has been contaminated with naturally occurring inorganic arsenic (Smith et al., 2000). Due to labor and technical limitations only part of these chemicals are monitored; beyond this the focus is addressed to well-known substances or groups of chemicals (and not the individual elements). The main sources of chemical hazards are (WHO, 2011):

- Naturally occurring: rocks, soils and the effects of the geological setting and climate.
- Industrial sources and human dwellings: mining (extractive industries) and manufacturing and processing industries, sewage, solid wastes, urban runoff, fuel leakages, pharmaceuticals, hormones, personal care products.
- Agricultural activities: manures, fertilizers, intensive animal practices and pesticides.
- Water treatment or materials in contact with drinking water: coagulants, DBPs, piping materials.
- Pesticides used in water for public health: larvicides used in the control of insect vectors of disease.
- Cyanobacteria producing unwanted metabolites: eutrophic water bodies.

The effect of chemical contaminants may be categorized as follows:

- Toxic to live stock.
- Toxic to fish, shellfish or crustaceans, in particular in aquaculture.
- Toxic to crops (phytotoxic).
- Accumulation in fish, livestock, plants and products derived from them.
- Toxic to humans, either directly or indirectly.

Chemical hazards are usually not related to acute toxicity while concentrations are usually very low. Of concern, however, is exposure to very low concentrations with effects that are only evident after a very long period of time.

An extensive overview of chemical hazards has been described by the WHO. Without being complete this list includes the following categories.

Inorganic

This group of potential hazards includes metals and metalloids (like lead, iron, nickel, zinc, mercury, arsenic, boron, cadmium and molybdenum), salts (sodium, chloride, potassium, calcium, manganese and magnesium), nitrate and nitrite and the parameter total hardness.

Some of the inorganic substances are derived from soil and/or rocks, but some metals are potentially released from pipeline systems. An epidemiological study on the extent of lead exposure via tap water in Hamburg (Germany) showed that people with lead in tap water above 5 mg/L showed significantly higher blood lead levels compared to those with

no detectable lead in the tap water. Elevated levels of lead (and other metals) may cause adverse health effects after prolonged periods of exposure (Cidu, 2011).

In the UK an incident affecting five children attending a summer camp was related to consumption of "blue colored" drinking water. The contamination occurred in an old building which was being used for the first time after a few months. Because the stored water had been left standing for many months it had become blue tinged due to the copper pipes and tanks. The children's symptoms were consistent with excessive copper ingestion. After the system had been completely flushed through, the water returned to its natural colorless state and the levels of copper were confirmed to be below the (UK) guideline values (Paranthaman, 2010).

These examples elucidate the urge to analyze risks associated with the tap water distribution system.

Nitrate toxicosis can occur through metabolism of nitrate to nitrite, which in turn oxidizes the iron atoms in hemoglobin from ferrous iron (2+) to ferric iron (3+), rendering it unable to carry oxygen. This process can lead to generalized lack of oxygen in organ tissue and a dangerous condition called methemoglobinemia. Methemoglobinemia in infants is known as blue baby syndrome. Although nitrates in drinking water were once thought to be a contributing factor, there are now significant scientific doubts as to whether there is a causal link to disease (Wikipedia, accessed 29 August 2012).

Although salts are necessary for the human body and physiology, excessive salt concentrations may be hazardous. Fresh water normally has a salt concentration <0.05%. Drinking water with elevated amounts of salt can have unfavorable effects on blood pressure and heart rate, and produce physiological changes (headache, dizziness, nausea, blood-stained stools, vomiting). In extreme cases, the increased salt content of drinking water may cause severe illness and even death.

In conclusion, inorganic hazards may cause severe illness in humans. However, the chance that the threshold concentrations end up in tap or bottled drinking water can be controlled relatively easy with an appropriate HACCP system.

Organic

Organic pollutants are a comprehensive group of chemicals that include (Wikipedia, accessed August 2012; WHO, 2011):

- Detergents.
- Disinfection by-products found in chemically disinfected drinking water, such as chloroform.
- Food processing waste, which can include oxygen-demanding substances, fats and grease.
- Insecticides and herbicides, a wide range of organohalides and other chemical compounds.
- Petroleum hydrocarbons, including fuels (gasoline, diesel fuel, jet fuels and fuel oil), lubricants (motor oil) and fuel combustion by-products from storm water runoff.
- Tree and bush debris from logging operations.
- Volatile organic compounds (VOCs), such as industrial solvents, from improper storage.
- Chlorinated solvents that may fall to the bottom of reservoirs, since they do not mix well with water and are denser.

- Polychlorinated biphenyl (PCBs).
- Trichloroethylene.
- Perchlorate (both a naturally occurring and man-made chemical that is used to produce rocket fuel, fireworks, flares and explosives). Perchlorate can also be present in bleach and in some fertilizers (http://water.epa.gov, accessed December 2012).
- Various chemical compounds found in personal hygiene and cosmetic products.

The WHO guideline for drinking-water quality provides detailed information on many of the organic hazards and proposes methods to prevent and control them (WHO, 2011).

Disinfectants

Disinfectants commonly used in the food, drink and catering industries include the following:

- Surface active agents (surfactants). These include the amphoterics (based on amyl alkyl glycines), the cationics (quaternary ammonium compounds – known as QACs or quats) and biguanides/diguanides. Many of the amphoterics and cationics are classified as skin, eye and respiratory irritants. Biguanides/diguanides are of low toxicity and irritancy and are useful skin disinfectants.
- Alcohols. These are used as skin cleaners as well as a transport medium for other active ingredients, but nevertheless are irritating to eyes, nose and throat at high airborne concentrations and can be a fire risk.
- Aldehydes. Glutaraldehyde is classified as a skin and respiratory sensitizer. Formaldehyde is a strong respiratory irritant and is also classified as a category 3 carcinogen.
- Peracetic acid is a powerful oxidizing agent used in the food and drink industries and is also extremely corrosive.
- Hypochlorite and organic chlorine-releasing compounds are corrosive in their concentrated form and are classified as eye and skin irritants in their dilute form (5–10%).

Most disinfectants are used to disinfect equipment or the premises. But drinking water used for food production may also contain disinfectants which are added by water suppliers to control pathogens (see "Water Treatment Technologies for Safe Water Production," on page 367). Disinfectants themselves can react with naturally-occurring materials in the drinking water to form by-products, such as trihalomethanes and haloacetic acids, which may pose health risks. The challenge for water suppliers is to control and limit the risks from pathogens and disinfection by-products as well as health risks to customers from disinfection by-products. For actual information on allowed disinfectants and maximum residual disinfectant levels, food companies shall address to local suppliers and legislation.

The food industry may also be at risk directly because chemicals are used for cleaning and disinfection. Residues may come in contact with the product(s) causing hazards, e.g. as with the supplied drinking water, and HACCP plans should cover these risks appropriately.

Pharmaceuticals, Hormones and Drugs

As a consequence of strong increases in human (and animal) healthcare more and more pharmaceuticals, hormones and drugs are prescribed. Part of the substances themselves or

their metabolites are excreted and may reach water sources. In particular substances that are designed to be active in the human body at low levels are of concern. For other substances small quantities mean that effects are only evident after a long period of time. Therefore most standards for drinking water are based on risk assessments for long-term exposure.

A study in 2010 reviewed various QPhRA (quantitative pharmaceutical risk assessment) studies to identify potential threads (Kumar, 2010). In general, for low concentrations of APIs (active pharmaceutical ingredients), none of the QPhRA studies has identified any human health risks via exposure to drinking water, but uncertainties related to the QPhRA still exist and warrant consideration. In particular, knowledge about chronic effects and mixture effects of pharmaceuticals is very limited and requires further study.

Radiological Hazards

Radiation may originate from a number of naturally-occurring and human-made sources. Natural materials like uranium, thorium and potassium-40 can be found in diverse environments. Radioactive constituents of drinking water can result from:

- Naturally-occurring radioactive substances.
- Technological processes from which radioactive materials are released (like mining, processing of mineral sands or phosphate fertilizer production).
- Radionuclides discharged from nuclear fuel recycle facilities.
- Manufactured radionuclides (e.g. for medical and industrial use) that are not properly discharged.
- Past releases of radionuclides into the environment, including water sources (nuclear research programs and tests).

Radiation risks are limited, in particular when water is supplied by reliable suppliers. Food companies using natural sources should analyze the possible radiological risks by assessing the environment and if necessary testing for contaminants.

Greater concerns are related to nuclear disasters.

In 1986 the Chernobyl accident contaminated 125,000 square miles of land in Belarus, Russia and Ukraine with radio nucleotides including cesium-137, strontium-90 and plutonium-239. It is interesting that the water supply is not nearly as contaminated as the soil. Levels in water bodies fell rapidly during the weeks after fallout through dilution, physical decay and absorption of radionuclides to catchment soils. Bed sediments are an important long-term sink for radioactivity. Aquatic habitats also tend to be more tolerant of radioactive contamination (http://environmentalchemistry.com, accessed August 2012 + Chernobyl's Legacy: Health, Environmental and Socio-economic Impacts and Recommendations to the Governments of Belarus, the Russian Federation and Ukraine. The Chernobyl Forum: 2003–2005).

The Fukushima-Daiichi nuclear plant disaster after the earthquake and tsunami that struck Japan on 11 March 2011 again illustrated the risk of radiological contamination of water. Most of the radioactive material ended up in the sea and will be strongly diluted and therefore will not cause concern for the drinking water, as illustrated by Yasuhiro Sonoda (MP) drinking a glass of decontaminated water taken from puddles inside the housing of the reactors. However, some scientists fear that deep water fish, fish at the top of the food

chain, mollusks and other filtrating sea life are most sensitive to nuclear contamination/concentration.

For the food industry radiological hazards from (drinking) water may be relevant only if the company is located near a disaster area or when water is imported from these areas. A thorough risk analysis and monitoring program is required under these conditions.

Organoleptic (Taste, Odor, Appearance) Hazards

Taste and odor in drinking water are two of the most widespread causes of customer complaints. Although there are in general no associated health effects, the importance for the food industry is significant while organoleptic problems may influence product quality.

Since taste and odor work together it is often difficult to distinguish the two. Common organoleptic deviations include (http://extoxnet.orst.edu, accessed September 2012):

- **Strong chlorine taste or smell:** Generally this occurs when the water is treated at the water treatment plant by disinfection (see "Chemical Hazards Associated with Drinking Water," above).
- **Metallic taste:** Some water systems have a high mineral concentration causing a salty or soda taste. In the case of iron and manganese, a strong metallic taste is readily detected.
- **Rotten egg odor:** This is usually a result of decaying organic deposits underground. As water flows through these areas, hydrogen sulfide gas is picked up, and when this water reaches the surface or comes out of the tap, the gas is released into the air. Hydrogen sulfide gas produces the rotten egg odor, can be corrosive to plumbing at high concentrations and can tarnish silver rapidly. As little as 0.5 ppm (parts per million) can be tasted in drinking water.
- **Musty or unnatural smells:** These smells are normally a result of, even low amounts of, organic matter or even some pesticides in the water supply.
- **Turpentine taste or odor:** This smell can be a result of methyl tert-butyl ether (MTBE) contamination. MTBE is a gasoline additive, used as an oxygenate to raise the octane number. The odor threshold of MTBE is fairly low, so many people can smell it.
- **Red or brown color:** A red, brown or rusty color is generally indicative of iron or manganese in the water. It may cause stains in sinks, or discolored laundry.
- **Yellow color:** This coloration occurs in regions where the water has passed through marshlands and then moved through peat soils. It is more commonly found in surface water supplies and shallow wells. Although the yellow color may be displeasing, it presents no health hazard, as it is only small particles suspended in the water.
- **Blue or green color:** A green or blue color is generally a result of copper in the water supply, or copper pipes and corrosive water. Copper has a taste threshold of around 5 ppm. Copper can become a problem if the concentration is higher than 30 ppm. Effects at this dose are vomiting, diarrhea and general gastrointestinal distress.
- **Cloudy white or foamy water:** Cloudy water is usually due to turbidity. Turbidity is caused by finely divided particles in the water. When light hits the water, it is scattered, giving a cloudy look to the water. The particles may be of either organic or inorganic nature. Neither one causes any harmful effects to the body, although they can cause abrasions to pipes, or possible staining of sinks.

When water is used for food production, or may be in contact with food, organoleptic hazards are part of the HACCP plan. If necessary, appropriate measures shall be taken to mitigate aberrant characteristics of the water.

Miscellaneous Hazards

To ensure the safety of water in the food industry, apart from environmental and processing care to produce safe water, the role of the staff in the food industry also needs to be considered. The workers need to be aware that they may be asymptomatic carriers of pathogens and therefore need to exercise optimal (hand) hygiene after defecation. For instance, cruise ships are regularly involved in large-scale gastroenteritis outbreaks associated with norovirus often due to insufficient hygiene of kitchen workers. Water has been epidemiologically identified as one of the risk factors (Verhoef et al., 2008). Prerequisite programs on ship sanitation such as by the WHO and CDC should cover this. In 2011 the WHO launched the third edition of the guide to ship sanitation with global reference on health requirements for ship construction and operation. And the Vessel Sanitation Program (VSP) at the CDC assists the cruise ship industry to prevent and control the introduction, transmission and spread of gastrointestinal illnesses on cruise ships.

The design and maintenance of the entire water distribution system (tanks, boilers, piping) shall be as optimal as possible. Dead ends shall be removed and long setting times must be followed by adequate flushing with hot water (or disinfectant). In particular care should be taken to avoid growth of *Legionella*. The WHO has issued an extensive document on *Legionella* and the prevention of legionellosis (WHO, 2007a). This WHO document has separate chapters on potable water and in-building distribution systems and on cooling towers and evaporative condensers.

Drinking water is also a potential vehicle for the deliberate use of microbial pathogens, microbe-derived products or chemicals that cause harm to humans, livestock or agricultural crops. Food companies shall conduct assessments of their vulnerabilities to terrorist attack or sabotage and set up preventive programs or systems to provide a safe and reliable supply of drinking water (for further information see Chapter 35).

RISK ASSESSMENT AND RISK MANAGEMENT

The most effective means of consistently ensuring the safety of a drinking-water supply is through the use of a comprehensive risk assessment and risk management approach that encompasses all steps in the water supply from catchment to consumer. The WHO has proposed such a water safety framework and the implementation of comprehensive water safety plans (WSPs) to consistently ensure drinking-water safety and thereby protect public health (WHO, 2011). Failure to ensure drinking-water safety may expose the community to the risk of outbreaks of intestinal and other infectious diseases. Outbreaks of waterborne disease are particularly to be avoided because of their capacity to result in the simultaneous infection of a large number of persons and potentially a high proportion of the community.

Water safety plans (WHO, 2009, 2011) are suggested to comprise of:

- A system assessment to determine whether the drinking-water supply (from source through treatment to the point of consumption) as a whole can deliver water of a quality that meets the health-based targets.
- Operational monitoring of the control measures in the drinking-water supply that are of particular importance in securing drinking-water safety.
- Management plans documenting the system assessment and monitoring plans and describing actions to be taken in normal operation and incident conditions, including upgrade and improvement, documentation and communication.

HACCP CASE STUDIES

Determination of Water Safety

As with any hazard, radiological, chemical and (micro)biological hazards in drinking water should be assessed using principles of HACCP (see Chapter 31).

The first step is to establish the intended use of the water. Questions that should be answered: does the water come in contact with the product and, if so, at what stages? Are consumers exposed to the water and, if so, in what form (drinking water, adherent water, ice, steam)? A simple classification for the "fit for purpose" is (adapted from ILSI, 2008):

	Chemically potable	Chemically non-potable
(Micro)biologically potable	Class 1	Class 3
(Micro)biologically non-potable	Class 2	Class 4

For each application the right category shall be chosen. For products with little or no further processing for safety, class 1 water shall be used as ingredient. If only class 2 water is available, an appropriate pretreatment shall be applied, or the processing itself contains appropriate steps to eliminate microbiological risks. Classes 3 and 4 will normally not be suitable for water as ingredient, but may be used as processing water that will not be in direct contact with the product itself.

Treatment of the water may change the class. Heat treatment may change class 2 water to class 1 water. Ultrafiltration and additional chemical treatment may even change class 4 water to class 1 water.

To establish whether the water is safe for the intended use, a decision tree was published by ILSI (adapted from ILSI, 2008 – see Figure 14.2).

Water Treatment Technologies for Safe Water Production

An increasing number of technologies are developed to process water for safety. Typical industrial wastewater treatment consists of a combination of physical, biological and chemical processes to remove solids and organic matter, and, if necessary, pathogens, metals and

1. Is the water potentially contaminated with either radiological, chemical or (micro)biological hazards at concentrations which are significant for human health? The fit for purpose classification.	→ NO (Class 1 water)	"SAFE" WATER
→ YES (Class 2, 3 or 4 water)		
2. Will the water be consumed without further treatment or come into contact with products that will be consumed without further treatment?	→ NO (Class 2, 3 or 4 water)	
→ YES (Class 2, 3 or 4 water)		
3. Is the water treated to eliminate potential hazards before consumption or contact with the product that will be consumed?	→ YES (Class 1 water)	
→ NO (Class 2, 3 or 4 water)		
4. Will subsequent treatment of the product for consumption, either in the factory or at home by consumers, eliminate the hazard?	→ YES (Class 1 water)	
→ NO (Class 2, 3 or 4 water)		
UNSAFE WATER		

Question 1 defines the fit for purpose class and refers to knowledge of the potential hazards and criteria set in water guidelines and (inter)national regulations. If no criteria are available a full risk analysis is necessary to establish potential hazards and judgment of chance and impact/severity.

Question 2 refers to the intended use of the water and whether a potential hazard may be in contact with the consumer either directly or indirectly. Therefore this question involves an evaluation of exposure and risk. Is exposure of the hazard to the product or consumer likely (the chance)? If so, how much and how long and what will be the potential consequence (severity)? Interestingly water not fit for use (Classes 2, 3 and 4) can be considered safe when not used for indirect or direct consumption.

Question 3 refers to existing steps in the process that will (un)intentionally act as mitigation step(s) to potential hazards and risks? Steps can involve, for example, heating, filtration, chemical treatment, UV treatment, ozone treatment.

Question 4 addresses the additional mitigation steps, either at the consumers' home or at the producers' factory. In the latter case this usually involves process steps that are not intended to reduce the risks but as side effect do so.

FIGURE 14.2 Water safety decision tree. *Adapted from IL51, 2006.*

nutrients from wastewater. Table 14.5 summarizes some water treatment alternatives for given challenges.

The goal in designing a processing system to obtain safe water is to develop an integrated cost-effective scheme that is capable of reliably meeting water quality and safety objectives. The degree of treatment required in individual water treatment facilities varies according to the specific (re)use application and associated water quality requirements

Filtration

Filtration involves porous material (filter) to separate (suspended) solids from the water. Most applied systems are granular filtration and require the use of filter cartridges (EHEDG, 2004). Granular filtration uses a filter bed consisting of one or more layers of sand and anthracite. Factors that influence effectiveness are the size, form and nature of the particles, the strength, the porosity, the filtration rate and the bed height. Filter cartridges are usually placed in a pressure vessel. Effectiveness is determined by the right pore size and fouling. Pressure drop over the filter indicates saturation with solids. In time, replacement of the

TABLE 14.5 Water Treatment Alternatives

Challenge	Treatment Option	Advantage	Concern
Microbiological hazards (bacteria, viruses, protozoa)	Chlorination	Easy to handle, effective to most bacteria	Most protozoa are resistant and some viruses are not eliminated. Chemical by-products. Elevated turbidity reduces effectiveness
	Ozone	Very effective against most bacteria and viruses. Viruses generally more resistant than bacteria, effective to *Cryptosporidium*	Complex technology, bromate formation, some viruses are not eliminated
	UV	Easy to handle, effective to *Cryptosporidium*	TSS, turbidity and color may render it inefficient
	Membranes (ultra-filtration, nano-filtration)	No by-products, no smell, no taste	Costs, fouling
	Heating (sterilization)	Very effective, no smell, no taste	Costs (energy)
Suspended solids	Granular media, filters	Low cost, readily available, simple and effective. Large volume, low pressure	Require regular maintenance
	Screen filters	Widely available in specialized materials	Relatively coarse separation. Not suited to heavy loads, clogging
	Tubular screen filters	Robust and offer repeated use	Selection of screen material must match process conditions
	Membrane (micro-filtration, ultra-filtration)	No by-products, no smell, no taste	Higher operating costs, fouling
Organic matter	Advanced biological treatment (e.g. bio-filtration).	Low cost	Only for biodegradable substances
	Adsorption (PAC, GAC)	Very effective for non-polar substances	Costly, residuals (spent carbon)
	AOP (advanced oxidation processes)	No residuals produced	Formation of unknown (biodegradable) compounds
Inorganic compounds: heavy metals	Flocculation/precipitation		Chemicals used increase salinity
Inorganic compounds: salinity	Ion-exchange	Effective	Cost, salt increase
	Reverse osmosis	Effective	Residuals to be disposed may need to be treated to reduce corrosivity

(Adopted from USI, 2008 and WHO, 2011).

TABLE 14.6 Types of Membrane Filtration (EHEDG 2004)

Type of Membrane Technology	Pressure Applied (bar)	Porosity (cut-off value)	Retention
Micro-filtration (MF)	1–2	20–1000 nm	Solid particles, bacteria, yeasts, protozoa, colloids
Ultra-filtration (UF)	1–5	20–200 nm	Above + polysaccharides, proteins
Nano-filtration (NF)	5	1–10 nm	Above + sugars, amino acids, hardness (calcium salts), multiple charged ions (e.g. sulfates, phosphates), viruses
Reversed osmosis	15–50	<2 nm	Above + salts

filters or back-washing (water flow in the opposite direction) is necessary. Drawbacks are long running times, insufficient frequency of back-washing or filter replacement and installation of non-compliant cartridges in pressure vessels. For filtration of small solids, soluble materials and microorganisms, membrane filtration is necessary.

Membrane Filtration

Membrane filtration is a pressure-driven technology. Depending on the pore sizes particles are retained (Table 14.6).

The choice of a filtration system is complex and requires specific knowledge of available materials (organic polymers, ceramic and stainless steel), membrane geometry (spiral, tubular, capillary, hollow fiber) and the application involved (temperature, pH, particles in the fluid, cleaning methods/chemicals). Like any filtration technology, membrane filtration is susceptible for fouling and systematic cleaning (or replacement) is required. Leakage of membranes due to chemical and mechanical damage induces risk of post-filtration contamination. Reversed osmosis water may have corrosive properties due to removal of minerals. Remineralization may be required in certain applications.

Chlorination

Chlorination is one of the most used disinfection systems for potable and utility water.

Sodium hypochlorite (N_aOCl) is the predominant chemical used for chlorination. The main reasons are availability, simplicity of the application, cost effectiveness and, if properly used, reliability. Chlorine is effective at inactivating bacteria and viruses, and under certain circumstances parasites like *Giardia*. However, chlorine has little impact on the parasite *Cryptosporidium* at typical water treatment concentrations (up to 5 mg/l). Chlorine's general disinfection capability with respect to microorganisms can be illustrated in the following way from most effective to least effective: bacteria > viruses > *Giardia* cysts > *Cryptosporidium* oocysts (USPHC, 2006).

Even higher numbers of bacteria are generally killed in minutes. This is particularly true for Gram-negative bacteria like *E. coli* and *Salmonella*. Gram-positive bacteria, especially spore-forming species like *Bacillus* and *Clostridium*, tend to be less sensitive but can still be eliminated at appropriate concentrations of chlorine and contact times.

TABLE 14.7 The Various Forms of Chlorine (CAWST, 2012)

Product	Strength	Remarks
High test hypochlorite (HTH) (calcium hypochlorite)	65% – 70%	Usually in granular form. Stable (approximately 2% active chlorine loss per year)
Chlorinated lime, aka bleaching powder	30%	Usually in powder form. Not stable.
Household bleach (sodium hypochlorite)	2.5–10%	Liquid form. Not stable; only use if manufactured recently (<3 months) and stored away from heat and light
Sodium dichloro-isocyanurate (NaDCC), used in products such as "Aquatabs"	50–60% as granules. 5 mg to >5 g active chlorine per tablet	Usually in tablet form, also available in granular form. Tablets pre-dosed for water treatment. Very stable (shelf-life approximately 5 years)

Chlorine has been shown to be a highly effective viricide. Most viruses are killed very effectively after exposure to chlorine within minutes. The most resistant virus was a poliovirus, requiring more than 60 minutes for 4-log removal.

Chlorine has been shown to have limited success inactivating protozoa. An important indicator, *Giardia lamblia*, requires prolonged contact times (30–60 minutes) at chlorine residual concentration (2–3 mg/l) to achieve 99.9% (3-log) inactivation.

The parasite *Cryptosporidium*, however, is very resistant and requires high chlorine concentrations and extreme long exposure times to eliminate cells and oocysts. One *Cryptosporidium* study reported that 80 mg/l of free chlorine required 90 minutes to achieve only a 1-log (90%) inactivation of oocysts! These exposure times and concentrations are generally not feasible and therefore chlorination is not an option to control protozoa.

Chlorine kills bacteria and viruses by interfering with chemical bonds and in particular inactivation of enzymes.

Chlorination for the control of microbiological contamination of drinking and processing water involves the following parameters (WHO, 2011):

- Residual concentration of free chlorine minimal 0.5 mg/l, typical 2–3 mg/l and maximum 5 mg/l.
- Contact time at least 30 min at pH <8.0 (optimum pH 5.5–pH 7.5).
- The contact time is valid at 18–20°C and above. For every 10°C drop in temperature the efficiency of disinfection reduces by 50–60% (at close to 0°C disinfection efficiency is very poor).

Chlorine is available in several forms (see Table 14.7).
Despite the benefits, some disadvantages must be addressed (EHEDG, 2005):

- Reduced effectiveness at pH >8.0 and lower temperatures.
- Reacts with nitrogenous compounds forming chloramines (unpleasant odors and health concerns). Also reactive with several organic materials forming compounds with possible health impacts.

- Easily quenched by organic matter and turbidity in the water.
- Highly corrosive.

An alternative to chlorine is the use of chlorine dioxide, a highly reactive compound that cannot be stored in its active form. Therefore it is generated on site, close to the point of use. Compared to chlorine it mitigates most of the disadvantages; however, the costs and the necessity to generate it at the point of use makes it a less interesting option for smaller companies.

Filtration and Chlorination

While chlorination alone is not (always) effective against protozoa, a dual approach may be applied. Several (household) water treatment systems incorporate both a physical filtration step for particle removal and a chlorination step for disinfection. Alternatively particles, including protozoa, may be removed by flocculation prior to chlorination, using coagulants. Aluminum coagulants include aluminum sulfate, aluminum chloride and sodium aluminate. Iron coagulants include ferric sulfate, ferrous sulfate, ferric chloride and ferric chloride sulfate. Other chemicals used as coagulants include hydrated lime and magnesium carbonate. Overall *Giardia* and *Cryptosporidium* removals after coagulation and filtration may be approximately 5-log (for further reading: www.iwawaterwiki.org, assessed January 2013).

Water Reuse in Food Processing

Fresh water resources are globally subjected to increasing pressure in the form of consumptive water use and pollution. On national and international levels awareness is growing that water resources should be protected both qualitatively and quantitatively. The food industry is in general regarded as a major water consumer resulting in relatively high water footprints. Apart from increased efficiency, reuse of water is a way to reduce fresh water exploitation. When applying reused water it is necessary to identify whether the reused water will be in contact with the product(s) or not. Typical applications of reused water are indirect cooling or the generation of steam that will not be in contact with the product. Direct contact applications may include washing and/or transport of raw products (like fruit or vegetables that will be processed) or cleaning of equipment.

Any food industry considering the application of reused water should ask the following questions (ILSI, 2008)[1] :

- What is the proposed reuse? Will the water come into contact with food or will it be used as a noncontact processing aid (e.g. coolant)?
- What are the regulatory, consumer safety and technical requirements for the water in the proposed reuse application?
- What is the starting quality of the intended reuse criteria and what treatments or controls can be applied so that it meets the criteria defined in the previous question?

[1]ILSI is working on a Water Recovery Guideline which is expected to be released in 2013 (www.ilsi.org).

- What monitoring procedures need to be put in place to adequately monitor the performance of the treatments and/or controls?
- What procedures need to be put in place to overcome existing technical difficulties, such as chemical or biological fouling (e.g. biofilms)?
- What measures need to be taken if a deviation from the required quality is detected?
- What changes to availability or cost are likely in the future and may alter the current situation (e.g. proposals in Brazil to charge industry for water abstracted from either groundwater or rivers)?
- What changes to water supply quality are likely in the future (e.g. salination of groundwater)?
- What treatments will be required to ensure that the water meets the necessary standards?
- What modifications could be incorporated into either existing or new equipment (e.g. appropriate filters on bottle washers) or existing or new process lines to maximize the opportunities for water reuse?
- What regulatory conditions encourage (or discourage) optimized water use?

Example: Recycled Hot Water as a Decontamination Technique for Meat Carcasses

The European Food Safety Authority has delivered a scientific opinion on safety and efficacy of using recycled hot water as a decontamination technique for meat carcasses (EFSA, 2012). At the moment (2013) only the use of potable water is allowed in the EU for carcass decontamination purposes. However, recycled water (i.e. reusing water after reheating) is used for carcass decontamination in some countries (e.g. Canada, Denmark). Environmental care and energy-preserving motives are driving forces for recycling. The EFSA study has considered potential microbiological and abiotic risks for carcasses associated with recycled hot water decontamination and related control options.

From the study it is concluded that the decontamination efficacy of recycled hot water does not differ significantly from that of hot potable water.

By ensuring proper heating regimes of recycled water, vegetative bacterial cells and protozoan parasites are controlled. Microbial toxins are not significantly inactivated in the recycling process, but production of these toxins during the first round of carcass decontamination and prior to heating is not relevant.

According to the EFSA study, only microbiological risks associated with heat-resistant bacterial spores (*C. botulinum*, *C. perfringens*, *C. difficile* and *B. cereus*) are relevant for recycled hot water. These risks can be controlled by ensuring that recycled hot water is verifiably subjected to appropriate reheating and frequency of renewal regimes. These regimes shall ensure that the microbiological risk in recycled water is not higher than in hot potable water. For abiotic risks, the only concern with recycled hot water derives from the potential presence and accumulation of residues of veterinary drugs and other chemical contaminants in the water for decontamination of poultry carcasses.

As with any process recycling of water for decontamination of carcasses shall be subjected to HACCP. Important criteria for efficacy and control of possible risks include minimal heating temperature, time regime and frequency of renewal of recycled water. These criteria shall ensure compliance with existing microbiological criteria for potable water and prevent accumulation of heat-resistant spores. Recycling procedures shall be

microbiologically validated, continuously monitored by instrumental measurements, verified periodically by microbiological testing of water and documented. Compliance with the chemical criteria for potable water needs to be verified for recycled hot water by periodic chemical analysis of the water and documented. The absence of residues of veterinary medicinal products in recycled hot water used for decontamination of poultry carcasses has to be verified by periodical testing and be documented.

Finally, the application of recycled hot water applied on carcasses (temperatures, application techniques and related parameters) shall be subject to risk analysis in the same way as with hot potable water decontamination.

Bottled Water Safety

Aside from adhering to the various industry regulations, the best way to minimize the risk of contaminated bottled water is to have a good HACCP system in place. The seven principles of a HACCP system (see Chapter 31) provide the basis for safe production and will help to satisfy business owners and their customers that products are safe in an efficient, reliable and cost-effective way. It is achieved by focusing on hazard prevention throughout the product life cycle rather than relying on end-product testing.

An example from a multinational company that produces bottled water shows a typical production process and accompanying quality assurance and control measures (Figure 14.3).

1. **Source receiving and inspection**
   Water is carefully collected from the source, which may either be a well or municipal supply. Common method of receiving water is through stainless steel pipeline. Water from the source shall be tested prior to internal processing on microbiological and chemical aspects.
2. **Activated carbon filtration (municipal water only)**
   Activated carbon may be necessary to remove substances like chlorine and trihalomethanes. This filtration process should be monitored and tested regularly.
3. **Pretreatment**
   Water softener may be used to reduce water hardness.
4. **Demineralization process**
   Demineralization is the use of cation – and anion resin beds to remove minerals. Technologies include:
   a. Reverse osmosis: Use of high-pressure pump and special membranes, called semi-permeable membranes, to reverse the natural phenomenon of osmosis.
   b. Distillation: A process that boils the water and collects the condensate for bottling.
5. **Water storage and monitoring**
   Water is received into storage tanks. Storage environment and water carefully monitored daily.
6. **Micro-filtration**
   Using micro-filters, usually pharmaceutical grade, particles as small as 0.2 micron in diameter are removed. The pore size guarantees removal of microbiological contaminants.

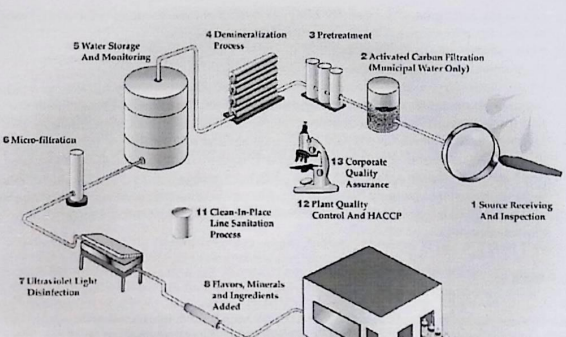

FIGURE 14.3 Bottled water production (http://www.nestle-waters.com/brands/water-quality/Pages/purified-water.aspx; assessed August 2012).

7. **Ultraviolet light disinfection**
   Application of ultraviolet light provides added assurance of product disinfection and safety. As with ultra-filtration this process should be continually monitored by instrumentation.
8. **Flavors, minerals and ingredients added**
9. **Bottling control**
   Bottling should be conducted under highly controlled conditions using state-of-the-art equipment. Each bottle shall be marked with a code that identifies the plant (location), bottling line and time produced. Filling room and environment are subject to high sanitary conditions.
10. **Packaging control**
    Packaging materials not meeting (internal) standards should be rejected before using them. Bottles, caps and labels should be controlled and monitored by lot.
11. **Clean-in-place line sanitation process**
    Line sanitation practices include preferably internal pipe and equipment cleaning methods (cleaning in place – CIP). Such processes should circulate detergent and

sanitizing solutions at the precise temperatures and time to affect total control and maximum effectiveness of the line sanitation process.

12. **Plant quality control and HACCP**
13. **Corporate quality assurance**
    Water, packaging materials and plant processes shall be carefully monitored to ensure they meet company specifications and (inter)national standards. Quality control and quality assurance departments, preferably independent from production, are responsible for the standards and specifications and monitoring of the plant quality programs. A comprehensive set of standards for industries active in bottled water production to ensure safety and quality has been published by the US International Bottled Water Association (IBWA, 2012). This code of practice for bottled water offers monitoring matrices for chemical, microbiological, radiological and organoleptic parameters.

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Further Reading

An extensive amount of information is available on the safety of water. Many documents are accessible (or can be downloaded) from websites. For further reading we recommend the following websites and documents (without the intention to be complete, many other sources may be valuable):

The European Hygienic Engineering & Design Group (EHEDG) issues guidelines which are regularly updated and complemented by new documents in various language versions (www.ehedg.org).

The International Life Sciences Institute (ILSI) disseminates science by publishing articles on original research, literature reviews and gap analyses, and meeting proceedings in peer-reviewed journals. ILSI Europe also publishes books, monographs, white papers and other reports through ILSI Press (www.ilsi.org).

The World Health Organization and Unicef have published many relevant documents on water safety. Most of them are freely available at www.who.int. In particular we recommend:

WHO (2011) Guidelines for Drinking-Water Quality. World Health Organisation, 4e edition, Geneva.

WHO (2007) Safe preparation, storage and handling of powdered infant formula; Guidelines.

WHO and Unicef (2012) A toolkit for monitoring and evaluating household water treatment and safe storage programmes. ISBN 978 92 4 150462 1.

The International Bottled Water Association produced a Bottled Water Code of Practice in 2012.

The European Food Safety Authority (EFSA) regularly publishes documents (opinions) on food and water safety. These documents can be retrieved from http://www.efsa.europa.eu. European legislation is available at http://europa.eu/eu-law/index_en.htm.

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CHAPTER

15

Pet Food

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OUTLINE

INTRODUCTION

Dog and cat pet ownership is popular throughout the world and pets are increasingly treated as members of the family. The pet food industry started in England in 1860, when the first commercial dog biscuits were marketed. Today sales of pet food in the USA alone exceed 18 billon US dollars a year (APPA, 2012). There are three main types of commercial pet food products: dry and semi-moist shelf-stable extruded food; thermally processed low acid canned products; and a variety of product forms sold as treats. With the exception of some treats, most products are formulated to be nutritionally complete and balanced. Thus,

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the modern pet food industry provides an essential service to pet owners by making nutri tious and palatable pet food convenient to acquire and feed.

The pet food industry utilizes the same ingredient streams as those of the human foo supply making use of many of the by-products and co-products. Therefore, the food safet hazards potentially present in pet food ingredients are the same as the ones facing the foo industry in general. There is, however, a difference in the severity of health effects of thes hazards to cats, dogs and humans. Pets tend to be very resistant to the clinical effects o infection by human food pathogens. On the other hand, they may be very sensitive to cer tain natural toxins or food components (e.g. alkaloids, caffeine, etc.) as well as veterinar drugs and feed additives.

The most significant historical pet food safety incidents in terms of frequency of occur rence and severity are related to aflatoxins, veterinary drug contamination, *Salmonella* recon tamination and, more recently, adulterated ingredients. Together, these hazards account fo the vast majority of safety incidents where pets were severely affected. With the exception of the food pathogen *Salmonella*, most other food safety hazards are ingredients or formu lations based and have no effective control measures in the manufacturing process itsel (Table 15.1). Potential HACCP control strategies to address these food safety threats will be discussed in this chapter.

BIOLOGICAL HAZARDS

Salmonella Contamination of Dry Pet Foods and Treats

Salmonella is a Gram-negative, non-spore-forming, rod-shaped bacterium belonging to the Family Enterobacteriaceae. This genus includes about 2400 different serovars. Non typhoid strains of salmonellae are a common cause of gastroenteritis and septicemia in humans and pets. Domestic and wild animals are often intestinal carriers of this pathogen. *Salmonella* is widespread in nature and has been found to survive for weeks in water and for several years in soil. In food ingredients, *Salmonella* can contaminate eggs, raw meats, poultry, fish and their by-products (Wareing and Fernandes, 2007). *Salmonella* is one of the leading causes of human gastroenteritis worldwide. In the USA there are an estimated 1.4 million cases a year and some 400 deaths (Voetsch et al., 2004). Salmonellosis remains the second most often reported zoonotic disease of humans in the European Union with 99,020 cases reported in 2010 (EFSA, 2012). Vulnerable populations include people with compro mised immune systems, infants and the elderly. The enteric infection has an incubation time of 8–72 hours with symptoms that include nausea, vomiting, abdominal cramps, diarrhea fever and headache. The symptoms can last from 2 to 5 days (Wareing and Fernandes, 2007).

Salmonella-contaminated feed may cause salmonellosis in animals. Generally, young animals are the most susceptible to an enteric-type infection but in more severe cases the infection may become systemic. In adult animals the infection is more likely to be asympto matic. Prevalence of *Salmonella* carriage rates have been reported as high as 36% in healthy dogs, and 18% in healthy cats (Leonard et al., 2010; Sanchez et al., 2002). Dogs infected with *Salmonella* often carry multiple strains at a time. Most infections are asymptomatic or mild and are commonly not identified. Prolonged and sporadic fecal shedding of *Salmonella* i

TABLE 15.1 Most Common Hazards Associated with Pet Food Safety Incidents and their Control

Hazard	Type	Root Cause	Control
Salmonella	Biological	Post-CCP cross-contamination from contaminated factory surface, environment or ingredient. Potential sources of contamination include: birds (feces, feathers) entering via air currents or water leaks. Presence of raw materials past CCP due to poor dust tightness, zoning or traffic patterns. Pests	Good manufacturing practices (GMP): e.g. ingredient quality measures, hygiene practices, hygienic design and process validation and verification procedures (GMA, 2009)
Ionophore toxicity	Chemical	Cross-contamination of feed ingredient with antibiotics via shared production lines with medicated feed or labeling errors of medicated feeds or vitamin premixes	Procurement of ingredients from suppliers that do not manufacture medicated products on the same production line
Adulteration (e.g. melamine)	Chemical	Fraud	"Trust but verify" ingredient supplier quality assurance and traceability programs
Nutrient toxicity or deficiency	Chemical	Misformulation or mixing error at batching	Careful accounting of the ingredient usage rate during batching. Vendor assurance measures, including validated mixing processes. Premix monitoring
Mycotoxin toxicity (e.g. aflatoxins and DON)	Chemical	Contaminated cereals (contamination may occur in the field and/or storage at supplier)	A cereal sampling and testing operational prerequisite program is required. Depending on prevalence of aflatoxin and DON, potentially all cereal deliveries to a factory must be sampled and tested before use. Good silo storage practices are required if grain is to be stored at the factory for any length of time
Metal and other hard bodies	Physical	Metal contamination from ingredients or equipment	GMP-based foreign material control programs including inspection, line magnets and metal detection of packaged product (verification)

a well-documented phenomenon (Morse et al., 1976). When symptomatic infections occur, clinical signs in young animals can include fever, anorexia, vomiting, intermittent diarrhea and bloody stools (Carter and Quinn, 2000). Infected dogs in the household pose a documented elevated risk of infection to their owners (Morse et al., 1976). Salmonellosis in cats is relatively rare, with subclinical infections and carriage rates among healthy cats reported to be very low. Nevertheless, cases of symptomatic infection, chronic carriage and transmission to humans have been documented (Van Immerseel et al., 2004).

TABLE 15.2 Recent North American Human Outbreaks of Salmonellosis Linked to Pet Food (FDA, 2012)

Country	Pathogen	Product	Date
Canada	*Salmonella* Infantis	Pig-ear dog treats	1999
USA	*Salmonella* Newport	Beefsteak-patty dog treats	2002
Canada/USA	*Salmonella* Thompson	Pet treats	2005
USA	*Salmonella* Schwarzengrund	Dry pet food	2006–2007

Pet food products contaminated with *Salmonella* pose a risk of infection to pet owners (Morse et al., 1976). Infection can occur via contaminated fomites or from ingestion of contaminated pet food (e.g. by children) (Behravesh et al., 2010; Morse et al., 1976). Numerous incidents in the USA have occurred where pet foods were found to be contaminated with *Salmonella* resulting in at least 13 recalls since 2006 (FDA, 2010a). Several human *Salmonella* infections and outbreaks have been linked to commercial pet food products (Table 15.2). One such outbreak of salmonellosis in the USA during 2007 was thoroughly investigated by the Centers for Disease Control and Prevention (CDC) and illustrates clearly the zoonotic potential of contaminated pet foods (CDC, 2008). Young children were found to be at a greater risk of infection than other family members. The specific family practices involved in the transmission of *Salmonella* to consumers included feeding the pet in the kitchen (Behravesh et al., 2010).

Dry pet foods are considered high fat, low moisture and low water activity (a_w) products. When formulated without humectants or preservatives, these products have an a_w of 0.65 or lower, corresponding to a moisture content of 12% or less. These are typically coated with fat (tallow, poultry fat) for enhanced palatability (Crane et al., 2000). At these low a_w levels, dry pet foods are shelf-stable because bacteria, molds and mites are unable to grow and spoil the food (FDA, 2012). Despite the inability of *Salmonella* to typically grow on low moisture foods, some cells have been shown to survive on pet foods and in pet food manufacturing environments for an extended period of time (GMA, 2009). The ability of some cells to survive on manufacturing surfaces can lead to the persistent contamination of processing areas, including air handling systems, floors and production equipment. The capacity to survive in a desiccated state is further enhanced by the presence of fat on product contact surfaces. Environmental moisture originating from cleaning and other sources can allow the multiplication of *Salmonella* in the factory (GMA, 2010a). Some factors that contribute to the possibility of cross-contamination include the existence of environmental conditions within the factory that generate microenvironments where *Salmonella* can grow in the proximity of the product stream. These include: condensation of moisture on production surfaces, poor hygienic practices (e.g. wet cleaning), poor equipment design, inadequate maintenance of equipment and inadequate zoning (e.g. incomplete segregation of pre- and post-extrusion environments and materials) (GMA, 2009). Important contributing factors for ineffective zoning include complex traffic patterns, poor dust control, uncontrolled ingress of external air and water, and the presence of pests and wild birds in and around the factory (GMA, 2010a). Contaminated ingredients used as post-extrusion flavor coatings can also be a source of *Salmonella* contamination.

Many typical pet food ingredients are potentially contaminated with *Salmonella*; these include meat and poultry by-product meals, raw meats and even cereal grains. HACCP studies of typical pet food manufacturing processes identify extrusion cooking as the only effective critical control point (CCP) for the elimination of *Salmonella*. Given the temperature profiles of subsequent unit operations, it is unlikely that any of the post-extrusion processing unit operations (e.g. kibble drying, flavor coating, cooling, intermediate storage and packaging) are consistently effective in reducing or eliminating *Salmonella*. This indicates that the presence of *Salmonella* on pet foods is the result of a cross-contamination event caused by direct inoculation of the kibble by a contaminated material (Behravesh et al., 2010). To minimize the potential for post-extrusion product cross-contamination, the manufacturer must implement a comprehensive food safety system encompassing good manufacturing practices (GMPs) and HACCP principles. The Grocery Manufacturers Association (GMA) describes in detail seven GMPs and HACCP elements that must be emphasized for the control of *Salmonella* in low moisture foods when additional processing occurs after a heat inactivation control process, as is the case in pet food factories. The seven elements include ingredient quality measures, hygiene practices, hygienic design and process validation and verification procedures (GMA, 2009).

Other Potential Significant Biological Hazards

There have been near incidents and some speculation about the possible contamination risk of commercial pet foods with pathogens other than *Salmonella*. In September of 2007, the FDA issued a recall notice for a frozen chicken blend raw food product contaminated with *Listeria*. In 2001 and 2006 ProMED-mail posts (http://www.promedmail.org: accessed 25 April 2012) discussed the possible transmission of *Escherichia coli* O157 from a dog to a child in the UK and the carriage of this organism by healthy dogs. No clear link was made to commercial pet food. The recent trend towards innovation in the industry for less processed and "fresher" product concepts has led to the introduction of raw, chilled and frozen pet foods. Given the high incidence of microbial pathogens in raw meats, it seems unlikely that products with minimal or no heat treatments can succeed without significant attention to pathogen control strategies in their manufacture. Invariably the search for shelf-stable "fresh" product forms will lead the industry toward emerging processing technologies such as ultra-high hydrostatic pressure (UHP or HHP) pasteurization, among others.

During the mostly European epidemic of bovine spongiform encephalitis (BSE), some 100 cases of feline spongiform encephalitis (FSE) were reported from 1986 to 2001 among domestic cats and exotic zoo felines, mainly in Europe. Commercial cat food was clearly implicated in some instances and the sporadic cases in zoos were probably caused by infected bovine offal. The disease is characterized by progressive neurological signs, behavioral changes and death. The properties of FSE are identical to BSE and the variant Creutzfeldt–Jakob agent. Fortunately the measures taken across Europe to prevent the inclusion of BSE-suspect material in animal feeds, feed materials and pet foods were very successful in preventing new cases. No additional cases of FSE have been reported in cats since 2001 (http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/bse/othertses, accessed on 25.02.2013). Even though the outbreak is now controlled and no new cases of TSE have appeared in domestic cats, it is important that control measures such as the strict

observance of the legally required controls on the disposal and feeding of specified risk materials be observed to prevent its re-emergence.

MYCOTOXICOSIS

Mycotoxins are toxic secondary metabolites produced by various molds (Richard, 2007). Mycotoxins are considered an important group of unavoidable chemical food safety hazards prevalent in many pet food ingredients. Mycotoxins commonly reported in pet food products include aflatoxins, ochratoxin A and the *Fusarium* mycotoxins such as fumonisins, deoxynivalenol (DON), T-2/HT-2 and zearalenone. Of these, only aflatoxins and DON have a significant history of pet food-related incidents. Fumonisins and zearelanone are frequently reported to contaminate pet foods in various concentrations but have not been directly implicated in commercial pet food safety incidents (Leung et al., 2006; Boermans and Leung, 2007). The toxicity of ochratoxin A (Szczech et al., 1973; Kitchen et al., 1977) and zearelanone (Gajecka et al., 2004) have been described for dogs. There is very little toxicological information with respect to cats.

Most mycotoxins are not reduced to an acceptable level or eliminated by typical pet food manufacturing processes. Thus, control of this hazard can only be realized through procurement of commodities with consistently low contamination rates. The sometimes poor track record of the pet food industry in managing this hazard is partly explained by the difficulty of routine and effective upstream supplier quality assurance strategies for agricultural commodities like cereal grains. For example, maize is generally harvested by a myriad of small to large producers and storage occurs in regional silos where the grain is comingled with that from an entire region. This situation combined with the seasonal variation and geographic incidence of various mycotoxins demands careful monitoring of each harvest and frequent verification of these levels in bulk deliveries to the factory. The factory monitoring programs must be based on statistically valid sampling plans and procedures (FAO, 2001). Care must be taken with local bulk storage of grains at the factory as unfavorable storage conditions may lead to molding and mycotoxin development in storage (Codex, 2003). Fortunately, rapid factory-friendly analytical methods, mainly ELISA-based assays, are available commercially to test most ingredients for many mycotoxins (GIPSA, 2013).

The sensitivity of cats and dogs to some prevalent mycotoxins, though not completely understood in all cases, is clearly a significant food safety hazard. In the following section, the specific cases of aflatoxins and DON contamination of pet food are discussed.

Aflatoxins

Aflatoxins are mycotoxins produced by the molds *Aspergillus flavus* and *A. parasiticus* as they grow on foodstuffs either under field conditions or during storage. The major types of aflatoxins are designated B1, B2, G1 and G2 with their main metabolites designated M1 and M2 (CAST, 2003). Aflatoxins are considered unavoidable natural contaminants of various pet food ingredients, especially maize (Table 15.3). The potential for significant aflatoxin contamination of susceptible ingredients varies due to seasonal and regional climatic conditions and local agricultural practices.

TABLE 15.3 Examples of Ingredients Known to be Potentially Contaminated with Aflatoxins

Cereals	Oilseeds/Nuts	Spices/Tubers
Maize (corn)	Peanut	Chili peppers
Corn gluten meal	Soybean	Black pepper
Corn gluten feed	Sunflower	Coriander
Dried distiller's grains (DDGS)	Cotton seed	Turmeric
Sorghum	Almond	Ginger
Millet	Pistachio	Tapioca (yuca, manioc)
Rice	Walnut	
Wheat	Brazil nuts	

Aflatoxins are rapidly and extensively absorbed from the gut and metabolized in the liver to toxic epoxides which bind to and damage essential cell components such as DNA, RNA and protein enzymes. In all animal species studied, the primary clinical effect of aflatoxin ingestion is related to liver damage. Different animal species will have different sensitivities to aflatoxin and young animals are more susceptible than adults (Bohm 2005). Dogs given a single dose of 100μg/kgbw of aflatoxin B1 have been shown to excrete both the aflatoxin metabolites M1 and Q1 in their urine with 90% of a single dose excreted in 12 hours (Bingham et al., 2004).

Tragic incidents involving aflatoxin-contaminated commercial pet food have been reported in several areas of the world. Table 15.4 lists results of either market surveillance or reports following outbreaks of aflatoxicosis. The US dog food recall that occurred in 2005–2006 had reports of aflatoxin concentrations of 223–598 ppb (Newman et al., 2007; Stenske 2006). Affected animals showed the following progression of clinical signs: feed refusal, lethargy, vomiting, jaundice, diarrhea, peripheral edema with final onset of bleeding disorders and seizures leading to death (Dereszynski 2008). Experimental work has shown that aflatoxins given to dogs at 500μg/kgbw can kill the dogs in as little as two doses and dogs fed for 10 weeks at 20μg/kgbw/day (approx. 360 ppb in the diet) developed classic liver lesions (Armbrecht et al., 1971). Dogs fed 5μg/kgbw/day for 10 weeks (approx. 90 ppb in the diet) did not have clinical changes but calculated projections indicated this level could result in serious problems, including sudden death if fed chronically. Dogs fed at 1μg/kgbw/day and below for 10 weeks (approx. 20 ppb in the diet and below) showed no adverse effects and were expected to have no chronic adverse effects.

Aflatoxins are stable under conventional pet food manufacturing conditions including extrusion cooking, baking and retorting and are therefore not reduced during manufacturing of pet foods (IARC, 2002). Because there are no critical control points (CCP) for this hazard in the manufacturing process, it is imperative that ingredients used to manufacture pet foods have low levels of contamination within regulatory constraints. Regulatory limits for pet food are set at or below 20 ppb in most countries (Leung et al., 2006). The burden of sourcing low aflatoxin-containing ingredients is especially significant for maize and

TABLE 15.4 Examples of Reports of Aflatoxin-contaminated Commercial Dry Dog Food Products and Home Rations

Location	Year	AFLA (ppb)	Reference
United States	1986	250–450	Liggett et al. (1986)
South Africa	1987	100–300	Bastianello et al. (1987)
United Kingdom	1997	2.1 and 370	Scudamore et al. (1997)
United States	2001	150–300	Garland and Reagor (2001)
Mexico	2001	mean 5 and 8	Sharma and Marquez (2001)
Turkey	2002	1.75–20	Gunsen and Yaroglu (2002)
Portugal	2003	not detected	Martins et al. (2003)
Brazil	2004	mean 19 and 16	Maia and Pereira Bastos de Siqueira (2002)
United States	2006	579	Stenske et al. (2006)
United States	2007	223–579	Newman et al. (2007)
United States	2008	40–800	Dereszynski et al. (2008)
Argentina	2009	2–167	Juri et al. (2009)

its by-products (e.g. corn gluten feed and meal) given its high usage rate in the pet food industry.

Deoxynivalenol

Deoxynivalenol (DON), also known as vomitoxin, is a common and unavoidable mycotoxin contaminant of cereals in temperate climates, especially maize and wheat. DON contamination has been reported in commercial pet food (Table 15.5). In 1995 a product recall occurred in the USA after a commercial dog food containing wheat had been associated with feed refusal and vomiting, with other more severe clinical signs reported but not confirmed (Hughes et al., 1999).

DON is most commonly produced by molds in the genus *Fusarium*. DON-producing *Fusarium* strains are ubiquitous in temperate regions. Plant infections with *Fusarium* molds and DON production occurs mainly in the field during the flowering period which are favored by humid and cool weather. DON contamination affects predominantly maize, wheat and barley, and less often oats, rice, rye, sorghum and triticale. DON can be found in combination with other fusarial mycotoxins such as zearalenone, as well as the trichothecene mycotoxins nivalenol, T-2 and HT-2 toxins. Closely related metabolites of DON include 15-acetyl DON and 3-acetyl DON. Carry-over of DON to food products from animal origin does not appear to be of concern due to the rapid elimination of the compound from the body (meat) and the very low transfer rates to milk and eggs (EFSA, 2007).

TABLE 15.5 Case Reports of DON Levels in Commercial Pet Foods

Country	DON Concentration	Reference
US	7–73 ppm	Hughes et al. (1999)
Germany	22–1837 ppb	Songsermsakul et al. (2007)
Portugal	100–130 ppb	Martins et al. (2003)
Austria	0–1386 ppb	Behm and Razzazi-Fazeli (2005)

TABLE 15.6 Observed Effects of Dietary DON in Cats and Dogs (Data from Hughes et al., 1999)

	Feed Refusal	Vomiting	
	NOAEL[a] ppm diet	LOAEL[b] ppm diet	NOAEL ppm diet
Dog	4.5	8	6
Cat	7.7	10	8

[a]NOAEL – *no observed adverse effect level.*
[b]LOAEL – *lowest observed adverse effect level.*

Cats and dogs are sensitive to the toxic effects of DON, but the variability between individuals is high with low levels associated with feed refusal, vomiting and gastrointestinal upset. DON is rapidly and extensively absorbed from the gut. It is rapidly metabolized and excreted and does not accumulate in the body. It has been shown to inhibit the synthesis of DNA, RNA and protein. Acute DON toxicity appears as vomiting (hence the name vomitoxin) and diarrhea within 1 hour of ingestion. At levels below those leading to acute effects, anorexia (feed refusal) and the associated subsequent altered nutritional efficiency and reduced weight gain have been observed (Table 15.6). These effects are rapidly reversible with removal of DON from the diet. DON is also reported to be immunotoxic *in vitro*. Dogs previously exposed to DON-contaminated food preferentially select non-contaminated food if given the choice (Hughes et al., 1999).

Levels of DON contamination of cereals can exhibit wide annual variation due to regional or local growing conditions. DON is not reduced by milling, and is concentrated by dry milling in the grain by-products, such as wheat midds, fiber or hulls and dry distiller's grains (DDGs). DON is stable under conventional pet food processing conditions and will not be reduced by extrusion cooking, baking or retorting (EFSA, 2007). As with aflatoxin and all other mycotoxins, control of this hazard requires the procurement of consistently low contaminated grain. Routine factory verification of DON levels in the "at-risk" materials remains the core preventive strategy.

TABLE 15.7 Veterinary Drug Residues in Pet Food Ingredients

Ingredients	Origin	Veterinary Drug	Reference
Molasses yeast from ethanol fermentations Dry distiller's grains (DDGS)	Ethanol fermentations	Penicillin Virginamycin Erythromycin Tylosin Ionophores Others?	RG-6 Regulatory Guidance: Ethanol Distiller's Grains for Livestock Feed. Canadian Feed Inspection Agency, 2013
Bovine, swine and poultry: Meat Lung Liver Kidney Viscera	Illegal use in farm animals	Clenbuterol Ractopamine	Chan (1998) Salleras et al. (1995) Sporano et al. (1998)
Fish Shrimp	Aquaculture	Chloramphenicol Malachite green Furazolidone	Ellis and Turner (2007)

TOXICITIES CAUSED BY MEDICATED FEED CARRY-OVER INTO PET FOOD RAW MATERIALS

Veterinary drugs added to feeds can be toxic to dogs and cats. Pets may be exposed to a variety of pharmacologically active compounds through ingredient residues resulting from farm or industrial practices, with some of these being illegal (Table 15.7). Nevertheless, the most devastating incidents of toxicities have been associated with cross-contamination of feed ingredients with medicated feeds during feed or premix processing, handling or delivery. The GMP requirements for medicated feed producers (European Union, EC No. 183/2005 and USA, 21 CFR 225.10) cannot completely eliminate the possibility of cross-contamination of medicated residues in subsequent batches. Significant carry-over can occur even after multiple sweeper batches of unmedicated product have passed through the system. The factors that can influence the degree of carry-over include: strength of feed/drug/carrier adhesion to line surfaces, particle size and density and electrostatic properties of the materials (EFSA, 2008). Polyether ionophore antibiotic cross-contamination of pet foods is an example of the potential magnitude of this veterinary drug hazard. In 1996 a very tragic incident involving paralysis and death of several hundred cats occurred in the Netherlands (Van der Linde-Sipman et al., 1999).

Ionophore antibiotics include salinomycin, lasalocid, monensin sodium and narasin among others. These commercially available feed additives are administered to poultry for control of coccidiosis and to beef cattle and swine for improved feed efficiency and meat production. Ionophores form lipid-soluble complexes with monovalent cations (Na^+, K^+)

and facilitate specific ionic transport across biological membranes. These result in changes in transmembranous ion gradients and electrical potentials. Salinomycin also increases the release of catecholamines (adrenalin, noradrenalin). The primary target organs of ionophore toxicity are cardiac and skeletal muscles and peripheral nerves. Dietary no observed effect levels (NOELs) of 1–2.5 mg/kgbw/d of salinomycin, lasalocid, narasin and monensin have been reported for dogs. However, toxicity has been observed in dogs after ingestion of canned pet food containing 10–15 mg/kg (ppm) of lasalocid. Assuming a 10-kg dog and a food energy content of 1.2 kcal/g, this would correspond to 0.6–0.9 mg/kgbw/d of lasalocid (i.e. slightly below the reported NOEL) (Oehme and Pickrell, 1999; Van der Linde-Sipman et al., 1999). In cats toxicity has been observed after ingestion of dry pet food containing 16–21 ppm of salinomycin. Assuming a food consumption of 16 g/kgbw/d, this would correspond to an intake of 0.26–0.34 mg/kgbw/d of salinomycin. In cats and dogs clinical signs appear as skeletal muscle paresis (incomplete paralysis). Usually the hind limbs are affected first, with more severe cases progressing to complete paralysis, dysphonia (altered voice production), respiratory distress and even death (Espino et al., 2003; Van der Linde-Sipman et al., 1999).

Because a drug may not be destroyed during the pet food manufacturing process, as is the case for ionophores, the most effective preventive strategy for this hazard is eliminating it all together. Pet food ingredient suppliers must be completely drug free. When this is not possible, exacting manufacturing quality control procedures and customer-managed verification programs must be in place.

ADULTERATION FOR PROFIT, THE MELAMINE CASE

The FDA defines an adulterated food as that containing "any poisonous or deleterious substances, such as chemical contaminants, which may or ordinarily render it harmful to health" and includes in this definition unavoidable contaminants that are either naturally present in agricultural commodities (e.g. mycotoxins and heavy metals) or are the result of industrial processing (e.g. dioxins and acrylamide) (FDA, 2010b). Another category of adulteration encompasses the criminal and willful substitution of a higher value ingredient with an ingredient of lesser cost. This type of fraud is defined by the GMA as "the intentional fraudulent modification of an ingredient for economic gain through the following methods: unapproved enhancements; dilution with a lesser value ingredient; concealment of damage or contamination; mislabeling of product or ingredient; substitution of a lesser value ingredient; or failing to disclose required product information" (GMA, 2012b). Food adulteration for profit has existed from ancient times and with today's globalized trade in foodstuff, it can impact any country. The range of recent food adulterations reported by the press actually shocks and disappoints, some recently reported incidents include: fake baby milk formulas, soy sauce made from human hair, fish soaked in ink for color, and eels fed contraceptive pills for enhanced growth (Barbosa and Barrionuevo, 2007).

Ruminants can obtain protein from non-protein nitrogen (NPN) through fermentation by their rumen bacteria and NPN is often added to their diet to supplement protein.

Melamine and cyanuric acid have been used as an NPN in cattle, along with urea, ammonium nitrate and biuret. Nevertheless, melamine is not considered a good NPN because its hydrolysis in cattle is slow and less complete than other NPNs (Newton and Utley, 1978). Melamine is used in a wide range of industrial applications including the production of plastic by combining it with formaldehyde. It is a major component of countertops, fabrics, glues, flame retardants, colorants for plastics, fertilizers and derivatives of some drugs. Cyanuric acid is a structural analogue of melamine and is often found as an impurity of melamine.

Pets and other non-ruminant mammals cannot utilize inorganic nitrogen in the food. Adulteration of protein-rich feed ingredients and feeds has always been a problem in the industry and buyers have routinely screened for NPNs. The use of melamine to adulterate pet food ingredients was unexpected (Dobson et al., 2008). In 2007, fake wheat gluten (a thickening agent and protein supplement), made by blending wheat flour and scrap melamine contaminated with cyanuric acid, caused the deaths of several hundred animals and significant kidney disease in thousands more. The mixture was formulated to match the apparent protein content of wheat gluten as measured by the commonly used Kjeldahl method for total nitrogen content (Rovner, 2008). Smaller amounts of corn gluten and rice protein concentrate were also implicated in other cases. The adulterated materials were all imported from China via a number of middleman transactions that obscured completely the identity of the original manufacturers. A series of canned pet food product recalls followed encompassing over 5300 lots, affecting over 1100 products and brands in North America (Nestle 2008). Another important development in this saga came with publications that identified melamine in tissues of animals that had died in 2004/2005 of kidney disease associated with a pet food recall in Southeast Asia; therefore the industry had been victim of this fraud once before (Brown et al., 2007)! Incredibly, once the pet food feed ingredient stream was no longer available to the counterfeiters, they turned their attention to the human milk industry. In late 2008, melamine was found in China as a contaminant in milk, milk products, infant formula and eggs, resulting in the deaths of several children and causing kidney stones in thousands more (Barbosa, 2009).

Melamine and cyanuric acid alone proved to be remarkably non-toxic, even in large concentrations. Melamine alone when fed to dogs at 3% of diet for 1 year had no adverse effect on general health and produced no histopathological changes (Hodge et al., 1965; Lipschitz and Stokey, 1945). Cats fed melamine alone at up to 1% of wet diet for 11 days (181 mg/kgbw/d) showed no adverse health effects. On the other hand, the combination of melamine and cyanuric acid proved toxic. Cats with a single oral exposure to a mixture of melamine and cyanuric acid at 0.2% of diet (32 mg/kgbw of each) developed depression, vomiting and feed refusal approximately 12 hours after ingestion. The melamine and cyanuric acid were excreted in the kidney where they combined to form crystals which blocked the kidney tubules and resulted in kidney disease or failure. Kidney function was impaired by 36 hours and animals were euthanized at 48 hours because of acute renal failure. Histopathological changes, including crystal formation in the kidney, were similar if not identical to those found in clinical cases of animals ingesting tainted pet food (Puschner et al., 2007).

The HACCP implications of this tragic situation are clear and include: "a trust but verify approach" throughout the supply chain (Henry, 2009), including frequent audits

suppliers. The implementation of routine product identity verification in addition to the standard quality control tests which can be fooled by an able counterfeiter. Reliance on early warning information is useful in allocating risk levels, for example a major fluctuation in ingredient prices can signal an attractive target for fraud. Most countries have now set regulatory limits on melamine and cyanuric acid. Although testing requirements and limits vary, the most common regulatory limit is 1.0 ppm melamine in infant formulas and 2.5 ppm melamine in other foods.

TOXICITIES CAUSED BY NUTRIENT MISFORMULATION

Essential nutrients such as vitamins, minerals and amino acids are many times added to commercial pet foods to assure that they are nutritionally complete and balanced as per trade or regulatory requirements (e.g. AAFCO 2012 Official Publication, http://www.aafco.org). Over- or under-supplementation of nutrients into the product can lead to regulatory non-compliance, risk of toxicity or risk of nutritional deficiencies. The risk of severe nutritional deficiencies exists because a given commercial diet may be the only food a pet animal consumes. A review of the product recall reports in the USA over the last decade shows an interesting pattern of multiple reports of excessive vitamin D_3 incidents involving dog foods and insufficient thiamine incidents involving cat products (Table 15.8). One report exists for excessive methionine in a dog product. Invariably, nutrient misformulation into diets can be traced to industrial accidents either at the pet food manufacturer or at the vitamin premix supplier, often due to formulation errors or improper mixing of the premix ingredients (Bischoff and Rumbeiha, 2012).

Control of this hazard is linked to GMPs at both the vendor of the ingredients and at the pet food manufacturer. Critical GMPs include mixing validation and process capability studies, careful reconciliation of ingredient use to assure proper formulation and ingredient monitoring. Interestingly, the case of vitamin D toxicosis reported in 2010 which involved the carry-over of a vitamin D supplement (25-hydroxy vitamin D) used in other feed products into a correctly formulated pet food premix points to the risks of additive carry-over into products manufactured on the same manufacturing lines as other feed products. This type of sequence error on shared manufacturing lines has also resulted in the carry-over of antibiotics with disastrous consequences (see "Toxicities Caused by Medicated Feed Carry-over into Pet Food Raw Materials," above).

CONCLUSION

Complete and balanced pet food products are formulated to be the single source of nutrition for a pet. Most pets are sustained mainly through feeding of a reduced range of commercial products and a limited number of production batches for a prolonged amount of time. The impact of the diet and therefore food safety hazards on the health of the pet is more like that of a human infant than an older person eating a varied diet. A careful review

TABLE 15.8 Nutritional Toxicities and Deficiencies

Year	Nutrient	Exposure	Root Cause	Number Affected	Reference
1999	Excessive vitamin D_3	14.65 mg/kg BW	Feed-mixing error	Toxicity or death reported in at least 25 dogs	Rumbeiha and Morrison (2011)
2000	Excessive methionine	1.60–2.75%		Anorexia or vomiting was reported in 21 dogs	
2006	Excessive vitamin D_3	Up to 2664 IU/1000 kcal (ME)	Misformulated vitamin premix containing up to 284,700 IU vitamin D_3/kg	Toxicity or death reported in six dogs and five cats	Rumbeiha and Morrison (2011)
2009	Insufficient thiamin	Canned cat food. 1.5 ppm in the product	Misformulated vitamin premix	13 to 20 cats with reversible neurological symptoms including limb ataxia, rigid paralysis, flaccid neck, blindness, circling behavior, seizures, nystagmus and vomiting	Pet Food Recall 2009 – presentation by Karyn Bischoff Assistant Professor Animal Health Diagnostic Center College of Veterinary Medicine Cornell University Ithaca, New York 14853
2009	Excessive vitamin A	Feline research diet	Misformulation	Hypervitaminosis in cats	Bischoff and Rumbeiha (2012)
2010	Insufficient thiamin	Canned cat food			https://www.avma.org/News/Issues/recalls-alerts/Pages/pet-food-safety-recalls-alerts.aspx
2010	Excessive Vitamin D_3	Dry dog food	Scheduling error by Vitamin D supplier allowed for carry-over of vitamin D supplement (25-hydroxy vitamin D) into pet ingredient	16 dogs in eight states hypercalcemia, increased thirst and urination, weight loss, anorexia or azotemia	Hypervitaminosis D in Dogs Associated with Diet – Kent R. Refsal, DVM, PhD Diagnostic Center for Population & Animal Health | 4125 Beaumont Road, Lansing, MI 48910-8104 | PH: 517.353.1683 FX: 517.353.5096 | www.animalhealth.msu.edu WEBCD.GEN.REF.026.01 Issue Date: 10/8/2010
2011	Insufficient thiamin	Canned cat food "less than adequate levels of thiamine"		One consumer complaint received by the FDA	https://www.avma.org/News/Issues/recalls-alerts/Pages/pet-food-safety-recalls-alerts.aspx

of the industry record with regards to pet food safety reveals issues with the control of a small number of food hazards that account for the vast majority of incidents, these are:

- Aflatoxin.
- *Salmonella*.
- Sporadic adulteration of ingredients with veterinary drugs, inorganic nitrogen sources, specific risk materials (BSE) and heavy meals.
- Nutritional misformulation.

Most of these hazards originate in the raw material supply and have no effective control points in the process. Thus their control relies on food safety management practices by the raw material suppliers and a "trust but verify" vendor management program. All raw materials must be risk assessed via a comprehensive HACCP program and all potential hazards defined and controlled. Factories making low moisture pet foods need specific programs aimed at *Salmonella* control in the environment.

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CHAPTER

16

Food Contact Materials

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OUTLINE

INTRODUCTION

And last, but not least, food contact materials. This sentence is usually heard in seminars and symposiums on food safety because, in principle, food contact materials (FCM) were previously not considered a source of food safety issues. But this perception is changing. Twenty

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years ago, if we asked consumers about their worries regarding packaging materials they would probably have said that waste was their main concern. Waste is certainly a concern that remains today but there is an increasing concern about the inertness of FCM following the issues of recent years. The move of perception from "source of waste" to "source of chemical contamination" is reflected in discussions with consumer associations or simply with friends, where it is quite common to hear consumers using terms that were the "reserve" of experts: migration, phthalates, set-off, benzophenone, functional barrier and bisphenol A (BPA). A simple exercise with the internet using the words "packaging waste" and "packaging migration" could give an indication of this change of perception. The "Eurobarometer survey report on risk perception in the EU" published in November 2010 shows that chemical contamination is the first thing that comes to consumers' minds when they are questioned about possible risks related to food. For the first time, FCM appear in the report where 59% of the European population admit to be worried about substances contained in materials coming into contact with food.

If we look back over the last 10 years we find the reasons why there is an improvement in consumers' vocabulary. Several crises regarding FCM were hitting food and packaging industries and damaging consumers' confidence. In 2003 the semicarbazide (SEM) and epoxidized soyabean oil (ESBO) issues impacted the metal closure industry. Two years later the isopropyl thioxanthone (ITX) case put on the table the issue of set-off in printed bricks. The migration of certain phthalates from recycled cardboard or that of BPA from polycarbonate was again showing that FCM are not always as inert as we think. In all the cases mentioned the industry was identifying gaps and authorities were setting new directives or regulations.

As the time of writing mineral oils from printed paperboard are under the close watch of authorities, consumers and industry, showing that there is room for improvement in the way FCM are handled. The food chain and especially the food safety professionals now have the challenge of returning the confidence on FCMs to consumers.

DEFINITIONS

Food contact material (FCM): From a food safety perspective, all bodies that could transfer their constituents to food under the intended conditions of use (considering expected mishandling and misuse). Includes raw material packaging, processing lines, food packaging (having direct or indirect contact), auxiliary items, some parts of vending machines and food dispensers (e.g. coffee dispensers, ice cream dispensers), among others.

Direct contact: Intimate contact with the foodstuff–food contact layer (physically or in contact with the headspace).

Indirect contact: Corresponds to all layers placed between the food contact layer and a functional barrier. There is no intimate contact but during the contact period there is a potential transfer of constituents into the food.

No contact: The potential of transferring material constituents to food is excluded (it could be proved).

Migration: Migration is the transfer of constituents from the given material or article into the food. It is a time-based process but highly dependent on temperature. It is

important to keep in mind the time of contact (e.g. primary packaging from filling to consumers' last serving) and the temperature in the process (e.g. hot filling, retorting, microwaving...).

Overall migration (OM): This is a measure of the inertness of the material and prevents an unacceptable change in the composition of the foodstuffs. It is the sum of all molecules migrating.

Specific migration (SM): Applies to individual molecules. Limits are different depending on the toxicological information of the molecule.

Set-off: This normally refers to transfer of ink/lacquer constituents from the no-contact side to the contact side of the material during storage/transport of the finished article (e.g. stack, reel).

Functional barrier (FB): May be considered to be a barrier consisting of one or more layers which either reduces the migration of authorized constituents below the specific migration limit or reduces the migration of non-authorized substances into foods or food simulants to a "not detectable" level.

Declaration of compliance (DoC): A document delivered by the supplier stating the conformity of the finished article with the applicable laws. This document is a legal requirement in some countries (e.g. European Union member states).

Certificate of analysis (CoA): A document accompanying the DoC proving with data what is stated on the DoC.

Not intentionally added substances (NIAS): Impurities originating from the manufacturing or extraction process of substances used in the manufacture of plastic materials or articles.

Active materials: Materials that are intended to extend the shelf-life of or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.

Intelligent materials: Materials and articles which monitor the condition of packaged food or the environment surrounding the food.

Auxiliary items: Items that are intended for food contact and/or mouth contact and are used for food consumption, e.g. teats, measuring spoons, on-pack straws, ice cream sticks, etc.

Promotional items: Objects not necessary for food consumption placed in or on the package, e.g. toys, gadgets, cards, etc.

Recycled material: Material reprocessed in a production process of the waste materials for the original purpose or for other purposes, excluding energy recovery (direct incineration).

Reworked material: A special case of recycled material (high quality) where the cuts and scrap of the virgin material is added to the same production process without leaving the production area.

Reused material: A material that has been conceived and designed to accomplish within its life cycle a minimum number of trips or rotations, and is refilled or used for the same purpose for which it was conceived, with or without the support of auxiliary products present on the market enabling the packaging to be refilled; such reused packaging will become packaging waste when no longer subject to reuse.

CLASSIFICATION OF MATERIALS

There are different ways to approach the classification of materials used in the food industry. It is important to consider different angles because of the combination of factors that could determine the risk of use, e.g. quality of material for a given use (time of contact, type of contact). A classification based on type of contact, type of material and function is shown below.

Type of Contact

Not all materials in a processing line or in a packaging material are in contact with food. It is thus important to distinguish which ones have the potential of transferring their constituents to food from those that have no contact. There are many adjectives to define the type of contact but not always with the same understanding. The key ones are:

- **Direct contact:** Intimate physical contact with the foodstuff. The surface in contact constitutes the food contact layer.
- **Indirect contact:** Corresponds to all layers placed between the food contact layer and a functional barrier. There is no intimate contact but during the contact period there is a potential transfer of constituents into the food. Transfer of volatiles via headspace is also considered indirect contact.
- **No contact:** The potential of transferring material constituents to food is excluded.

There are other adjectives that are less used. The definitions here could be used as guidance:

- **Incidental contact:** The material design could not exclude the potential direct contact with the food for a short period (e.g. splashes, consumer foreseeable misuse).
- **Not intended contact:** The potential of transferring material constituents to food is avoided by design but could not be excluded.

Type of Material

There are many materials that could be used in the food industry. Here we group them by families adding some specific comments on food safety.

- **Metals and alloys:** These are normally used in processing equipment and household utensils. Metals are rarely used individually but the main part of the equipment is made from alloys. There are many different metals that could be used in contact with food: aluminum, chromium, copper, iron, manganese, nickel, silver, tin, titanium and zinc. They are normally present as components of alloys like stainless steel (iron–chromium), bronze (copper–tin), brass (copper–zinc) or German silver (copper–nickel–zinc).

  The main restrictions applying to metals are related to heavy metal content. It could be specified in terms of content in the material or on migration/leaching. Special attention should be paid to welding (e.g. sieve reparation) in order to avoid the introduction of lead. Alternative welding materials with a mix of tin and silver are available.

Because of the extended use of stainless steel in processing and the number of references used, it could be useful to list them for clarification. A table is available as an annex to this chapter.

- **Glass:** The composition of glass is based on sand, soda, lime and glass from recycling, so called "cullet." Modifying the minor ingredients gives an array of different colors (e.g. flint, half white, sky, sapphire, royal blue, Georgian green, light green, emerald, champagne green, dark green, antique green, feuille morte, light amber, amber or red amber). In order to facilitate production, filling and handling an external coating of polyethylene wax is applied to render the container slippery and more resistant to scratches.

  Glass is perceived by the consumer as a high-quality packaging material but from the food safety perspective glass is one of the major concerns because of the potential formation of foreign bodies.
- **Wood:** Wood is widely used for vegetable and fruit boxes but also in toothpicks, chopsticks and ice cream sticks. Pine, bamboo, birch or beech is normally used for these purposes.

  Pest infestations or the growth of molds and fungus could present a food safety issue (e.g. presence of mycotoxins). In order to avoid this kind of issue, wood is normally treated with pesticides or fungicides. A well-known issue arises from the use of 2,4,6-trichlorophenol and 2,4,6-tribromophenol during surface treatment of wooden or wood-based materials. Wine lovers, and thus the wine industry, can suffer from the musty or moldy off-odor associated with these molecules, which is perceptible from as low as 4 ng/liter (WHO, 2005). Checks for the presence of residual levels of these chemicals should then be performed.
- **Cork:** A key application in the food industry is stoppers of bottled wines and spirits. Following a Council of Europe definition, cork stoppers should contain at least 51% of cork and could be made of different pieces bound together by means of glues, adhesives or any other means.

  As in wood materials, checks for residues of fungicides and pesticides should be made.
- **Paper and paperboard:** These are made almost exclusively from cellulose fiber derived from wood. The main difference is their grammage and following international standards it could be considered that material weighing less than 250 g/m^2 is paper and the rest paperboard (ISO, 1995). Common types of paper and typical applications are mentioned here. *Newsprint* is normally used in cheap pocket-books. *Commercial* is used for higher quality articles. *Grease-proof paper* is used when contacting fatty food or food with fats on their surface. A typical application is pet food bags. *Natural Kraft* paper is the strongest type and is extensively used in carrier bags. *Bleached Kraft* is used when appearance is important while keeping the strength, e.g. sugar and flour bags. *Tissue* paper is applied to any light paper and can be used as a laminated component of packaging or stand-alone as kitchen paper towels. *Solid bleached sulfate paper* (SBS) is normally used in water-resistant applications like freezer boxes or wet food contact. When a superior printing surface is needed, the *clay-coated SBS* is the correct option. *Corrugated liner and medium* are, together with adhesives, the components of so-called corrugated boxes. The inner side of the liners is rougher to allow the adhesive gluing the medium or flute to both sides. The structure

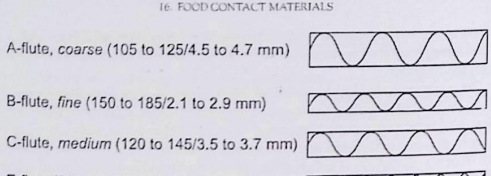

FIGURE 16.1 Comparative of corrugated board grades (approximate number of flutes per meter/flute heights).

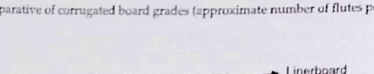

FIGURE 16.2 Structure of corrugated board.

could be doubled or tripled. Their sizes do not follow a logical alphabetical order, going from bigger to smaller A, C, B, E and micro flute. Figures 16.1 and 16.2 show the structure of the corrugated board and a description of the different types. *Chipboard* is 100% recycled paperboard and is the cheapest, with an appearance from light gray to brown. *Newsboard* is made mostly from recycled newspaper. Both are used for rigid boxes where appearance is not critical. Chipboard could be lined with virgin or high-quality recycled liner that improves the appearance. Clay coating is another option when appearance is important.

In the case of printed and/or recycled material the risk of migrating chemicals should be carefully evaluated. In many cases an intermediate barrier (e.g. plastic liner, bag in box) will be necessary. Greaseproof paper could also transfer its components to foodstuff (e.g. perfluoro compounds).

- **Regenerated cellulose:** Commonly called cellophane, the European Commission describes regenerated cellulose film as a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface (Directive 93/10/EEC). Regenerated cellulose film may be coated on one or both sides. It is widely used in food packaging to protect baked goods and candies, and also has applications with oily products.
- **Ceramic:** Ceramic articles are manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enameled and/or decorated (Directive 84/500/EEC).

Potential migration of lead and cadmium is the main concern of food contact ceramics, especially when contacting acidic foods. In Europe, it is mandatory that a declaration of compliance (Directive 2005/31/EC) accompanies the ceramic article.

- **Plastic:** There are several polymers used for food contact. The main ones are (name/abbreviation/recycling number): polyethylene terephthalate/PET/1, high density polyethylene/HDPE/2, polyvinyl chloride/PVC/3, low density polyethylene/LDPE/4, polypropylene/PP/5 and polystyrene/PS/6. The recycling number 7 corresponds to all other resins (e.g. polyamide, polycarbonate). They could be processed by injection molding, blow molding, thermoforming or lamination. Thermoplastic rubbers are integrated into the rubber classification. These polymers incorporate additives to control or improve certain properties. As constituents of the material, antistatics, antioxidants, slip agents or UV stabilizers could migrate into food.

  The restrictions on plastic materials are usually related to their chemical composition (starting substances) and to the amount of those migrating into food (individually (SML) and globally (OML)).
- **Silicones:** Silicones constitute a group of polymeric substances and preparations, all containing polysiloxanes (characterized by Si-O-Si and Si-C bonds). Copolymers and polymer blends of polysiloxanes with organic polymers are also covered by the term "silicones," provided siloxane monomer units predominate by weight over each of the other monomer units present (CoE ResAP, 2004). We could differentiate three types of silicones based on their physical properties: oils and pastes (e.g. lubricants or release agents), resins (e.g. heat-resistant coatings) and elastomers (e.g. sealants).

  The restrictions follow the same approach as applied to plastic materials, restricting the starting substances and the amount of those migrating into food.
- **Rubbers and elastomers:** This category designates a family of materials having properties of high elasticity. In an unaged state, rubber can be substantially deformed under stress, but recovers almost to its original stage when the stress is removed. Rubber is usually made from a mixture of materials (solid and/or liquid) and can be subjected to a curing process, which changes its nature. There is also another group of rubbers, the thermoplastic rubber. This is a polymer or blend of polymers that does not require vulcanization or cross-linking during processing, yet has properties, at its service temperature, similar to those of vulcanized rubber. These properties disappear at processing temperature, so that further processing is possible, but return when the material is returned to its service temperature.

  The special properties of rubbers make this type of material ubiquitous. It can be found in food transportation (conveyer belts, hoses and tubing), food handling (gloves), food netting, pipework components (seals, gaskets, flexible connectors and diaphragm/butterfly valves), pumping systems (progressive cavity pumps stators, diaphragm pumps), plate heat exchangers (gaskets), general seals and gaskets (used in machinery and storage vessels), can sealants, bottle seals and closures or feeding teats and breast caps (nipple shields).

  Nitrosamines should be prevented, especially in sensitive applications like feeding teats and breast caps. Migration of plasticizers is another point to control since its migration could reach high levels, so much so that the use of certain plasticizers, e.g. phthalates, is a worldwide concern.

- **Resins for ion exchange and absorption:** These are synthetic organic macromolecular compounds which can be used in the processing of foodstuffs to bring about exchange o ions or adsorption of foodstuff constituents. They do not include, however, cellulosic ion exchangers (CoE ResAP(2004)3).
- **Coatings:** Coatings are finished materials prepared mainly from organic materials applied to form a layer/film on a substrate in such a way as to create a protective layer and/or to impart certain technical performance. Lacquers and varnishes are part of the coating family. Depending on their composition, there are plastic, water-based, UV cured and conventional epoxy phenolic coatings.

  Migration of chemicals due to insufficiently cured lacquers could become a food safet issue. The composition of the coating should fit food contact requirements, e.g. absence of bisphenol F diglycidyl-ether and novolac glycidyl ethers, also known as BFDGE and NOGE, in epoxy phenolic coating.
- **Adhesives:** These are complex systems. They are composed of basic raw materials (binders) which determine their adhesiveness (adhesion) and internal strength (cohesion), and of additives which determine particular end use and processing characteristics. Binders are mainly high polymers. An adhesive formulation typically consists of a binder (polymer) and one or more of the following additives: water or organic solvent carrier, plasticizers, biocides and fungicides – for natural product adhesives, paper and board adhesives, catalysts, emulsifiers, antioxidants, etc. (Bonell and Lawson, 1999).

  Chemicals migrating from adhesives (ingredients or reaction products) could cross th different layers of a plastic laminate and reach the food. An appropriate selection of the adhesive and the layers in between the food and the adhesive is needed.
- **Inks:** This category comprises complex mixes of binders, colorants, pigments, plasticizers, solvents and other additives. In their final state inks are thin layers that are dried or hardened on the material surface. Food packaging inks should not be mistaken for direct food contact printing, where food additives are used (e.g. food colorants). Inks must only be applied to the external part of the packaging material and must not be in contact with food at any stage.

  The risk of using inks in FCM use comes from an insufficient curing (e.g. high level of residual solvents, contamination of internal face by set-off) or from migration through the base material (e.g. migration of oils from printing paper inks through paperboard and plastic liner). The right quality of inks should be selected for a given application. Special attention should be given to heavy metal content of pigments (e.g. lead), photoinitiator migration of UV-cured inks (e.g. migration test of benzophenone) and to saturated and aromatic hydrocarbons from mineral oil used in paperboard printing inks (e.g. ink solvent composition).
- **Lubricants:** Lubricants are oily substances used for reducing friction, especially in the working parts of production lines. Food grade lubricants must correspond to the former USDA H1 classification, which means that the lubricated part may have incidental food contact not exceeding 10 mg/kg.

  Two factors to reduce the risk of contamination from lubricants are the right mapping of the processing line identifying the parts with incidental food contact and the right dosing of lubricants.

Further information on the basics of packaging materials can be found in the references (e.g. Soroka, 1996).

Function of Material

The tendency is to assign FCM to primary packaging of the final product, but this is quite a narrow vision of FCM. Packaging materials are already present in the transport of raw food products and ingredients (e.g. wood boxes for fruits from the producer to the fruit transformer) or in intermediate storage (e.g. transport of dried fruit pieces from the fruit supplier to the yogurt producer). The classification below intends to extend this vision into FCM.

- **Packaging materials:** These are present from the farm to the fork and could be single use (plastic wrapper for a chocolate bar) or repeated use (microwavable plastic tray for lasagna where the consumer washes and reuses it).
- **Processing materials:** Typically these are materials used by the food industry to transform the food ingredients into the finished product (ovens, vacuum dryers, mixers, extruders, etc.).
- **Auxiliary items:** Materials that are normally sold with the finished product and intended for food contact and/or mouth contact, e.g. teats, measuring spoons, on-pack straws, ice cream sticks, etc.
- **Vending machines and dispensers of prepared foods:** Typically these are beverage or ice cream machines, where the containers of ingredients and fluid parts have the potential to transfer their constituents to the food product. Special attention should be given to the hot parts (e.g. tubing after the heating block).
- **Promotional items:** Items that are sold together with the finished product and are placed in or on the package (e.g. toys, gadgets, cards included in a breakfast cereal box that are not separated by a functional barrier).

HAZARD IDENTIFICATION

Physical Hazards

Food contact materials are a potential source of physical hazards. From a food safety perspective, physical hazards are the main concern when using FCM. We could distinguish two different types, foreign bodies (such as small pieces of plastic from a badly cut container) and the finish of the food contact material itself (e.g. sharp edges on a spoon).

The safety risk of foreign bodies could due to size, leading to choking hazard, or shape, hard or sharp foreign bodies. It is not always evident to identify the potential source of foreign bodies if you are not familiar with them. If you were requested to label one type of material from the classification shown in this chapter (metal, glass, wood, paper, etc.) as a high potential of generating foreign bodies, would you select metal? Contrary to our first thought, it is the hardest materials that create the highest number of consumer complaints. The main part of the surfaces contacting food or primary packaging during production is made of metal. Food contact materials have to be carefully designed to avoid metal-to-metal

friction and potential generation of particles. An appropriate lubrication is also a key factor to reduce this risk.

In evaluating the risk of physical hazards, the first hazard which may come to mind is glass. In fact, when auditing a production site against good manufacturing practices (GMP) the risk of creating glass foreign bodies is always covered (e.g. from broken lamps on the ceiling). Glass materials are of special risk since glass pieces are normally sharp and could produce injuries when touched or eaten.

But foreign bodies could be already present in the raw materials used in production or be introduced when equipment is opened (e.g. during cleaning). Correct control (e.g. sieving incoming food powder ingredient) and design of the equipment should lower the occurrence to correct levels. Once a foreign body is found it is not easy to trace its origin. Heathcock and Gibson (1990) proposed a rapid non-destructive procedure to identify the nature of glass and, in many cases, the origin of the contamination.

The finish of the FCM is another potential source of injuries. A typical case is the pieces of rigid plastic made by molding. When the pieces of the molds are not tight enough the melted plastic flows into cavities generating fine strips that could cause wounds, punctures or cuts.

Less obvious cases could arise from the selection of inappropriate materials, e.g. not-tempered glass for a tea mug, or labeling with inadequate explanations, e.g. how to open easily and correctly. The first case could result in a burn while the second in a small cut or a broken nail. How many times have we agonized when trying to open a bottle with too high a torque force? In most of these kinds of cases the potential physical hazard can cause inconvenience and should be controlled. A clearer example is the use of shelf-ready secondary/tertiary packaging. The number of accidents caused when placing articles on the shelves due to the use of cutters could be as much as 50% of total accidents at the retail stage. Even if not directly linked with food safety this illustrates the impact that an appropriate packaging design could have on the safety of workers.

Foreign bodies can be detected by human inspection, metal detection, magnetic traps, machine vision, ferrous-in-foil detection and X-ray detection. In the case of empty glass bottles electronic bottle inspection (EBI) could be a good option. In order to select the best detection system the magnitude of the problem must be studied and balanced with equipment ability.

Biological Hazards

Food contact materials are normally not considered to be a source of biological hazards. However, it is important to prevent contamination from pests (e.g. rodents during warehouse storage), dust, manure, contaminated water or raw materials as these may be a source of contamination with several pathogens (*Listeria, Salmonella*, leptospira, lassa virus, etc.). Published data demonstrate that the presence of pathogens in the vicinity of unprotected product in processing lines represents a significant risk of recontamination (Reij et al., 2004). Moreover, under certain circumstances some microorganisms can grow in FCM, increasing their numbers and forming biofilm; both harmless microorganisms and human pathogenic bacteria can form biofilms. Biofilms can develop on wet FCM such as those made of stainless steel and they are difficult to remove. Microorganisms in biofilms are usually protected

against sanitizers due to the limited ability of the latter to penetrate the protective layer of microbial polymers in the biofilm. The poor hygienic design of equipment is often the cause of these problems. The correct hygienic design and proper maintenance of equipment as GMP are crucial to avoid recontamination through, for example, dripping condensation water or accumulating residues, cracks, micro-holes, etc.

In the last decade, FCM containing antimicrobials have been introduced to the market as a new concept to improve hygiene, by contributing to reduce the risk of cross-contamination (Moretro and Langsrud, 2011).

Raw material may also contaminate FCM, e.g. *Salmonella* in pet food factories. Therefore, process flow must ensure that raw materials move through the facility from input, where there can be high levels of contamination, to output, where levels of contamination are controlled (levels below given limits).

Microorganisms can also be carried on water droplets throughout the packing and storage areas. For instance, *Listeria* can survive in aerosols for up to 3 hours, and therefore spread throughout FCM. For this reason, water used for washing and cleaning equipment and processing lines that comes into direct contact with food must be of a high microbiological quality.

Workers can carry pathogens on their hands and in their digestive systems despite being free of symptoms of illness. In addition, workers with open sores, boils or open wounds are also a potential source of microorganisms. Unless workers understand and follow hygienic measures, they may unintentionally contaminate FCM and thereby create the opportunity to transmit pathogens.

Chemical Hazards

In general terms, chemical hazards migrating from FCM are not considered to create health issues but, as presented in the introduction, consumers' perception is changing. It is known that migration of compounds from FCM to food occurs during handling, production, storage and distribution. The majority of the potential migrants are known, coupled with their potential safety risk associated with the toxicological information available. An illustration of this is found in Table 16.1. In 2003, Laurence Castle pointed to the molecules in the table as "risk priorities." Five years later, two sound issues shook the food packaging and food industry: BPA in 2008 and benzophenone in 2009.

There are positive lists of starting substances, negative lists of non-authorized substances and lists mentioning restrictions (e.g. specific migration limit or maximum concentration in the material). These lists are sometimes in the form of law (e.g. European Regulation EC 10/2011 or USA List of Indirect Additives Used in Food Contact Substances) and sometimes in the form of recommendations or industry guidelines. Both types are normally open documents available by request or directly downloadable from the internet. The site http://www.foodcontactmaterials.com/ is a good source of these texts.

Control of migration by analysis is not an easy task (Pinalli et al., 2011) and it could be expensive and time consuming. Migration is a process that ensures that the same material could be safe and not just depend on the conditions of contact (time, temperature, etc.). The way the material is used should be considered to validate a certain application, but

TABLE 16.1 Food Contact Materials, Risk Priorities Based on Report FD 03/3 Dec2003 from Laurence Castle (Principal Scientist, The Food and Environment Research Agency, UK)

Material	Chemical
Epoxy resins/coatings and PC	Bisphenol A
PVC film	DEHA
PS	Styrene
Printed cardboard	Benzophenone
Grease-resistant paper and board, kitchenware	PTFE
PVC	Crotonic acid

foreseeable misuse should also be included. An example is the use of kitchen paper towel to absorb oil after frying foods. Even if these towels are not directly intended for food con tact the fact is that consumers use them quite often. Because of this, the contents of certain plasticizers in the paper (e.g. phthalates) were readjusted.

Food contact materials may contain thousands of different molecules and not all of them have a validated method to measure their migration. Some substances like heavy metals are well known and restrictions apply to all FCM. There are materials more susceptible to containing heavy metals like inks or metals, but the main part of the components of FCM are not that toxic. Substances that are CMR (carcinogens, mutagens and substances toxic to reproduction) must not be used in the composition of FCM. The toxicity of the substances migrating is normally based on a lifetime exposure (e.g. TDI) and it is regulated via specific as well as overall migration limits (overall migration and specific migration).

An important food safety risk of packaging materials is normally linked to the use of fungicides and antimicrobials in wood, cork and paper. Active materials could also be a source of antimicrobials in a different way and should not be confused with wood treatment.

The applicable controls may come from the dosing of fungicides, as requested by the Agence française de sécurité sanitaire des aliments, and/or the residues of mycotoxins and pesticides, as recommended by the Council of Europe (ResAP(2004)2).

Two technologies are used to give antimicrobial properties to FCMs: the use of releasing molecules and the immobilization of active molecules in the FCM surface. In both cases a correct surveillance is necessary to warranty food safety (e.g. migration test).

Ultimately, FCM manufacturers and suppliers need to show evidence that articles placed on the market are safe and compliant. In order to satisfy the due diligence checks, manufacturers send their products for analysis but, before sending the samples they need to answer "the question": What should I check for? In the best case a Certificate of Compliance listing the molecules having restrictions (safety/quality) is available, simplifying the response. An issue arises when the information available is scarce. It is the aim of this book to be a practical guide so I tried to answer "the question" myself, in a context of no information available. I am not a visionary and Table 16.2 is by no means exhaustive, but following my experience it gives some useful tips on what to focus on.

TABLE 16.2 Guidance on "What to Look for" when Information is Scarce

Material	What to Focus on (Not Exhaustive)	Comment
Active packaging	Releasing technologies (active components migrating into foodstuff or headspace)	Antimicrobials and nanotechnologies should be carefully evaluated
Coatings for metal packaging	– Bisphenol A – Migrants below 1000 daltons	– Consumer perception to be considered – Identification and check with available lists (e.g. Council of Europe Resolution or USA-FDA)
Grease-resistant paper and board	Fluoro-based compounds	Special care when used in oven (e.g. popcorn bags, pizza boxes)
Ceramic articles	Heavy metals (cadmium, chromium VI, lead, mercury)	Especially if vitrified decoration is applied
Cork, wood and paperboard	Phenols and derivative products	The famous "cork taste" in wines could be also found in food coming from wood (e.g. pallets treated). Sensory test is highly recommended since human threshold is at low part per trillion level
Metal closure gaskets	Gasket: plasticizers (overall migration could be high) and blowing agent (Europe)	Phthalates were traditionally used; it is highly recommended to obtain information on identity of plasticizers. Azodicarbonamide is not allowed in Europe
Mineral hydrocarbons/waxes	Mineral waxes	It is important to know its composition and purity. Allowed only for contact application with dry foods
Packaging inks	– Pigments – UV printing – Inkjet printing	– Swiss positive list could be a reference. – Photoinitiators and acrylates – Methanol and ethanol residual content Exclusion lists (e.g. CEPE, Japan)
Polyacrylonitrile	Acrylonitrile and polyacrylonitrile residues	
Polystyrene	Styrene, styrene oligomers and polystyrene residues	– Max 500 mg/kg in polystyrene – Max. 0.3 mg/kg in food – The residual oligomer content in PS must be documented – Must not be used in oven application
Polyvinylchloride	– Vinyl chloride residues – Plasticized PVC	Special focus on plasticizers (phthalates are still used in a high variety and quantity)
Polyvinylidene chloride	Vinylidene chloride residues	

Allergen Hazards

The risk of allergenic reactions is due to wrong labeling (e.g. undeclared ingredie mixed labels) or potential cross-contaminations rather than from food contact mater themselves.

FCM are not a source of allergenic hazards but there are a few exceptions. Natural r ber latex (NRL) could be considered as one of these and needs a special focus. Offici there are 13 latex allergens listed by the World Health Organization. Depending on the N manufacturing processes some of these proteins lose their allergenic properties. The pre lence of latex allergy in the general population is less than 1%, but in the general pedia population, latex sensitization is not rare when young infants have a family history of la allergy. NRL is commonly used in gloves, cold seal adhesives but also in nipples, baby b tles or pacifiers. To minimize the risk, the quality of latex must be controlled. As a referen a cut-off level of 0.15 μg/g of material was proposed by Palosuo et al. in 2007 as a limit bel which NLR can be considered as low allergenic. Cold seal adhesives based on NRL are common solution when sealing flow wrapped articles (Topping, 2006). In these cases t exposed cold seal surface must be kept to a minimum.

Alternative materials such as vinyl or nitrile could replace NRL in gloves. In the sa way, thermoplastics (TPE) or silicone could replace NRL in many other applications. In t case of newborns or prematures this replacement is not yet possible since these materia are not flexible enough. This lack of flexibility entails a risk of low nutrition because of t higher effort needed to suck (infants could fall asleep before finishing the recommend serving).

MANAGEMENT OF SAFETY OF FOOD CONTACT MATERIALS

The Codex Alimentarius includes food contact materials in their General Principles Food Hygiene (Recommended International Code of Practice, 2003). Section 4, dealing wi design and facilities, states that surfaces and materials, in particular those in contact wi food, must be non-toxic in intended use and, where necessary, suitably durable, and eas to maintain and clean. The reference to "toxic" could be linked to the correct selection materials to avoid chemical or allergenic hazards. The reference to "easy to clean materials could be linked to microbiological hazards. Physical hazards seem not to be a focus unles we look into the definition of contaminant: "any biological or chemical agent, *foreign matter* or other substances not intentionally added to food which may compromise food safety suitability."

As presented in Chapter 31 in this book, prior to application of HACCP to any sector the food chain, that sector should have in place prerequisite programs.

For the food manufacturing and processing industry, managing the suppliers of FCM is an important prerequisite program. This should include providing clear specifications and auditing suppliers for their practices. In principle, if the supplier of the FCM has an effective food safety management system and takes adequate measures to ensure safety of materials (i.e. respecting the regulations and applying good manufacturing practices), the packaging

TABLE 16.3 Comparative of Standards Applicable for Food Contact Materials

	BRC-IoP 3 Global Standard for Packaging Materials	EN 15593 Packaging – Management of Hygiene in the Production of Packaging for Foodstuffs – Requirements	ISO 22000:2005 Food Safety Management System – Requirements for any Organization in the Food Chain
Focus	Packaging manufacturer (GMP)	Packaging manufacturer (GHP)	Food industry but includes FCM producers (hazard analysis)
Packaging materials	Fully dedicated	Fully dedicated	Considered as part of FCM
Processing line materials	Considered under chemical risk (cleaning and lubrication)	Considered under chemical risk (cleaning and lubrication)	Considered as part of FCM (requiring DoC as a PRP)

material should not present a problem and the amount of chemical migrating into the food, if any, will not be such so as to present a health risk for consumers. In such conditions, in applying the HACCP system to food manufacturing, chemicals are often not considered as a significant hazard and the hazard analysis will be as follows:

- Is the presence of the potential hazard in the food contact material probable? The answer is normally YES.
- Is an unacceptable level of this hazard in the product probable? The answer would be NO.

However, this does not preclude the processing or manufacturing industry to have a monitoring program and to verify that the prerequisite program is indeed effective. To this end the products need to be periodically tested for the chemicals which may potentially migrate to the product to confirm compliance.

For FCM, the suppliers' food safety management system could be audited against different standards. Among the different standards available, three are taken here as reference: the ISO 22000:2005, the BRC-IoP 3 and the EN 15593. Table 16.3 highlights the main characteristics of these standards.

These standards are designed to look into how the product is *manufactured*, e.g. GMP, but there is less of a focus on how the material is *designed*, e.g. chemical composition of materials or migration. Today, this is a gap in the food chain and there is a need for improvement. The last food packaging issues were pointing to this gap, showing the need of increasing the knowledge on the material composition, the lack of surveillance and the lack of partnership along the food chain. A better flow of information is needed and there are excellent tools available to develop this area (audits, specifications, declarations of compliance (DoC) and certificates of analysis (CoA)).

Some case studies about PRP and HACCP are presented in the final section of this chapter. Two of them are directly related to what was discussed above: "Extrusion of retortable and microwavable plastic bottles" and "Printing of multi-material paperboard bricks."

Regulatory Aspects

There is a link between FCM regulations and food safety. The main part of the regu
tions and recommendations made by authorities has positive and/or negative lists of ing
dients and starting substances. These lists are based on experience (e.g. substances
used to manufacture FCM are not listed or removed from existing lists) but also on to
cological data. As an example, the specific migration limits to some molecules set by t
EU Commission are based on their admissible daily intake (ADI). Making the assumpti
that an average consumer weighs 60 kg and eats 1 kg of packed food per day, the SML is t
result of multiplying the ADI by 60.

The FCM must be compliant with the applicable regulations in the country where th
are used/sold. The problem is that regulatory status of FCM around the world is quite hete
ogeneous. There are countries without any specific regulation on FCM and countries whe
national and supranational regulations apply. In the first case the industry takes the foo
regulation as reference, where almost all countries have a general statement like "the foo
placed on the market must be safe for consumption." Here, proving compliance could resu
in ambiguity. In the second case, compliance could become a complex task requiring a dee
knowledge of the different regulations applicable.

The many differences found in the level of regulatory development by countries are sim
ilar to the ones found if we look into the different classification of FCM. From the "typ
of materials" perspective, plastic materials are one extreme, being highly regulated i
many countries. On the contrary, metal and alloys or inks used in the FCM have almost n
dedicated regulations around the world. This contrast is the same when we look into th
functions of these materials. There are countries that regulate the materials used in foo
packaging but they make no reference to the materials used during processing.

Two regulations are generally taken as reference in the food chain, the Europea
Regulation on Food Contact Materials and the US Code of Federal Regulations for Food and
Drugs (US Department of Health and Human Services). There are countries and supranat
tional regulations that are directly inspired by these two regulations (e.g. Mercosur and EU
regulations). The approach from the EU Commission and US FDA is different. The EU share
the responsibility of FCM compliance all along the food chain while the USA centers th
responsibility of FCM safety on the producers of the article (e.g. plastic bottle manufacture
or cereal extruder manufacturer). The ways to control compliance are also adapted to the
approach. In the EU it is the responsibility of the supplier to deliver a compliant product and
the responsibility of the customer to verify it. This cascade of responsibilities is not followed
by the USA where each new packaging application is directly validated by FDA and the cus-
tomer has almost no information on the composition of the material (e.g. starting substances).

Ensuring compliance of FCM is a way to ensure the safety of the food in contact. As
a result of this, the industry and authorities are developing models of Declaration of
Compliance. The EU Commission developed one for plastic materials in 2007 and the
French Association of Food Industries (ANIA), together with the French Industry of Food
Processing Equipment (FIM) and the European Hygienic Engineering & Design Group
(EHEDG), developed a common document to declare compliance of all the materials used
in the processing equipment. The trend is to have these models for all different FCM as
reflected by national regulations of some European countries (e.g. Italy, Denmark).

RECYCLING AND REUSE

Needless to say, the quality of a product is directly linked to the quality of the ingredients. This principle is also applicable to FCM. Using virgin, recycled or a mix of both could impact the risk of introducing chemical hazards.

The risk related to the use of recycled materials for food contact could be minimized through a good selection of recycled materials (e.g. selecting waste material from the first recycling step – virgin fiber) and through an adequate recycling process (e.g. capable of removing contaminants from waste material). Plastic and paper materials have a long history of recycling and provide examples of both cases. In the first example, the recycling process used for paper was not able to remove the adhesive used for gluing the paper boxes and their components were entering the paper fibers. In this way molecules that were not expected in paper material were migrating into the food (e.g. dibuthylphthalate – DBP). The solution for this issue came from the adhesive industry by replacing the DBP with other additive. In the second example, the origin of the waste resulted also in food contamination. Waste paper from offices was used as part of the waste material used for recycling. In 1994 the first cases of food packaging samples contaminated with diisopropylnaphthalene (DIPN) were detected. The origin of this contamination was the carbonless copy paper coming from this portion of the total waste (Zhang, 2008).

THE POTENTIAL ENVIRONMENTAL IMPACT

Besides the obvious risk linked to human health with using additives irresponsibly, there is also another risk that should be addressed when it comes to additives in food packaging material. Certain additives that may not induce a risk to direct human health can have a negative environmental impact (hence, a potential "boomerang" chain effect for humans). Laws and regulations regarding the environmental impact during fabrication, usage and disposal exist in many countries (e.g. European Union, the USA, Japan) (Zweifel, 2009). Also, specific toxicological analyses on the physicochemical properties are required (e.g. acute toxicity test, skin sensitization, repeated-dose toxicity, mutagenicity testing) as part of these regulations. These tests look mostly at direct impacts on the health and environment during usage and to some extent on disposal as well.

Another aspect regarding the environmental impact from additives is the upstream, e.g. inks. Standard petroleum-based inks have a higher impact than soy-based inks. The manufacturing process of traditional inks produces a lot more pollutant in the form of VOCs (volatile organic compounds) compared to soy ink. In addition to this the recycling process of paper/cardboard of soy-based inks is easier as the de-inking process is less energy intensive and more cost efficient (US EPA, 1994). When evaluating materials and additives the full life cycle should be taken into account and a life cycle assessment (LCA) performed. This can be done by collecting as much information as possible about the scenarios (from cradle to grave) of interest and then looking at desired impact indicators such as carbon footprint. Table 16.4 lists a few impact categories together with examples of classification data and possible characterization factors. It should be pointed out that LCA is a very complex task to perform and evaluate. Today there is, however, some guidance available, e.g. ISO 14040.

TABLE 16.4 A Few Possible Impact Categories that can be Used to Assess the Environmental Impact when Performing a Life Cycle Assessment (Info from EPA's Website)

Impact Category	Scale	Classification (i.e. LCA data)	Characterization Factor
Global warming	Global	Carbon dioxide (CO_2) Methane (CH_4) Chlorofluorocarbons (CFCs)	Global warming potential
Eutrophication	Regional	Phosphate (PO_4) Nitrogen oxide (NO)	Eutrophication potential
Water usage	Regional Local	Water used or consumed	Water shortage potential
Acidification	Regional Local	Sulfur oxides (SOx) Hydrochloric acid (HCl)	Acidification potential

LESSONS FROM CASE STUDIES

Printing of Multi-material Paperboard Bricks

The issue: During an analysis of potential contaminants in infant milk a substance that was never detected before was detected and finally identified as isopropyl thioxanthone (ITX), an additive of printing ink used on the design of milk cartons. The issue was communicated to authorities (Italian Ministry of Health and European Food Safety Agency). Sparse information on the toxicity of this molecule was available at that time and following the precautionary principle Italian authorities recalled the concerned products (European Food Safety Agency, 2007). The recall and withdraws were progressively extended to other European countries, companies and products. The economic impact was huge and the damage to consumer confi- nce difficult to calculate (see also Chapter 41).

'ause: The printing technology used to print the external side of the brick cartons, ultra- t printing, has many advantages, e.g. the absence of solvents. On the other hand, it res a strict control of GMPs. In this case the ink was not correctly applied/cured, result- ı set-off. Regardless of the type of food that was put in contact subsequently, part of the reacted photoinitiator was already transferred to the food contact layer during storage .d transportation. Once the brick carton was filled the ITX was migrating into the food. The quality controls at packaging supplier level were not sufficient. Customers were not sufficiently aware of the ink composition and the surveillance plans were not developed accordingly.

Learnings: GMPs must be respected and quality controls must consider worst-case scenarios (e.g. set-off). The lack of knowledge and surveillance along the food chain created a chain of gaps that allowed the contaminated products to reach the market. This issue was strongly impacting all sectors related to food safety in the food chain. Ink manufacturers developed new photoinitiators with lower migration profiles, packaging manufacturers reviewed their GMPs and quality controls, and the food industry reinforced the surveillance plans and reviewed the specifications of certain applications. The actions reached

the authorities and new regulations were developed (e.g. EU 2023/2006/EC on Good Manufacturing Practices).

Bag in Box without Sufficient Barrier or Excess of Waxes in the Liner

The issue: In 2010 several consumers in North America complained to the producing company about the smell or taste of their breakfast cereals. Some of them reported nausea and vomiting. The company investigated the issue and decided to issue a voluntary nationwide recall of four types of their breakfast cereal.

Cause: Following the company statements, *a higher-than-normal amount of certain chemicals in its package liners caused the unusual smell and flavor*. An investigation revealed that elevated levels of hydrocarbons – including methylnaphthalene – in the packaging liners had leached into and tainted the product. The chemicals were migrating from the liner, through the inner bag into the cereals. The bag in the box was not offering sufficient protection (functional barrier) and the chemicals contaminated the food before the end of the shelf-life. Several causes were at the source. First, GMPs were not properly applied and amounts of waxes were present at a higher level than foreseen Second, the quality controls in place were not able to detect this excess of chemicals. Third, the design of the packaging was not considered to have potential excess of waxes as a worst-case scenario and the selected material for the inner bag was not able to offer the necessary barrier properties. This resulted in a voluntary recall of 28 million boxes of cereal in June 2010. The results in North America were strongly impacted by the voluntary recall. "The estimated impact of the recall, including lost sales, reduced earnings per share by approximately $0.10 in the quarter." This corresponds approximately to a loss of 40 million dollars. The damage to company's image is difficult to consider.

Learnings: GMPs should be correctly applied (e.g. control of wax levels). Quality controls should cover worst-case scenarios. A correct selection of different packaging materials (primary, secondary) could reduce the risks of migration to a negligible level.

Extrusion of Retortable and Microwavable Plastic Bottles

The issue: At the customer's site the operator receiving the lot detected an unfamiliar odor smell when inspecting the truck. He sent some samples to the quality department for a sensory test (sniff test) where the lot obtained a score on the limit (just-out). Because of the intended use, retorting and microwaving, migration tests were requested (overall migration and volatile screening). The results showed an overall migration exceeding the specifications and levels of one molecule subjected to restrictions exceeding the specific migration limit (SML). The lot was returned to the supplier.

Cause: During a shift change on the day of production the incoming operator was informed of the delay in production due to several stops on the line (the extruder was blocking). In order to avoid the blocking issue the operator increased the temperature during the extrusion so the viscosity could be reduced, the blocking issue could be resolved and the line could run faster. The temperature was exceeding the levels specified for this application (retortable and microwavable bottle). The quality controls did not detect any physical defect and the lot was released.

Learnings: Increasing temperature and pressure over the specifications resulted in a polymer with shorter chains, increased level of volatile organic compounds (VOCs) and a higher migration (volatiles and non-volatiles). The positive release of the lot at supplier level should include sensory tests and the GMP awareness of the people operating the line should be improved. The sniff test at the customer level did not consider the retorting and microwaving steps that increase the release of VOCs.

Equipment Reparation

The issue: After reports of issues with the particle size of a cereal product, the breakage of a sieve in equipment was detected. The sieve was repaired and production restarted. During routine control of contaminants (releasing parameter) high levels of lead were detected in the product. The production was stopped, the lot destroyed and an investigation opened.

Cause: The sieve was repaired with an inadequate solder. The material contained lead and the high surface of the sieve produced migration to unacceptable levels.

Learnings: Change management and reparations on the equipment used for food processing need special attention when food contact surfaces are involved. The quality controls in place were able to detect the issue and the product was not liberated. The guidelines were reviewed and adapted to existing standards. Following the Council of Europe: the *use of lead in food contact materials should be abandoned or avoided. Parts made wholly or partly of lead and lead solder for repair should not be used in materials and articles intended to come into contact with foodstuffs including the use of lead in soldered cans* (CoE, Technical Document 2002).

Biological Contamination

The issue: An outbreak of salmonellosis affecting 79 people between 2006 and 2008 was associated with contaminated dry pet food. Exposure of humans occurred through handling of contaminated pet food. More than 23,000 tons of pet food were recalled. The implicated company recalled 105 brands of dry pet food and permanently closed the plant (Behravesh et al., 2010).

Cause: The outbreak strain was isolated from the flavoring room of the manufacturing plant, where dry food was sprayed with flavor enhancers before being packaged. Spraying was made after the killing step in the process (validated time and temperature conditions) and the contaminated pet food was able to reach customers.

Learnings: Process flow must ensure that raw materials move safely through the facility from input to output. The regular monitoring of the processing environment for significant pathogens is needed to ensure proper cleaning and disinfection of FCM.

ANNEX

Common references used for food contact stainless steel (based on Gazzetta Ufficiale della Repubblica Italiana, DECRETO 21 dicembre 2010, n. 258).

UNI EN 10088-1					
Designazione Numerica	Designazione Alfanumerica	AISI/ASTM		UNS	Note
1.4373	X12CrMnNiN 18-9-5	AISI	202	S20200	
1.4310	X10CrNi 18-8	AISI	301	S30100	
1.4325	X9CrNi 18-9	AISI	302	S30200	
1.4305	X8CrNiS 18-9	AISI	303	S30300	
–	–	AISI	303Se	S30323	
1.4301	X5CrNi 18-10	AISI	304	S30400	
1.4306	X2CrNi 19-11	AISI	304L	S30403	
1.4307	X2CrNi 18-9				
1.4303	X4CrNi 18-12	AISI	305	S30500	
–	–	AISI	308	S30800	
1.4401	X5CrNiMo 17-12-2	AISI	316	S31600	
1.4436	X3CrNiMo 17-13-3				
1.4404	X2CrNiMo 17-12-2	AISI	316L	S31603	
1.4432	X2CrNiMo 17-12-3				
–	–	AISI	316N	S31651	
1.4571	X6CrNiMoTi 17-12-2	ASTM T	Type 316Ti	S31635	
1.4541	X6CrNiTi 18-10	AISI	321	S32100	
1.4460	X3CrNiMoN 27-5-2	AISI	329	S32900	
1.4550	X6CrNiNb 18-10	AISI	347	S34700	
1.4006	X12Cr 13	AISI	410	S41000	
–	–	AISI	414	S41400	
1.4005	X12CrS 13	AISI	416	S41600	
1.4021	X20Cr 13				
1.4028	X30Cr 13	AISI	420	S42000	
1.4031	X39Cr 13				
1.4016	X6Cr 17	AISI	430	S43000	
1.4105	X6CrMoS 17	AISI	430F	S43020	
1.4057	X17CrNi 16-2	AISI	431	S43100	
1.4125	X105CrMo 17	AISI	440C	S44004	(*)
1.4542	X5CrNiCuNb 16-4	ASTM	Type 630	S17400	

(*Continued*)

(Continued)

UNI EN 10088-1					
Designazione Numerica	Designazione Alfanumerica	AISI/ASTM		UNS	Not
1.4462	X2CrNiMoN 22-5-3	–	–	S31803	(*)
1.4590	X2CrNbZr 17 – – –	–	–	–	(*)
1.4362	X2CrNiN 23-4	–	–	S32304	
		–	–	S32101	(**)
1.4510	X3CrTi 17	–	–	–	
1.4509	X2CrTiNb 18	–	–	S43940 S43932	
1.4521	X2CrMoTi 18-2	AISI	444	S44400	
		ASTM		S44500	

(*)for materials intended for short contact at room temperature with foods that are related to simulants A and D during migration tests.
(**)only for materials exclusively intended for repeated use during short time at room or hot temperatures and for those for long contact at room temperature with foods that are related to simulant D during migration tests.
(***)for articles intended for repeated use at temperatures not higher than 70°C.

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SECTION II

TECHNOLOGIES AND FOOD SAFETY

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CHAPTER

17

Thermal Treatment

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OUTLINE

INTRODUCTION

The food industry applies several processing techniques for the inhibition and/or inactivation of microorganisms in order to manufacture safe products with a long shelf-life. Thermal treatments (cooking, pasteurization, sterilization, cooling, freezing) and non-thermal treatments (among others drying, irradiation, high pressure and other methods) alone or in combination can be applied to this end. Heat treatment at high temperatures is used widely in food processing, and it is the most important method of preservation, in

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particular in the canning industry. Thermal processing is among the most important me
ods for controlling, eliminating or reducing pathogens to acceptable levels and sometir
also for degrading toxins and antinutritional factors, e.g. lectins in red beans.

HEAT PROCESSING

There are several unit operations that apply heat in food processing. The purpose
many of them is to abolish the raw state of material to prepare the appearance and struct
of finished products. However, for raw materials that are likely to contain pathogens, the
operations are also essential for safety. Among these are cooking, baking, frying, roastir
broiling and boiling (Fellows, 2009). A milder degree of heating is used for melting, temp
ing and blanching.

Heat treatments, such as cooking, boiling, frying and the like, make food more palatab
and improve taste by altering texture, flavor and color, and improve digestibility. These
not achieve preservation, although they destroy a part of microorganisms, decrease the
number, as well as inactivate enzymes and toxins. Cooking, frying and roasting are proces
ing operations primarily used in the manufacture of meat products, whereas baking, coo
ing and boiling are mostly used in processing fruits and vegetables. These heat treatmer
are usually followed with pasteurization or sterilization in the case of canned products.

Blanching is also a cooking term that describes a preparatory process wherein the foo
usually a vegetable or fruit, is heated in steam or hot water for a short time, and cooled b
plunging into iced water or water spray to stop the cooking process. The purpose of blanc
ing is to soften food, by cooking partly or fully, or to remove a strong taste (for examp
of bacon, cabbage or onions). But more often, blanching is performed immediately precc
ing heat sterilization and can be applied before or after filling the containers (cans) wi
product. The reasons for blanching are the removal of gas from the tissues of the raw mat
rial; the shrinkage of this material; and the inhibition of enzymatic reactions, which, if n
stopped, will adversely affect the color and nutritive value of the food. Depending on i
severity, blanching will also destroy some microorganisms.

Another operation that applies heat is exhaustion. This is done after filling and befo
closing cans or jars. The purpose of exhaustion is to remove air from the contents and th
headspace and to enable a vacuum to be formed when the container is cooled. In additio
it will remove oxygen, and protect color and flavor from oxidation and vitamin C fro
destruction. Usually, exhaustion is carried out by passing the containers through a steam
box until the temperature at the center is at least 71°C (160°F). Because fruits are different t
most vegetables, they are not usually heat blanched because heating would cause softenin
and juice loss.

In contrast to heat treatment as described above, the most characteristic finishin
operation is heat preservation by pasteurization and sterilization. While heat processin
operations will inactivate enzymes, coagulate proteins and to some degree also destro
microorganisms, the primary purpose of heat preservation is to achieve the destruc
tion of microorganisms to assure lengthy shelf-life of canned products without spoilage
Sterilization means the use of high temperatures (over 100°C) for complete destruction o
microorganisms (but see below regarding commercial sterility), whereas pasteurizatio

means lower heat treatment (generally lower than 100°C) to destroy most vegetative pathogenic bacteria and to extend product shelf-life. Pasteurization is often combined with another means of preservation (concentration, acidification, refrigeration, etc.).

Before discussing the various methods of thermal treatment, first the fundamentals of heat destruction of microorganisms will be outlined, on which the processes of thermal treatment are based.

FUNDAMENTALS OF THERMAL DEATH OF MICROORGANISMS

The method of heat treatment rests upon the principles of thermal death of microorganisms according to which the death of a cell population follows the kinetic of a first order reaction:

$$dN/dt = -k.N$$

that is, the change in number of survivors (dN) in a given time (dt) is proportional to the actual number of living cells (N), where the k factor is called the death rate coefficient (with a negative sign as the cell number is decreasing). Integrating this equation between the limits of initial cell count (N_o) and surviving cell count (N_t) after t time, we arrive at the fundamental equation describing the death of microbial populations:

$$N_t = N_o e^{-kt}$$

often rewritten in logarithmic ($\log_{10}$) form which is called the equation of survival curve:

$$\log N_t/N_o = -k.t$$

When the logarithm of the surviving cell number is plotted against time, a straight (linear) line is obtained, the slope of which is related to the death rate coefficient (Figure 17.1).

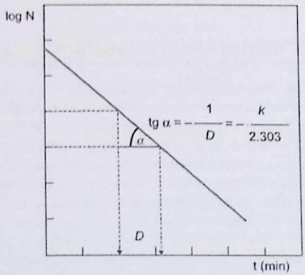

FIGURE 17.1 The survivor curve and the D value.

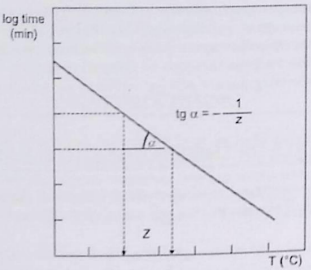

FIGURE 17.2 The thermal death curve and the z-value.

The decimal reduction time D is the time through which the number of survivors decreases to one-tenth.

$$D = t/(\log N_o - \log N_t)$$

The value of D (in minutes) is independent from the size of population but depends on the degree of temperature. Thus, the D value is also a measure of the heat resistance of a given kind (species or strain) of microorganism. The dependence of D on temperature is expressed by the value of z (in °C or °F) defined as the degrees of temperature causing a decimal change of D (Figure 17.2).

D and z are the two basic parameters defining completely the heat resistance characteristics of microorganisms.

HEAT RESISTANCE OF MICROORGANISMS

The heat resistance of microorganisms is primarily a genetically determined specific characteristic that can be modified by the environmental conditions. In general, heat resistance is in proportion to the growth temperature (Table 17.1). Psychrophilic vegetative bacteria become inactivated at about 40°C, whereas mesophiles have a decimal reduction rate of about 1 min at 55 to 60°C. Certain thermoduric bacteria (e.g. *Enterococcus*, *Microbacterium* species) may survive 30 min heating at 60°C, with a fairly large z-value of 15 to 20°C. Heat resistance of most vegetative pathogenic bacteria occurring in foods is similar to that of mesophiles, and they can be inactivated with the conventional pasteurizing treatments at temperatures below 100°C. The unusually high heat resistance not typical of pathogens is shown by the serotype *Salmonella* Senftenberg, approaching that of thermoduric species.

Although the vegetative cells of spore-forming bacteria are equally sensitive to heat as other bacteria are, their endospores possess high heat resistance (Table 17.2). This is attributed

TABLE 17.1 Average Heat Resistance of Vegetative Microorganisms

Physiological Group	*D* value (min) at 40°C	*D* value (min) at 50°C	*D* value (min) at 60°C
Psychrophilic bacteria	0.3	–	–
Psychrotrophic bacteria	–	1–5	–
Mesophilic bacteria	–	5–40	0.2–1
Thermoduric bacteria	–	–	1–30
Thermophilic bacteria	–	–	100
Yeasts and molds	–	1–5	0.02–0.4

Source: Tomlins and Ordal (1976).

TABLE 17.2 Thermal Resistance of Microorganisms

Microbe	*D* value (min)	*z*-value (°C)
Pasteurization at 65°C		
Salmonella spp.	0.02–0.25	4.4–5.5
Salmonella Seftenberg	0.80–1.00	4.4–6.7
Staphylococcus aureus	0.20–2.00	4.4–6.7
Yeasts, molds	0.50–3.00	4.4–6.7
Pasteurization at 100°C		
Alicyclobacillus acidoterrestris	3.0–8.0	6.0–8.0
Bacillus cereus	5–10	7.0–10.0
Clostridium botulinum E	15–50	5.0–8.9
Clostridium sporogenes	60–190	9.0–13.0
Sterilization at 121.1°C		
Clostridium botulinum A, B	0.10–0.20	7.8–10.0
Desulfotomaculum nigrificans	2.0–3.0	9–12
Geobacillus stearothermophilus	4.00–5.00	7.8–12.2
Clostridium thermosaccharolyticum	3.0–4.0	12–18

Data from Stumbo (1973) *and* Deak et al. (1980).

to the specific structure and composition of endospores, and is due essentially to the manifold layers of spore coat and the dehydrated state of spore cytoplasm. There is not much difference in the heat resistance of aerobic or facultative *Bacillus* species and anaerobic *Clostridia* in this respect; however, the thermophilic spore-forming species are remarkably more heat

resistant than mesophiles. Heat resistance of mesophilic spores is characterized with D of 0.01–0.1 min, while that of thermophiles may reach 2–5 min decimal reduction time at temperature. From the point of food safety, *C. botulinum* is the most heat-resistant pa genic spore-former, having 0.1–0.2 min $D_{121°C}$, in particular the strains belonging to serot A and B, whereas the psychrotrophic E serotype strains are less resistant, characterized D_{80} value of 0.3–3 min. Among the spore-formers causing spoilage in canned foods are m heat-resistant species compared to toxigenic *C. botulinum*. Spores of *G. stearothermophilus* *C. thermosaccharolyticum* have D_{121} values of 3–5 min, and these can survive heat treatme calculated for the destruction of *C. botulinum* (see the discussion on commercial steri below). Heat resistance of spores is also characterized with z-values two or three times hig than vegetative cells, in the order of 8 to 12°C, and some spores may reach 20–30°C.

The majority of yeasts and molds possess heat resistance similar to mesophilic vegeta bacteria. Heat resistance of sexual spores or asexual conidia does not surpass that of vege tive cells. However, ascospores of certain molds, such as species of *Byssochlamys*, *Neosarto* and *Talaromyces*, have rather high heat resistance with 7–22 min D value at 88°C, and th can survive 30 min heat treatment at 90°C causing spoilage of pasteurized fruit juices a canned fruits.

The thermal resistance and thermal death of microorganisms are influenced by seve environmental factors. Moreover, although heat resistance is a specific characteristic, it m differ between strains of a species, and may change according to the physiological state cells. Cells in the exponential phase of growth are usually more sensitive to heat than th being in the stationary phase. For the practice of heat processing, the most important fac influencing heat resistance is the composition of the product, in particular its water activi and pH.

Decrease of water activity significantly increases thermal resistance. This often the ca in foods with high sugar concentration or containing many proteins or fats. Acidic en ronment and low pH decrease heat resistance. Product pH is of outstanding importan for heat processing. pH 4.5 (in the USA pH 4.6) signifies a dividing line; products wi pH lower than 4.5 can be pasteurized at 100°C or below, while foods of higher pH tha 4.5 must be sterilized over 100°C. The fundamental safety reason for this is that the mo heat-resistant pathogenic endosporic microorganism, *C. botulinum*, cannot grow or produ toxin at pH <4.6, and the spores that may survive heat treatment could not germinate eith (Table 17.3, and see "Factors Determining Heat Treatment," below).

Factors affecting heat resistance are in force before, during and after heat processing Cells surviving heat treatment become damaged and can be repaired only under optimu conditions, though not in products which may contain certain chemicals, such as preserva tives and nitrite, nor in products stored at low temperature. These products, although the may contain living bacteria, are, however, not able to start growing, and such product remain in a state of "commercial sterility" without spoilage.

DETERMINATION OF HEAT PROCESS REQUIREMENT

Determination of heath process requirement and its validation is important when desig ing control measures in an HACCP study and determining monitoring parameter and

TABLE 17.3 Heat Processing Requirements – Dependence on Product Acidity

Acidity Class	pH Value	Food Commodity	Heat Processing Mode
Low acid	5.3–6.0	Vegetables, uncured meat, poulty, fish, soups	High temperature sterilization (115–121°C, 240–250°F)
	5.0	Tomato products	(105–115°C, 221–240°F)
Medium acid	4.5–5.3	Fruits, fruit juices	Pasteurization
			(100°C, 212°F)
Acid	3.7–4.5	Fruits	(80°C, 176°F)
High acid	3.0–3.7	Pickles, sauerkraut	(80°C, 176°F)

Source: Desrosier and Desrosier (1977).

critical limits. These need to be validated on a case-by-case basis, considering various factors which may affect the outcome such as initial bacterial load, acidity, water activity, etc. Therefore the subject is explained in detail.

The extent of microbial destruction during the process of heat treatment depends on the combined action of temperature and time. In this regard it is essential to be aware that increasing the flow rate in a pipe or the speed of a conveyor belt reduces the residence time of the product. There have been cases where an increase in the flow rate of the conveyer belt has led to an outbreak of foodborne illness (Motarjemi and Kaferstein, 1999).

In the practice of heat treatment, various degrees of temperature are applied. The values of D (or its multiple the thermal death time, TDT) at any given temperature can be obtained using a reference value, F, at a reference temperature (Figure 17.3). For the latter, 121.1°C was chosen, a temperature important in the sterilization practice (this value corresponds to a round figure, 250°F). Also, a z-value of 10°C was selected as the slope of this particular thermal death curve. With these determined points, the equation of the thermal death curve is:

$$\log(t - F) = -(T - 121.1)/z$$

This equation is used for the calculation of the thermal processing requirement and the lethality of the sterilization process. For these calculations, the lethal effect of any other temperature should be compared to the reference temperature, 121.1°C. From the above equation, the relative rate of heat destruction at various temperatures compared to that of 121.1°C can be obtained as:

$$F/t = \text{antilog}(T - 121.1)/z$$

In the practice of heat treatment (sterilization, pasteurization) the temperature is not constant but changes, increasing during warming up and decreasing during cooling. In calculating the heat process requirement, the task is to sum up the lethal effects of changing temperatures for changing time. This can be done if the thermal death time (or rate) at various temperatures is expressed in a similar manner to be integrated. As shown above, the death time of any temperature related to the reference temperature 121.1°C is expressed as

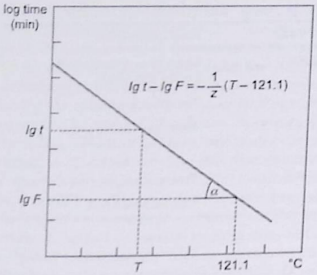

FIGURE 17.3 The reference thermal death curve.

F/t; and the integrated time-equivalent, F_i, of different temperatures in relative fractions of 121.1°C can be obtained as:

$$F_i = \int_o F/t\,dt$$

e.g. if the time-equivalent of a thermal process is $F_i = 3$ min, it means that the sum of lethality of all corresponding temperature–time combinations during heat treatment will be equal to the effect of 3 min instantaneous treatment at 121.1°C. In this interpretation, the F_i value does not relate to a given kind of microorganism but to a given heat process, hence it can be used to compare the efficacy of different thermal processes.

The heat resistance of microorganisms, however, differs and changes also with temperature (as expressed by the D and z-values). For safety reasons, the minimal degree of thermal process chosen should be adequate to kill the most resistant pathogenic microbes which may occur in the practice of canning. According to common experience, it is the toxigenic *Clostridium botulinum* which constitutes the greatest health hazard and whose endospores have high heat resistance. The D value of the most resistant spores of *C. botulinum* at 121.1°C is 0.21 min, and its thermal dependence, the z-value, is 10°C. This has been chosen universally for the calculation of thermal process requirements, and the summarized lethality value of temperatures related to 121.1°C is distinctively marked as the F_o value, and called equivalent sterilization treatment. In contrast to the F_i thermal time-equivalent which may refer to any TDT curve no matter which z-value, the F_o value relates to a thermal process characterized with a thermal death curve of $z = 10$°C value.

The F/t values can be graphically integrated by taking the relative death rates corresponding to the different temperatures of the heat penetration curve, and plotting with time to obtain the so-called sterilization curve. The area below the sterilization curve will be equivalent with the sterilization treatment in minutes of F_o (Figure 17.4). For practical reasons the summing up of F/t values usually starts when the internal temperature reaches

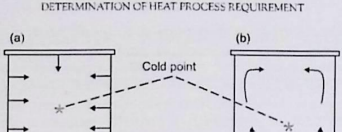

FIGURE 17.4 The sterilization curve and the sterilization equivalent value F_o.

100°C and includes also the cooling part until 100°C. The F/t values associated with temperatures below 100°C are very small and hence do not contribute significantly to the overall amount of heat treatment. On the other hand, omitting the effect of high temperatures during cooling would result in oversterilizing of the product, possibly unnecessarily resulting in additional quality losses. In recent times, with the development of computing technology, programs are available to determine thermal process requirements, and also online monitoring and controlling of the thermal process (Fellows, 2009).

Based on the sterilization equivalent F_o values, not only the efficacy of various thermal processes can be compared but also the minimal degree of heat treatment required for safety can be determined. It is a universally accepted practice to apply a heat treatment which should destroy the number of *C. botulinum* spores to 10^{-12} proportion. This is the 12D concept, which is equivalent with $12 \times 0.21 = 2.52$ min heat treatment at 121.1°C, which is the F_o for *C. botulinum* (also called "botulinum cook"). This provides high safety for heat sterilization. In modern terminology, it is referred to as "performance criterion" (see chapter 31 in this book on Hazard Analysis and Critical Control Point). Since it was introduced for commercial canning at the end of the 1920s, there is high degree of safety with industrialized canned food. Most cases of botulinum intoxications are associated with home preserved food. In the USA about 10 to 30 outbreaks of foodborne botulism are reported each year, almost all from home canning (Shapiro et al., 1998). An outbreak involving eight people, the first in 33 years, was caused by a commercially made canned food (hot chili sauce produced by a factory in Augusta, GA) (Schmit, 2008). FDA officials stepped up inspections at other canneries, and discovered botulinum spores in cans of green beans produced by a plant in Michigan. Although no illnesses were reported, the producer recalled 1.2 million cans of vegetables because of the risk.

The 12D principle of sterilization should be applied for low acid products with pH >4.5 in which *C. botulinum* can grow. In these products, however, spore-forming bacteria may occur whose heat resistance is higher than that of *C. botulinum* (Table 17.4). Although these do not present health hazards, they can survive the minimal requirement of safe heat treatment (i.e. $F_o = 2.52$ min), and can cause spoilage. For economic reasons, the spoilage ratio should be kept lower than 0.1%. When thermophilic spore-formers are to be accounted for as contaminants having D_{121} values of 3–5 min, the equivalent sterilization treatment should be much higher, sometimes reaching $F_o = 15$–20 values (Table 17.4).

TABLE 17.4 Sterilizing Time-equivalent (F_o) for Certain Canned Products

Product Type	pH	F_o (min)
Pickles	3.4–4.1	0.0002–0.004
High-acid fruits	3.2–3.8	0.002–0.007
Tomatoes	4.2–4.5	0.01–0.07
Medium-acid fruits	3.7–4.5	0.1–0.4
Medium-acid vegetables	4.0–4.5	0.1–2.0
Cooked meats	5.0–6.5	2.5–5.0
Low-acid vegetables	5.0–6.5	4.0–14.0
Ready-to-eat foods	4.5–6.5	5.0–30.0

Selected data from Richardson (2004).

On the other hand, for the heat preservation of products whose pH is lower than 4.5 (th so-called acid and high acid foods), not even the minimal requirement for botulinum cook (F_o=2.52 min) need be applied. Partly, *C. botulinum* could not grow at or below pH 4.5, and the acidic environment will decrease the heat resistance of microbes. These products can be pasteurized by heat treatment lower than 100°C.

Analogous to the calculation of the sterilization requirement and efficacy in F_0 value, in the case of pasteurization the D and z parameters are to be related to fixed reference values and the cumulative thermal destruction equivalent of changing temperatures and times is expressed in pasteurizing units (PU) or pasteurizing equivalent (P). The reference temperature should be marked, e.g. at 80°C the value is P_{80}.

$$P_T = \int_{T_w}^{T_c} 10^{(T-Tr)/z} dt$$

where P_T is the pasteurization equivalent at T temperature of heating, integrated between the cooling temperature T_c and the warming temperature T_w, related to the reference temperature, T_r, and t is the time of heating.

CONVENTIONAL HEAT PRESERVATION

There are two main processes of preservation by heating: sterilization and pasteurization.

Sterilization

Sterilization means the complete destruction of microorganisms usually by temperature over 100°C using pressurized equipment (autoclaves or retorts). Because of the resistance of bacterial spores to heat is different, sterilization frequently means a treatment of at least

121°C (250°F) of wet heat for 15 min or its equivalent to inactivate to a large extent spores of the pathogenic *C. botulinum* and most of the spore-forming spoilage microorganisms. Sterilization also means that every particle of the food must receive adequate heat treatment. Hence, the slowness of heat transfer through the food should also be considered in determining the overall heat destruction effect of the sterilizing treatment.

In practice, however, a product subjected to sterilization may not be sterile. Because the principle of exponential death rate following absolute sterility cannot be achieved (not all microorganisms will be eliminated), the probability of survival must be minimized to an acceptable degree. This has been set for a 10^{-12} part survival of *C. botulinum* spores, called 12D concept (equivalent to $F_0 = 2.5$ min heat treatment). Even in this case, some heat-resistant spore-formers, e.g. *C. thermosaccharolyticum* or *Geobacillus stearothermophilus*, may survive this and further intensive heat treatment ($F_0 = 5$ or higher values). Being of thermophilic nature, these surviving microorganisms cannot grow under the normal conditions of storage prevailing in temperate zones (at ambient temperature without refrigeration), and this condition is termed commercial sterility. In practice, most of canned or bottled products receiving the minimal 12D botulinum cook or higher exist as commercially sterile, in which some survivors of high heat-resistant spore still remain, although these will not grow under normal storage temperature at a temperate climate. However, in tropical areas an ambient temperature of 45°C may prevail long enough to cause cans to explode due to the activity of thermophiles.

Canning

Food preservation by heat treatment of products packed in containers – called canning – is a common practice of food industry. Although, from the microbial point of view, it would be ideal to employ a heat treatment that would eliminate the risk of any surviving microorganisms, most canned food products cannot be subjected to such a degree of heating because it would degrade the sensory quality and result in loss of nutritional value. Hence, in practice, a compromise is needed in order to provide a heat treatment intensive enough for the microbiological safety of the products and at the same time moderate enough for preserving product quality. Commercial sterility is a generally accepted practice of canning.

As discussed above, *Clostridium botulinum* is used as a reference organism for manufacturing safe and stable products by heat treatment with a minimum F_0 value of 2.52 min. Based on microbiological considerations and including a sufficient safety margin, most sterilized canned products should be produced with F_0 values of 4.0–5.5. The retort temperatures to be used may vary between 117 and 130°C (depending on the heat sensitivity of the individual products). It is known, however, that certain thermophilic organisms such as *G. stearothermophilus* or *C. thermosaccharolyticum* are extremely heat resistant and may survive F_0 values of 4–5.5. In the case of survival they will not grow under normal storage conditions of up to 25°C and do not pose a risk in countries with moderate temperatures. However, they may grow under tropical conditions, in particular with storage temperatures of 25°C and above. Hence, F_0 values of 12–15 have to be employed in cases having this risk (Table 17.5).

Contrary to the excellent safety record of commercially canned foods, microbial spoilage of canned products does occur, and is usually related to the following factors (Evancho et al., 2009): (1) insufficient processing, which permits survival of mesophilic microorganisms, (2) inadequate cooling after processing or high temperature storage and distribution

TABLE 17.5 Spore-forming Bacteria Causing the Spoilage of Canned Products

Type of Spoilage	pH	Products	Spoilage Bacteria	Heat Resistance (D, min
Flat sour	>4.5	vegetables, meat dishes	thermophiles *B. stearothermophilus*	4–5
Gaseous souring			*C. thermosaccharolyticum*	3–4
Sulfide stinker			*D. nigrificans*	2–3
Flat sour	>4.5	vegetables, canned meat	mesophiles *B. cereus, B. subtilis, B. brevis*	0.001–0.004
Gaseous putrefaction			*C. sporogenes, C. botulinum*	0.1–0.2
			C. putrefaciens	0.001–0.01
Flat sour	<4.5	vegetables, tomato products	thermophiles *B. coagulans*	0.01–0.07
Gaseous souring	<4.5	pickles, tomato products	mesophiles *B. polymyxa, B. macerans*	0.01–0.05
Gaseous putrefaction		canned tomato,	*C. pasteurianum*	
Butyric fermentation		canned fruits	*C. butyricum*	0.004–0.01

From Denk et al. (1980).

conditions promoting growth of thermophilic bacteria, and (3) post-processing microbi contamination due to leakage. Table 17.5 lists the possible causes and signs of spoilage canned foods.

Insufficient processing of low-acid foods is a serious situation from the public healt iewpoint because of the potential development of toxigenic spore-formers and their to is. High-temperature (thermophilic) spoilage may occur in low-acid canned foods owth of extremely heat-resistant spore-forming bacteria surviving the heat proces g occurs. Certain ingredients (e.g. sugar and starch) may introduce excessive numbe of these organisms in the product. If thermophilic spoilage occurs, it may be caused *Geobacillus stearothermophilus* and *B. coagulans*, so-called flat sour bacilli because they pr duce acid without gas and the cans do not swell. When thermophilic anaerobes such *C. thermosaccharolyticum* cause spoilage, producing large amounts of gases (H_2 and CO_2), th cans become swollen and may even burst. The third type of thermophilic spoilage, sulfid stinker, is caused by *Desulfotomaculum nigrificans*, which produces hydrogen sulfide boun by the food or the can walls can become black. In the case of container leakage, usually mixed spoilage population develops, consisting of lactobacilli, enterococci and other ba teria. Recontamination through faulty sealing is often due to cooling with contaminate water. Post-contamination was responsible for the largest outbreak of salmonellosis in th history of the USA affecting some 160,000 to 200,000 people in Chicago (Ryan et al., 1957).

TABLE 17.6 Comparison of Parameters of Various Methods of Pasteurization

Method	Temperature °C	Time (min, s)
Batch (vat)	65	30 min
HTST	72	15 s
Ultra pasteurization	89–100	1 s
UHT	138	2 s

From Robinson (2002).

Investigation of spoilage is important in order to determine the causes and apply control measures.

Pasteurization

Compared to sterilization, pasteurizing is a comparatively low order of heat treatment, generally at a temperature below the boiling point of water. The general objective of pasteurization is to extend product shelf-life by inactivating all non-spore-forming pathogenic bacteria and the majority of vegetative spoilage microorganisms, as well as inhibiting or stopping microbial and enzyme activity. To be effective, pasteurization is frequently combined with another means of preservation such as concentration, acidification, chemical inhibition, etc.

In pasteurizing, two types of processes can be used: slow and rapid. Slow pasteurization uses pasteurization temperatures for several minutes; e.g. typical temperature–time combinations are 63 to 65°C over 30 minutes or 75°C over 8 to 10 minutes. Rapid, high or flash pasteurization uses pasteurization temperatures of about 85 to 90°C or more for a time only in the order of seconds. Typical temperature–time combinations can be 88°C (190°F) for 1 minute; 100°C for 12 seconds; 121°C for 2 seconds (Table 17.6).

Methods of high temperatures for short time (HTST) and ultra-high temperatures (UHT) for very short holding times have been developed, replacing traditional pasteurization or sterilization processes. Such short holding times and high temperatures require special equipment to ensure uniform heat treatment, and generally are applicable for liquid products. Taking into account the short time and rapid performance of operations, this can only be achieved in a continuous process, using heat exchangers. In this process the product is heated separately, then cooled down rapidly to the temperature for filling, which will be performed in aseptic conditions in sterile receptacles.

In aseptic technology, heating is applied prior to packaging. This will cause inherently less damage to food quality. It can be applied where the food (such as liquids) can be readily distributed for rapid heat exchange. However, these methods then require packaging under aseptic conditions to prevent recontamination. On the other hand, heating within the package frequently is less costly and produces quite acceptable quality with many foods, and most canned food products are heated in the package. In-line sterilization followed by aseptic packaging is gaining in popularity for heat treatment even in the traditional canning factories.

Pasteurization is commonly associated with milk for which it is used all over the w
For the pasteurization of milk temperatures below boiling temperature are typically
since at very high temperatures casein micelles will irreversibly aggregate (or "curd
There are two main types of milk pasteurization used today: the conventional batch me
by which the bottled milk goes through a heat treatment on a conveyor belt for the req
time (e.g. at 63°C for 30 min), and the high temperature short time (HTST) method by w
the milk is pasteurized at 72°C for 15 s using a continuous heat exchanger. In recent t
ultra-high temperature (UHT) is also used for milk treatment. It is in fact a sterilization
cess at 135°C for 2–5 s only before packaging of milk which is then filled into contai
aseptically. Nowadays, batch pasteurization of milk is rarely used in large companies
may be still used in smaller businesses and for foods other than milk (e.g. fruit juices). H
pasteurized milk typically has a refrigerated shelf-life of 2–3 weeks, whereas UHT milk
last much longer even unrefrigerated, sometimes 6–9 months. The HTST pasteuriza
should achieve a 5-log reduction in the number of viable microorganisms in milk, kil
almost all yeasts, mold, and common spoilage and pathogenic bacteria. UHT treatme
expected to destroy bacterial spores as well. Ultra pasteurization (UP) is a process sim
to HTST pasteurization, but using slightly different equipment and higher temperatu
UP pasteurization results in a product with longer shelf-life but still requiring refrigera
Pasteurization regimes for certain dairy products differ depending on the fat content of
product. Ice cream, dairy dessert mix, cream or processed cheese require more robust t
ment, e.g. 70°C for 25–30 min or 80°C for 25 s.

Products, including dairy products, are also heated very rapidly by steam injection
cooled down by evaporation of the same amount of water as was added by the inject
This is an ultra-fast process.

Pasteurization is also widely applied to various liquid and certain viscous and parti
lated foods such as juices, soft drinks, beer, cider, wine, cream and processed cheese, liq
eggs, syrups, sauces, soups and some ready meals. With many products, like fruit juices
soft drinks, it is the intrinsically low pH of the product which secures a long shelf-life a
the mild heat treatment. To be effective, pasteurization is frequently combined with anot
means of preservation such as concentration, acidification, chemical inhibition, etc.

Meat products, cured or uncured, are often subjected to pasteurization carried out
temperatures around 80°C for several minutes resulting in a limited shelf-life and the n
for refrigeration. Although cooking would destroy vegetative pathogens and most spoila
bacteria, heat-resistant lactobacilli and streptococci may survive, and psychrotrophic spec
may cause spoilage.

Most vegetables are low-acid products with pH >4.6 and have to be sterilized, w
the exception of pickles and fermented vegetables which represent high-acid produc
Acidified pickled products in salt brine with 0.6–1.0% vinegar and also containing sugar
pasteurized at 80–85°C. Tomatoes are fairly acidic with a pH value around 4.6 or less, her
they can be preserved by mild heat treatment generally with pasteurization. Tomato pa
is a common product which can be preserved by hot-filling at a temperature of 90–92
without further pasteurization. Fruit products, juices and preserves have generally low p
of 3.2–3.8, and are usually pasteurized at 70–75°C. This assures a 5-log cycle reduction
vegetative form of pathogenic bacteria; however, heat resistance of yeasts can be high
Hence, yeasts are the primary spoilage agents in fruit-based beverages and soft drink

Heat-resistant molds and alicyclobacilli may also survive pasteurization; however, being aerobic organisms, their spoilage potential in carbonated beverages is limited (Parish, 2006). Pasteurized fruit preserves (jams, jellies, marmalades) can be spoiled by certain fungal species with heat-resistant ascospores such as *Byssochlamys fulva*, *B. nivea*, *Neosartorya fischeri*, *Talaromyces flavus*, *T. bacillisporus* and *Eupenicillium baarnense* and some other *Eupenicillium* species (Beuchat and Pitt, 2000). Among other foods and beverages, pasteurization is widely used for beer filled and sealed in cans or bottles.

FACTORS DETERMINING HEAT TREATMENT

Since heating applied to destroy microorganisms may also exert adverse effects on the quality of foods, in practice a minimum possible heat treatment is to be used which can guarantee destruction of pathogens and toxins and give the desired storage life, but also retain the characteristic organoleptic properties of food products. This compromising requirement will determine the choice of heat treatment.

The heating (sterilization or pasteurization) process can be subdivided into three phases. By means of a heating medium (water or steam) the product temperature is increased from ambient to the required sterilization temperature (phase 1: heating phase). This temperature is maintained for a defined time (phase 2: holding phase). In phase 3 (cooling phase) the temperature in the product is decreased by introduction of cold water on the surface of the container.

In order to effectively and safely preserve foods using heat treatment, it is not enough to apply the required time–temperature combination to inactivate the most heat-resistant pathogens and spoilage organisms in a particular food. In addition to this, another factor should be also considered: the heat penetration characteristics in a particular food. In order for the heat sterilization to be efficient, the preservation processes must provide a heat treatment which will ensure that every particle of food within a container will reach a sufficient temperature, for a sufficient time, to inactivate the most resistant pathogens and the majority of spoilage organisms as well. It is usually the centermost particle, called the cold point, where the heat would penetrate least (Figure 17.5).

The course of temperature during thermal processing in a retort depends on several factors related to: (1) heating conditions (retort type, loading, time–temperature formula), (2) heating mode (still or agitated), (3) heating medium (water, steam, with/without overpressure), (4) product type (solid, liquid), and (5) container type, shape and size. The thermophysical properties of the product, in particular its consistency, will influence the mode of heat transfer, and are of utmost importance for the speed of heat penetration. Basically, heat will spread in solids by conduction and in liquids by convection; however, in real foodstuffs it is usually between the two extremes, and may change during the heating process. In the context of HACCP, determining the coldest point and monitoring temperature at this point is particularly important and from the above it can be understood that the coldest point is not always the center.

Heat penetration is extremely important, because it is the determining factor for the success of the whole operation. The most suitable and practical method to speed up thermopenetration is the movement of containers during the thermal process. Rotation of

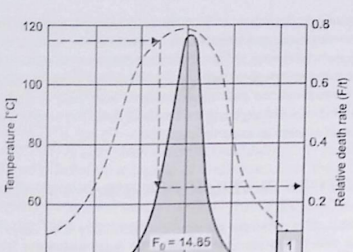

FIGURE 17.5 The slowest warming-up cold point in containers. Heat transfer is (a) by conduction, (b) by co vection. *Reproduced by the authorization of the Food and Agriculture Organization of the United Nations from Heat t Hautzinger (2007).*

containers around their axis is an efficient means to accelerate heat transfer, because this wi rapidly mix the contents, enabling a more uniform heating of products, and reducing hea ing time and organoleptic degradation. Heat penetration is slow, especially in the case of th pasteurization of products packed in glass containers.

In addition to the composition and moisture of the food, the acidity and pH value hav tremendous impact on the efficacy of heat preservation. It is customary to divide foods int groups concerning heat treatment according to their acidity. Acid foods have pH below 4. and low-acid foods are those with pH above 4.5. Acid foods include most fruits, and pa teurization would suffice for preservation; low-acid foods are those like meat and most veg etables, which should require sterilization treatment. Table 17.3 lists various types of food and their pH value, together with the heat processing requirements.

NON-TRADITIONAL HEAT TREATMENT

The conventional method of heat sterilization often leads to overcooking of the foo material causing unwanted loss of nutrients and organoleptic changes. Electric heat ing methods offer novel possibilities for sterilization providing better retention of quali attributes. Two types of electrical heating methods are known and have been practica explored: direct and indirect. In the case of the direct method electrical current is passe directly into the food (called ohmic heating, OH, or electrical resistance heating). With indi rect electroheating the electric energy is first converted to electromagnetic radiation whic subsequently generates heat within a product. These methods are microwave (MW) an radiofrequency (RF) heating (Figure 17.6) (Marra et al., 2009; Ramaswamy and Tang, 2008

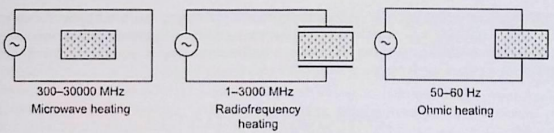

FIGURE 17.6 Schematic of electrical heating methods.

In OH the product is placed in direct contact with a pair of electrodes through which a low-frequency (50 to 60 Hz) electric current is transferred. Heat is generated due to the resistance of molecules to electrical conduction. Indirect methods apply much higher oscillating frequencies of electromagnetic waves – MW (300 MHz and 300 GHz) and RF (3 kHz–300 MHz) – which result in heating of dielectric materials by induced molecular vibration as a result of dipole rotation or ionic polarization. Changing polarity of electrical field forces oscillation of ions whose friction generates heat in the product. Movement of dipolar water molecules contributes mainly in heating due to the higher frequencies of MW. With OH an additional non-thermal effect is electroporation of cell membranes which might occur even under low frequencies (60 Hz) building up charges in the cell envelope (Lebovka et al., 2005).

OH and RF are used only for industrial purposes while MW is applied very commonly domestically and finds commercial application as well. Two frequency bands of MW are allocated in the USA. The 915 MHz band is used for industrial heating only, and the 2450 MHz band is used both in the industry and in domestic microwave ovens. Ohmic heating can be used for heating liquid foods containing large particulates, such as soups, stews, fruit slices in syrups and sauces, and heat-sensitive liquids. The technology is useful for the treatment of proteinaceous foods (e.g. liquid egg) which tend to denature and coagulate when thermally processed. Juices can be treated to inactivate enzymes with less destruction of the flavor. Other potential applications of ohmic heating include blanching, thawing, dehydration and extraction.

Due to their lower frequency levels, RF waves have a larger penetration depth than MW and hence could find better application in larger size foods. Cooking time of meat and meat products was found much shorter than conventional cooking in a water bath, and caused lower juice losses. RF radiation is also considered for post-harvest treatment and disinfestation of fruits. RF heating is also applicable for continuous flow processing of liquid foods such as fruit juices and milk.

Plastic packaging materials are transparent to microwaves. Microwaves can, therefore, be used to process prepackaged food products. Examples of in-package microwave sterilized products include different pasta dishes, pasta sauces, rice and other ready-to-eat dishes.

Electroheating has found many applications in the food processing industry, including tempering of frozen foods for further processing, precooking of meat, and finishing the drying of pasta products. In those applications, electric heating methods demonstrate significant advantages over conventional methods in reducing process time, improving food quality and reducing environmental impacts. Electric sterilization can have a major advantage over

conventional retorting because of the relatively short heating time and potential to pr high-quality self-stable food products. Increasing numbers of commercial equipment a on the market enabling more development in technology. Approaches are currently in opment for continuous flow processing with aseptic packaging.

COMBINED TREATMENTS

Consumers raise increasing demand for ready-to-eat, fresh, minimally processed f preserved by relatively mild techniques in order to minimize the loss of quality a control microbial growth, and thus ensure product safety. To meet this demand, a h approach appears to be the best method (Leistner, 2000; Alzamora et al., 2000). Hurdle nology is the term often applied when foods are preserved by a combination of process the design of hurdle technology several preservation systems can be applied by the co nation of factors such as temperature, water activity, pH, redox potential, preservatives packaging. Two or more preservation methods can be applied together in smaller deg that separately would not produce safe products. The combination can ensure not safety but also results in better, more natural quality, and is economic by saving energy is because different hurdles in a food often have an additive or synergistic effect. If sev hurdles are used simultaneously, a gentle preservation could be applied, which neverthe secures stable and safe foods of high sensory and nutritional properties. Using combi technologies, moreover, the diversity of products can be increased and new types of f can be developed. Conventional and novel thermal technologies are often combined w other treatments in order to moderate the severity of doses required if applied alone (Ukuku and Geveke, 2010; Liu et al., 2011).

Examples of hurdle technology for fruit and vegetable processing are the intermedi moisture fruit product (IM, containing two hurdles as pH and a_w), a high-moisture fr product (HMF, preserved by mild heat treatment, low pH and a_w, and/or preservative without refrigeration), as well as a minimally processed refrigerated fruit product (MP treated with mild heat, then packaged and refrigerated) (Barbosa-Cánovas et al., 2003).

Several types of meat products, mainly various sausages, are processed with the co bination of different preservative factors (mild cooking, low pH and a_w, nitrite or smok curing, fermentation, refrigeration) and usually can be stored at ambient temperatures for given time before organoleptic deterioration starts. They are called shelf-stable food (SSF and their stability is due to the synergistic interactions of preservative effects (Kanatt et al. 2002; FSIS-USDA, 2005).

Novel types of meat products and ready-to-eat dishes can be preserved by combine treatments when packaged under vacuum, heat pasteurized at mild temperatures for lon time then refrigerated. Sous-vide (French for "under vacuum") is the name of the metho of cooking food sealed in airtight plastic bags in a water bath for a long time (24 to 72 hour are usually applied) at an accurately determined temperature much lower than normall used for cooking, typically around 45–60°C (111–140°F). Sealing the food in sturdy pla tic bags keeps in juices and aroma that would otherwise be lost in the process. The use temperatures much lower than for conventional cooking is an equally essential feature o

sous-vide. In English these dishes are also called Repfed (refrigerated processed food of extended durability) emphasizing the third hurdle factor, i.e. low temperature storage.

These products can be stored for several weeks and are directly consumable. The mild but long heat treatment kills most vegetative bacteria. The stability and safety of sous vide products depend on the delicate balance of preservative treatments under strict hygienic conditions. Neither the cooking time nor the storage temperature provide, however accurately controlled, absolute safety for these kind of foods. In particular, spores of some strains of *C. botulinum* can survive mild cooking and grow and produce toxin at 3–5°C (Hyytiä-Trees et al., 2000). Hence, FDA suggests an additional hurdle (e.g. preservative) to be combined to ensure the safety of these foods.

A novel manufacturing technique has been suggested for the production of extended shelf-life (ESL) milk with fresh taste and prolonged stability of up to 4 weeks when distributed maintaining a cold chain. This method combines processing by microfiltration, pasteurization and subsequent refrigeration. Raw milk is separated into skimmed milk and milk fat, the former is microfiltered through caramic membranes (with pore size of 1.4 μm) and pasteurized thereafter (77°C for 30 s). The milk fat is heated at ultra-high temperature (125°C for 4 s) and then reverted to the skimmed milk. Packages should be stored at temperatures below 10°C. Various spoilage and pathogenic microorganisms (among them *B. cereus*) may survive or contaminate products post-process, hence jeopardizing the safety and stability of ESL milk (Elwele and Barbano, 2006).

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CHAPTER

18

Non-thermal Processing Technologies

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OUTLINE

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INTRODUCTION: IDENTIFICATION OF RISKS IN NON-THERMAL PROCESSES

Every food manufacturing and processing operation has inherent risks affecting th safety of food products. Non-thermally processed foods are not exempt from those risk which include, among others, incorrect process conditions, variability in microbial, chemica and physical characteristics of raw materials, post-processing contamination and mishan dling or abuse during packaging, storage, shipping and distribution.

The biological, chemical and physical risks must be assessed for each manufacturin process, considering the type of product and the involved technologies. Therefore, th information provided in this chapter should be considered as a starting point for a mor detailed analysis once a particular technology is identified to process a food product. Th uncertainties regarding specific biological hazards can be clearly stated based on the tech nology and the product and, consequently, the selection of proper processing condition and definition of critical process parameters can be made as well as the best way of moni toring them.

Overall Product Life Cycle

The first step in assessing the risks is to understand the overall product life cycle Figure 18.1 shows a general life cycle of a product manufactured using in-line non-thermal processes.

Each step along the manufacturing process must be designed to prevent contamination or to reduce the extension of the assessed risks. In terms of product life cycle, such objec tives require proper packaging of the raw materials, appropriate shipping and storage con ditions, protection of raw materials from insects or rodents, aseptic handling of the raw materials during dispensing, appropriate cleaning and sanitization/sterilization of process ing equipment, setup and operation of the equipment, controlled formulation and holding of the product prior and after non-thermal processing, packing of the product into sterile containers, integral container closures, proper storage of processed product, and proper dis tribution, retailing and handling of the product once in the market.

Assumption of the established good manufacturing practices (GMPs), hygienic plans and related safety tools by the different stakeholders of the food production chain are critical for the successful development and implementation of quality assurance plans. Their applica tion is recommended or even compulsory in most countries.

Raw Materials

The chemical and physical properties of the raw materials will define the microbiological characteristics of the formulated product, and in turn the shelf-life of the unprocessed prod ucts, the minimum process conditions required to ensure microbial safety after processing as well as suitable post-processing storage and handling conditions. Table 18.1 summarizes the chemical and physical properties typically associated with microbiological characteris tics of food products.

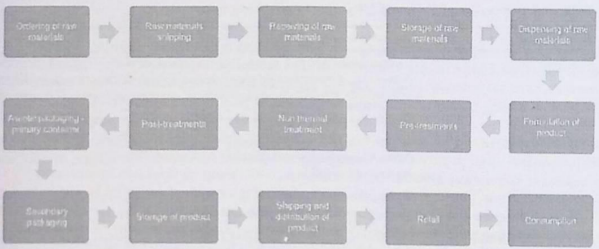


FIGURE 18.1 Overall life cycle of a product processed using non-thermal technology.

TABLE 18.1 Chemical and Physical Properties of Foods

Physical Properties	Chemical Properties
Solid	pH
Powder	Acidity and type of acid
Liquid	REDOX potential
Viscosity	Water activity
Aqueous	Protein content
Oil	Carbohydrate content
Internal structure (e.g. size distribution in emulsions)	Lipid content
	CO_2, O_2 concentrations
	Preservatives

The source and type of raw material will also have a determining influence on the kind of microorganisms that can grow in it. Table 18.2 summarizes the nature of microbial contamination related to different food products.

Non-thermal Food Processing

Food processing using non-thermal processes such as irradiation, pulsed electric fields, high-intensity pulsed light, high hydrostatic pressure, membrane filtration or a combination of any of these through a hurdle approach represents a change from the traditional heat processes that are well characterized. The technological advances associated with these processing methods and extensive scientific information demonstrating the ability of these methods for microbial inactivation provide assurance of their effectiveness in extending the shelf-life of food products. A key advantage of non-thermal processes is better retention of

TABLE 18.2 Typical Microorganisms in Food Products (ICMSF, 1998)

Food Products	Typical Microorganisms
Raw milk	Lactic acid bacteria, *Pseudomonas*, *Flavobacterium*, *Micrococcus*, *Bacillus*, *Enterobacter*, *Aeromonas*, *Alcaligenes*, viruses, *Salmonella*, *Yersinia enterocolitica*, *Campilobacter jejuni*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Escherichia coli*
Liquid eggs	Diverse mixtures of Gram-positive and Gram-negative bacteria
Cattle and sheep carcasses	*Salmonella* spp., *C. jejuni*, *E. coli*, *Bacillus cereus*, *L. monocytogenes*, *S. aureus*, *Clostridium perfringens*, *Pseudomonas*, *Acinetobacter*, *Psychrobacter*, lactic and acetic bacteria and yeasts
Raw marine fish	*Pseudomonas*, *Vibrio*, *Acinetobacter*, Coryneform bacteria, *Flavobacterium*, *Micrococcus*, Enterobacteriacae and yeast, *Anisakis simplex*
Raw vegetable products	Pseudomonads, *Erwinia carotovora*, coryneforms, spore-formers, coliforms and micrococci, several species of fungi, *B. cereus*, *L. monocytogenes*, *Clostridium botulinum*, *Cl. perfringens*
Raw fruits	Fungi, yeasts

TABLE 18.3 Risks Associated with Non-thermal Processes

Non-Thermal Process	Risks
Irradiation	Suboptimal irradiation dose, non-homogeneous treatment, damaged treatment containers
High hydrostatic pressure	Incorrect pressure setup or duration, too low and inhomogeneous temperatures, damaged treatment containers, contaminated treatment fluid
Pulsed electric fields	Incorrect pulse intensity strength or treatment time, too low temperature, non-homogeneous treatment, inadequate pre-decontamination of process line
High intensity pulsed light	Incorrect pulse intensity or treatment time, non-homogeneous treatment
Membrane filtration hurdle technology	Incorrect pore size, compromised membrane. Depending on the combination of technologies used

nutrients and sensory attributes close to those observed in fresh or minimally processed products. As previously mentioned, these methods have inherent risks involving the potential of microbiological contamination. Table 18.3 summarizes the risks associated with each method.

From a safety point of view, all the processing treatments mentioned above have been specifically designed to eliminate or reduce the likely occurrence of biologic hazards to an acceptable level. Therefore they must be considered critical control points (CCP) in any hazard analysis and critical control point (HACCP) program.

Packaging

Packaging of food products processed using non-thermal technologies such as pulsed electric fields, high-intensity pulse light and membrane filtration, or a combination of them, will require aseptic conditions. Aseptic packaging is not usually required for irradiated and high-pressure processed foods, which allow prepackaging of the product prior to the decontaminating step.

The use of aseptic techniques to package a product requires proper sanitization of the processing equipment. Failure to clean the equipment will result in cross-contamination or adulteration of the food product. Also, residues of the cleaning agents may represent a potential risk to food safety. Meanwhile, cleaning of the equipment may not suffice to protect the product quality. Sterilization of the processing equipment is often required to reduce or eliminate post-processing microbiological contamination. Proper sanitization or sterilization parameters must be developed and demonstrated to ensure the effectiveness in reducing or eliminating microbial contamination from the product contact surfaces.

Packaging containers must be compatible with the product and properly designed for the intended application or processing method. Containers used for products processed using pulsed electric fields, high-intensity pulsed light or membrane filtration must be sanitized or sterilized and protected from contamination prior to the filling operation. Meanwhile, containers used for products processed using irradiation or high pressure must keep their integrity throughout the processing steps and during the shelf-life of the product.

Distribution

Distribution of minimally processed food products requires proper controls to prevent spoilage or damage of the product. The main concern during distribution is the potential thermal abuse (exposure of a food product to extremely high- or low-temperature conditions). Product containers and shipping conditions are critical to protect the quality of a food. Product containers must withstand the shipping and handling process while maintaining their integrity.

NON-THERMAL TREATMENTS FOR FOOD PRESERVATION

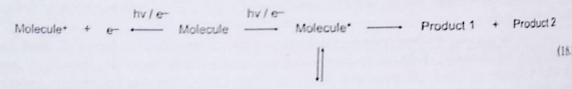
In this section we will discuss the requirements for monitoring the manufacturing process, the critical control points and critical process parameters for each of the technologies being discussed.

Irradiation

Principles

Irradiation requires transferring energy from high energetic sources such as unstable isotopes or machine-powered irradiators to food products to inactivate/kill microorganisms so that biologic hazards are eliminated or reduced up to acceptable levels.

The isotopes used for food processing are ^{60}Co and ^{137}Cs: both irradiate γ-ray Meanwhile, electron beams or X-rays are produced by electrical devices. All of them ha the capability to randomly excite and ionize molecules, hence the name ionizing radiatio (WHO, 1997):



(18.1

Being the most common component of many foodstuffs, water is a good example to show the chemistry of radiation. The products formed from water radiolysis are displayed in th following equation:

$$H_2O \xrightarrow{h\nu/e^-} H_3O^{\bullet} + HO^{\bullet} + H^{\bullet} + e^- + H_2 + H_2O_2 \qquad (18.2$$

In summary, irradiation triggers the formation of highly unstable compounds, radicals which are involved in several chemical transformations before yielding stable compound (Steward, 2001). These transformations are associated with the inactivation of microorgan isms. The extension of chemical changes on specific molecules is proportional to both th received irradiation dose and the compound's molecular weight (Miller, 2005).

The mean-life of the radiolysis species does not exceed a few milliseconds even though the low stability of such compounds could affect biological pathways of food microorgan isms disturbing the cellular homeostasis. However, the most direct effect on unwanted microorganisms occurs when ionizing radiation damages their DNA. Despite microbial repairing systems, some injuries lead to cellular death or inhibition of cellular reproduction (Dickson, 2001). Biological sensitivity to radiation can be measured as *D*-values, as occurs with thermal treatments.

Irradiation is not an intended step to reduce or eliminate physical and chemical hazards even though it should be kept in mind that some risks could come from interac tions between irradiation and exogenous agents. Releasing of chemicals (e.g. leachates) from the food package or the carrier system are examples of such interactions (Arvanitoyannis, 2010).

Critical Factors and Critical Limits

The described biological effects of the irradiation treatments are related with the spatial and temporal distribution of the energy transmitted by the ionizing radiation as well as with the degree of absorption of such radiation by the food product. Consequently, the criti cal parameters of the irradiation treatments are the dose (*D*, Gy), and exposure time (*t*, s) at every position in the product. Exposure time should be long enough to ensure the deliv ery of the minimum required dose to achieve the expected effects, without reaching a dose whose adverse effects compromise the product quality or even the throughput efficiency

TABLE 18.4 Estimated D_{10}-values for Common Organisms Subjected to Ionizing Radiation Treatments (Miller, 2005; Garcia-Gonzalez et al., 2007)

Type	Organism	Medium	Temperature (°C)	D_{10}-value (kGy)
Virus	Hepatitis A	Clams, oysters	Ambient	4.8
Non-spore-forming bacteria	*Campylobacter jejuni*	Ground beef	Ambient	0.15
	Listeria monocytogenes	Poultry meat	12	0.49
	Escherichia coli	Mechanically deboned chicken meat	10	0.23
	Salmonella Enteritidis	Low-fat ground beef	Ambient	0.7
	Staphylococcus aureus	Low-fat ground beef	5	0.75
Spore-forming bacteria	*Clostridium botulinum*	Beef stew	Ambient	1.5
	Clostridium perfringens	Water	Ambient	2.1
Yeasts and molds	*Aspergillus flavus*	Growth culture	Ambient	1.0
	Trichosporon cutaneum	Fresh sausage	Ambient	1.0
Parasites	*Entamoeba hystolytica*	Water, fresh fruit and vegetables	Ambient	<0.1
	Cysticercus bovis	Beef	Ambient	0.4
	Trichina spiralis	Pork	Ambient	0.1
Insects	Fruit fly	Fresh fruit	Ambient	0.15

of the facility. Both factors, dose and treatment time, depend on target, product and device parameters to provide safe products:

- Biological agent-dependent variables
  - Natural resistance: development stage, DNA reparation systems.
- Product-dependent variables
  - Product nature: composition, density, state, frozen or packaged goods, presence/absence of oxygen.
  - Geometry: shape and depth.
- Processing device variables
  - Source system: radioactive/electric generator device, emission energy or intensity.
  - Scanning system: single/multiple.
  - Conveyor system: continuous/batch processing equipment.

Assuming that the product receives a homogeneous dose of radiation, parasites and insect elimination require typically less than 1 kGy. Doses between 1 and 10 kGy are needed to destroy vegetative microorganisms. If sterilization is required, more than 10 kGy should be delivered. Minimum values and applications are legally defined in each country where ionizing radiation treatments are allowed for food applications (Table 18.4).

As far as maximum levels of irradiation are concerned, exhaustive studies for several dec ades concluded that no upper dose limit needs to be imposed, and that irradiated foods ar deemed wholesome throughout the technologically useful dose range from below 10kGy t envisioned doses above 10kGy (WHO, 1997). Such studies also revealed that the compound produced after excessive irradiation cause severe changes in the sensory characteristics of th product. Furthermore, the compounds found in such overprocessed products were very simila to those observed on products after a severe thermal treatment. This fact suggests that the maxi mum dose levels should comply with GMPs in countries without government maximum limits

Monitoring

The measurement of the dose received by the product, both spatially and temporally, is the best way to monitor the irradiation process since it could change due to some factors which are more prone to change than others. Namely, the processing device variables are typically part of the design of the facility, thus well known and usually difficult to change. One paradigmatic example is the depletion of irradiation intensity with time when using isotope devices. Others, like those variables depending on the product characteristics, are commonly less homogeneous even though more easily modifiable.

Even so, there are several options to monitor the dose. Radiation dosimeters are the most direct solution and commonly used by industry. As there are several kinds of dosimeters, a way to control product dose could be by inserting a reference dosimeter on each piece of product. However, they are often very expensive and difficult to maintain, and they should usually be operated by trained people. Therefore the approach used in some facilities is to use reference dose measurements during the setup stage when a profile of the dose as a function of external dosimeters is mapped. Of course, reference dosimeters should be periodically inserted into the product or into a good product simulator in order to achieve proper data. Such information is the reference to link the external dosimeter measurements with the real dose received by products under real processing conditions. External dosimeters tend to be cheaper and more easily maintained than reference dosimeters. Moreover, they allow online data acquisition (Miller, 2005).

If the facility operates under design conditions, the described monitoring procedures should be enough. However, any product or device changes will require an exhaustive study to confirm that the minimum dose is homogeneously received prior to the commercial distribution of the product.

Supercritical Fluid Technology

Principles

This technology is grounded on the known inhibitory effect of carbon dioxide on microbial growth (García-Gonzalez et al., 2007) (Table 18.5). The effect is enhanced by maintaining such gas under specific environmental conditions, known as supercritical fluid (SCF) conditions, using pressure values between 5 and 30 MPa (Demazeau and Rivalain, 2011).

The mechanism of the bacteriostatic effect of CO_2 is still under discussion, even though the current working hypothesis states several steps:

- Solubilization of pressurized gas in the external liquid phase.
- Cell membrane modification.

TABLE 18.5 Examples of Susceptibility of Different Bacterial Species to Supercritical Carbon Dioxide Treatments on Several Media (Garcia-Gonzalez et al., 2007)

Target Microorganism	Solution	Process Conditions	Reduction
Saccharomyces cerevisiae	Hydrophilic filter paper disks	5 MPa, room temp., 420 min	3D
Listeria innocua	Growth medium	20.5 MPa, 34 °C, 36 min, 3 cycles	3D
		20.5 MPa, 34 °C, 36 min, 6 cycles	9D
Staphylococcus aureus	Growth medium	20.5 MPa, 34 °C, 36 min, 3 cycles	3D
		20.5 MPa, 34 °C, 36 min, 6 cycles	7D
Salmonella Salford	Growth medium	20.5 MPa, 34 °C, 36 min, 3 cycles	3D
		20.5 MPa, 34 °C, 36 min, 6 cycles	3D
Pseudomonas aeruginosa	Growth medium	20.5 MPa, 34 °C, 36 min, 3 cycles	6D
Escherichia coli	Growth medium	20.5 MPa, 34 °C, 30 min, 3 cycles	8D
Proteus vulgaris	Growth medium	20.5 MPa, 34 °C, 36 min, 3 cycles	8D
Legionella dumnifii	Growth medium	20.5 MPa, 40 °C, 90 min, 6 cycles	4D
Pseudomonas aeruginosa	Physiological saline	7.4 MPa, 38 °C, 2.5 min	7D
Bacillus subtilis	Physiological saline	7.4 MPa, 38 °C, 2.5 min	7D
Escherichia coli	Sterile water	20 MPa, 34 °C, 10 min	2.5D
Staphylococcus aureus	Sterile water	20 MPa, 34 °C, 10 min	3.5D
Saccharomyces cerevisiae	Phosphate buffer solution	7.4 MPa, 38–40 °C, 10 min	5.8D
Serratia marcescens	Phosphate buffer solution	7.4 MPa, 38–40 °C, 0 min	7.3D
Bacillus subtilis	Phosphate buffer solution	7.4 MPa, 38–40 °C, 2.5 min	7.6D
Saccharomyces cerevisiae	Grape juice	48.3 MPa, 25 °C, 5 min, 85 g/kg CO_2	5.1D
Candida stellate	Grape juice	48.3 MPa, 25 °C, 5 min, 85 g/kg CO_2	5.6D
Kloeckera apiculata	Grape juice	48.3 MPa, 25 °C, 5 min, 85 g/kg CO_2	3.7D

- Key enzyme inactivation and cellular metabolism inhibition due to pH reduction and direct effect of carbon dioxide or hydrogen carbonate anion such as promotion of disorders of the cellular homeostasis.

Other inert gases (N_2, N_2O, CF_2-CF_2, Ar, and mixtures between them) have been studied as a way to avoid chemical reactions promoted by carbon dioxide that could modify product characteristics. However, such gases yielded poorer results and few sensory and nutritional comparison studies have shown significant differences with unprocessed foods (Garcia-Gonzalez et al., 2007).

Critical Factors and Critical Limits

Apart from the type of gas, the most critical variables of the supercritical fluid tech ogy are, obviously, pressure, temperature (usually 20–40°C) and treatment time. Pres and temperature affect gas properties such as its solubility, density and therefore its di sion into cells. Time allows controlling in part the extension of the treatment effects. Cri values of the treatments should be considered on a case-by-case basis because the inhe variability of other external factors such as the nature of the food (physical state of the f product, chemical and physical properties), the pressurizing system if an auxiliar trans ter medium is used, and the microbial susceptibility (Spilimbergo et al., 2011).

High Hydrostatic Pressure

Principles

High pressure affects biological constituents and systems (Cheftel, 1995). On foods, it h been studied as a physical agent on high hydrostatic pressure (HHP) treatments, which us a range of pressures between 100 and 1200 MPa. The technology has the same advantage irradiation in the sense that it allows the treatment of solids, liquids and either packaged unpackaged goods. If packed prior to the treatment, it reduces the possibilities of microbi contamination after processing. Conversely to irradiation though, the treatment is inhe ently homogeneous and independent of the shape of the product because pressure chang are instantaneously and isotatically transmitted (Doona and Feeherry, 2007).

Otherwise, the HHP technology does not allow continuous processing since after th product is placed into a vessel containing the pressure transmission medium, the vess should be kept closed up to the end of the required treatment. The main characteristics o the treatment are the come-up, holding and down times, the pressure level and the tem perature of pressure processing. There exists a temperature variation (around 3–9°C) fo each pressure change (100 MPa) due to the fact that work is applied in adiabatic condition (Patazca et al., 2007).

High pressure affects microbial communities by changing cell morphology, damaging cel membranes and walls as well as by disturbing some key enzyme structures and metaboli pathways. Membrane permeabilization is considered a direct consequence of membran thinning by compression. Vacuolar compression and ribosome dissociation have also been reported (Considine et al., 2008). The technology does not deliver enough energy to break any covalent bond, so there are very few chemical reactions. Therefore changes of enzymatic activities are related with modifications of the second or upper structural layout (Palou et al., 1999; Balny and Masson, 1993). Similar processes occur in food cells. On a liquid product such an effect should not cause any concern but on solid products such treatments are often aimed at achieving texture changes rather than ensuring food safety (Table 18.6).

The discussed critical variables (treatment time and pressure) can be easily monitored online. Temperature should also be supervised because it plays a quantifiable role, as occurs with other non-thermal technologies. Furthermore, temperature does not possess the iso tropic behavior of pressure (Grauwet et al., 2010). Therefore it can be monitored selecting any of the different methods developed for thermal processing such as tracking the cold

TABLE 18.6 Bacterial Barotolerance Differences and Medium Influences (Rajkovic et al., 2010)

Pathogen	Food Product	Treatment Conditions	Log_{10} Reduction
Escherichia coli O157:H7	Apricot juice (pH 3.8)	250 MPa, 5 min, 30°C	4.85
	Orange juice (pH 3.76)	250 MPa, 5 min, 30°C	5.1
	Sour cherry juice (pH 3.3)	250 MPa, 5 min, 30°C	5.28
	Apple juice (pH 3.5)	500 MPa, 5 min, 20°C	5
	Tomato juice (pH 4.1)	500 MPa, 5 min, 20°C	5
	Orange juice (pH 3.8)	500 MPa, 5 min, 20°C	1–2
	Raw minced meat	700 MPa, 1 min, 15°C	5
	Hungarian salami	600 MPa, 6 min, 25°C	>4
Listeria monocytogenes	Human milk	400 MPa, 1.5 min, 31°C	≈6
	Turkish white cheese	600 MPa, 5 min, 25°C	4.3–4.4
	Raw milk	500 MPa, 10 min, 20°C	>4
	Fish slurry	400 MPa, 5 min, 20°C	≈3
Campylobacter jejuni	UHT whole milk	325 MPa, 10 min, 25°C	≈2.5
	UHT skim milk	325 MPa, 10 min, 25°C	≈2.5
	Soya milk	325 MPa, 10 min, 25°C	≈3
	Chicken puree	325 MPa, 10 min, 25°C	≈3.5
	Phosphate buffer	325 MPa, 10 min, 25°C	8
	Milk	300 MPa, 10 min, 20°C	0.4–1
	Broth	300 MPa, 10 min, 20°C	3–6.7
	Chicken meat slurry	200 MPa, 10 min, 20°C	0.2–2.2

spot in every treatment or performing a previous analysis to guarantee a constant effect. Package or food envelop integrity should be controlled previously rather than after the treatment if the value of the product is worth it.

Critical limits should be defined taking into account the great deal of interactions between food product and microbial susceptibility. Typical reported treatments to deal with hazardous microorganisms in vegetative form use from 300 to 600 MPa at ambient temperature for several minutes. Spores, as usual, have enhanced resistance needing more pressure and temperature. A smooth treatment followed by a harder one could first activate sporulated forms to subsequently destroy them in a vegetative state. Nevertheless the effectiveness of multiple pressurization stages is still under study. A large dependency on the processed product is being reported. A similar disparity is observed for foodborne viruses (Donsi et al., 2010).

High hydrostatic technology is currently applied in several areas of the food industry (fruit juices, ham, salsa dips) in countries that have regulated the use of this technology, e.g. USA and the EU. This fact should help to promote this technology as well as confirm that it is safe enough to be used on other food fields.

Monitoring

The measurement of the applied pressure and the treatment time are basically the main parameters monitored during HHP. Meanwhile, temperature is a secondary parameter as enhanced inactivation will be obtained with changes in temperature.

Pulse Electric Fields

Principles

The idea of using electric power to improve food safety is older than other well-established non-thermal technologies such as irradiation. It was at the end of the 19th century when the first patents of devices designed to deliver electric current to flowing food products were issued.

Technical advances have shown that using electric fields instead of electric currents yields better results. The technology is based on the fact that external electric fields with field strengths of 20–80 kV/cm of predefined duration induce an opposing membrane potential between the internal and external surfaces of the cellular membrane. Quick modifications of the external electric field such as obtained by waveform or polarity changes produce stress on the membrane as cells try to compensate the changes on the external electric field. A long enough treatment can exhaust cellular resistance, inducing pore formation in the membrane, which destroys cellular homeostasis and eventually leads to cell death.

Electric fields also induce movements of the ionic components of the foodstuffs being processed that produce friction and, consequently, heat. Thermal effects could be used if they are properly controlled, even though temperature increase is usually avoided by shortening the electric field treatment in repeated pulses in the range of microseconds (1–10 μs) as well as by using refrigerating systems. In addition, the PEF processing treatment lasts only a few milliseconds and thermal consequences for the remaining components of the food are often negligible (Soliva-Fortuny et al., 2009).

From a food safety standpoint, the technology has been studied in a variety of goods providing promising results and a feasible alternative to thermal pasteurization, especially because it is one of the few non-thermal preservation technologies that allow continuous processing of fluid foods. However, the standardization of PEF treatment conditions still under investigation. At this time, inactivation of microorganisms using PEF continues to be product microorganism specific, which hinders the use of PEF at the industrial scale (Table 18.7).

Critical Factors and Critical Control Points

The processing step within a PEF device should be considered as a biological critical control point if there is not any further biological control point. The critical parameters to keep under control can be classified as in the previous cases (device dependent, food dependent and microbial dependent factors).

TABLE 18.7 Process Parameters used for the Inactivation of Pathogenic Microorganisms in Fluid Foods by PEF Treatment (Mosqueda-Melgar et al., 2008)

Microorganism	Food	E (kV/cm)	n^a	τ^b (μs)	t_t^c (μs)	F (Hz)	T (°C)	Log_{10} Reductions
Listeria innocua	Orange juice	30	6	2.0	12	–	54	6.0
	Skim milk	41	63	2.5	157.5	3	37	3.9
	Liquid egg	50	32	2.0	64	3.5	36	3.4
	Whole milk	29	312	0.8	250	100	36	2.0
	Dairy cream	37.5	250	1.0	250	100	36	2.0
Listeria monocytogenes	Whole milk	30	400	1.5	600	1700	50	4.0
	Skim milk	20	10	3.25	32.5	–	35	1.0
Escherichia coli	Liquid egg	26	100	4.0	400	2.5	37	6.0
	Orange juice	30	6	2.0	12	–	54	6.0
	Liquid egg	32.89	180	0.17	30	–	20	4.7
	Milk (1,5% fat)	23	20	–	–	–	45	4.0
Escherichia coli O157:H7	Apple cider	90	10	2.0	20	–	42	5.91
	Apple juice	29	43	4.0	172	1000	42	5.0
	Skim milk	41	63	2.5	157.5	3	37	4.0
	Liquid egg	11	40	2.0	80	1	60	4.0
Escherichia coli 8739	Apple juice	29	43	4.0	172	1000	42	5.4
Bacillus cereus	Skim milk	31	20	–	6.0	–	25	0.7
Staphylococcus aureus	Raw milk	40	40	–	–	3.5	–	4.0
	Skim milk	35	124	3.7	459	250	40	3.7
	Skim milk	31	35	–	6.0	–	25	3.0
	Skim milk	35	600	4.0	2400	100	25	1.0
Salmonella Typhimurium	Orange juice	90	50	2.0	100	–	55	5.9
Salmonella Dublin	Skim milk	35	164	1.0	164	2000	50	4.0
Salmonella Enteriditis	Eggs white	35	8	–	–	900	–	3.5

[a]Number of pulses.
[b]Pulse width.
[c]Treatment time.

The most important factors to achieve the expected effects during PEF treatments are t electric field strength, the initial temperature and the total treatment time measured the sum of the duration of all the delivered pulses. Typically, the longer the treatment tim the higher the microbial destruction that is achieved. Regarding the electric field streng (*E*) mathematical equations have been developed to predict the threshold values dependi on the form factor of the specific microbial targets (Heinz et al., 2002).

Spherical shaped cells:

$$\Delta\varphi_M = -\frac{3}{2} \cdot E \cdot f(\theta) \cdot R \cdot \cos\alpha \quad (18.$$

Ellipsoidal shaped cells:

$$\Delta\varphi_M = -f(A) \cdot R \cdot E \quad (18.$$

where $\Delta\varphi_M$ is the critical membrane potential (typically −1 V), R is the distance from the cente of the cell, α is the angle between the cell and the applied electric field vector, and $f(\theta)$ an $f(A)$ are functions of the electrical conductivities and the semi-axes considered.

Other electrical factors such as the pulse repetition rate and the pulse shape and width ar quite important as they influence how the energy is delivered to the target microorganism However, such parameters modulate the efficiency of the process rather than modify t enhance the treatment effects. Some processing factors exert influence on the homogeneit of the treatment. The most important studied are the flow regime, the specific distribution o the electric field vector with regard to the fluid flow, the number of treatment chambers and the circulation cycles of the product through the PEF device (Pataro et al., 2011). The ricl homogeneous treatment of solid goods is the main difficulty when using PEF technology o products containing solid particles of heterogeneous size.

The natural PEF resistance of the occurring microbial species and characteristics inherent to the foodstuff, such as electric conductivity and homogeneity (presence of particulate sol ids or bubbles) are the remaining critical parameters that should be specified before decid ing the critical limits for all the described critical factors.

Monitoring

Electric field strength and total treatment time can be measured and controlled online since they come from an electrical device. Flow rate governs the homogeneity of the treat ment and is managed by means of pumps that can also be controlled without effort with the currently available technology. Therefore, the whole PEF equipment can be easily linked to current computational machines. Keeping these parameters under the critical limits selected and established in the HACCP system should be enough to maintain safety of the processed product under control. The main consideration on PEF is that each system is specific in its design (e.g. number of chambers, incidence of the electric field on the food flow) and may not be modified, which requires a good understanding of the raw materials and products processed under PEF. Therefore, microbial and food characteristics must be well understood to ensure successful processing of the food product.

An important aspect that should not be forgotten is that electrodes can undergo corro sion, releasing chemicals to the product flow. All performed studies have shown that this

fact should not raise any toxicological concern because of the alternating nature of the pulses (Morren et al., 2003). Nevertheless, routine inspection of the electrode status should be considered. The monitoring could include a visual inspection of the electrode thickness, a scanning of the electrode surface or the measurement of the electrical conductivity of the treated food before and after the treatment chamber.

Intense Pulsed Light

Principles

Pulsed light is considered an updated version of a treatment with continuous ultraviolet germicidal light (UV-C). In pulsed light treatments, light pulses produced by xenon lamps are released in the form of ultra-short-duration flashes of an intense broadband emission spectrum from approximately 200 to 1100 nm (López-Gómez et al., 2007).

Intense light pulses has recently received much attention as a strategy for decontaminating food, packaging, water and air (Oms-Oliu et al., 2010). Furthermore, pulsed light technology is a strong candidate for contact surface decontamination in the healthcare setting (Farrell et al., 2010).

The photochemical damage to microbial DNA, either on vegetative cells or spores, was claimed as the cause of UV-C treatment effectiveness (Guerrero-Beltrán et al., 2004). A similar inactivation mechanism is defined for pulsed light as it is rich in this kind of wavelength (200–280 nm). However, the fact that applied light also contains visible and near-infrared photons suggests the possibility of a thermal effect that is also debated. Both mechanisms could coexist because the lethal effect of the photochemical process between both modes of application should not be so different, but there will be a more reduced product processing time.

Critical Factors and Critical Control Points

The most important factors related to the treatment devices affecting the efficacy of pulsed light decontamination are the number of light pulses applied, or exposure time, and the dose received by the product, also known as fluence (J/m^2). Actually, these are the same process variables affecting irradiation because both technologies share the use of electromagnetic fields as agents to deliver energy to the product. The dose received in intense pulsed light treatments is more dependent on factors such as the lamp discharge intensity, the distance from the lamp to the treated surfaces, shading effects and product thickness than irradiation, because ultraviolet photons are less energetic than photons of either X-rays or γ-rays.

Consequently, the critical factors to be controlled are the same as those discussed in irradiation although, with current technology, dosimeters are different and pulsed light devices can be much handier.

Regarding microbial resistance, much of the aspects to be considered are the same as discussed in other non-thermal technologies. Every microorganism has a particular behavior in front of pulsed light treatments. Moreover, the photo-reactivation phenomenon, consisting on the activation of the photolyase enzyme, which is able to repair damaged DNA by light, needs to be considered. As far as food composition is concerned, a consistent decrease of effectiveness on media containing proteins and fats has been reported (Garcia-Gonzalez et al., 2007) (Table 18.8).

TABLE 18.8 Examples of Differences between Microbial Susceptibilities as well as Product Interactions using Intense Pulsed Light Technology (Martín-Belloso and Soliva-Fortuny, 2010; Rajkovic et al., 2010)

Pathogen	Food Product	Treatment Conditions	Log_{10} Reduction
Escherichia coli O157:H7	Agar	3 J/cm^2, 200 pulses, 100 ns	6.2
	Agar	7 J/cm^2, 50 pulses, 30 μs	4.7
	Agar	3 J/cm^2, 512 pulses, 1 μs	6.8
	Salmon fillets	5.6 J/cm^2, 180 pulses	1.09
	Alfalfa seeds	5.6 J/cm^2, 270 pulses	4.89
	Apple cider	1.05 J/cm^2, 12 pulses, 360 μs	3.22
	Apple juice	1.05 J/cm^2, 12 pulses, 360 μs	2.52
	Strawberries	Total energy dose 64.8 J/cm^2, 180 pulses	3.3
	Raspberries	Total energy dose 72 J/cm^2, 180 pulses	3.9
	Blueberries	Total energy dose 32.4 J/cm^2, 180 pulses	4.9
Listeria monocytogenes	Agar	3 J/cm^2, 200 pulses, 100 ns	4.4
	Agar	7 J/cm^2, 50 pulses, 30 μs	2.8
	Agar	3 J/cm^2, 512 pulses, 1 μs	6.25
	Agar	1.5 J/cm^2, 1 pulse, 300 μs	1.6
	Salmon fillets	5.6 J/cm^2, 180 pulses	1.02
	TSBYEa	7 J/cm^2, 20 pulses, 30 μs	≈1.5
Serratia marcescens	Milk	12.6 J/cm^2, 20 ns	>2.0
Staphylococcus aureus	Milk	1.27 J/cm^2, 16 pulses	7.2
Clostridium sporogenes	Honey	5.6 J/cm^2	0.89–5.46
Foodborne viruses	Phosphate buffer	1 J/cm^2	4.8–7.2
Cladosporium herbarum	Paper-polyethylene packaging material	0.977 J/cm^2, 30 pulses	2.7
Listeria innocua	Stainless steel surfaces	1.27 J/cm^2, 3 pulses	1.93–2.77

Monitoring

The measurement of the applied light intensity, number of pulses, frequency of pulsed light and overall treatment time are basically the main parameters monitored during pulsed light treatments.

Membrane Filtration

Principles

Membrane filtration allows fluid components to be separated according to their size, and in some cases this effect can be modified by interactions between the fluid components and the filtering surface. Membrane filtration technology is usually classified following the average cut-off pore diameters of the membranes. To achieve what is known as cold pasteurization, microfiltration (MF) technology, with diameter pore sizes between 0.1 and 10 μm, is used. This application is used as an alternative to thermal treatments in milk, either skimmed or not, beer, wine and fruit juice processing (Moraru and Schrader, 2009). It is possible to achieve fluid sterilization with ultra-filtration (UF) membranes that can separate even viruses, although it is only applicable to clear fluids, typically water.

The main constraint of using membrane technology is the presence of food particles and components that are retained during the filtration process. Nevertheless, there has been interest recently in combining such technology with other non-thermal preservation technologies, particularly in the dairy products area (Walkling-Ribeiro et al., 2011; Hoffmann et al., 2006; Fritsch and Moraru, 2008).

Critical Factors and Critical Control Points

From the point of view of safety assurance, the critical variables of this technology are pore size, filtration time, flow rate and trans-membrane pressure. Of course, the critical limit in this case is the size of the smallest microbial agent targeted. However, this factor is really difficult to control. Therefore, some variables related with mean pore size must be monitored in order to verify the effectiveness of the treatment:

- Permeate flow (J), measured as the permeate, which is the portion of the feed that passes through the filter, velocity (Q_p) and the effective surface area (A_e) of the membrane:

$$J = {}^{Q_p}/_{A_e} \tag{18.5}$$

- Trans-membrane pressure (TMP), which is a variable of the utmost importance, as the separation is pressure driven.
- Transmission and separation efficiency of a particular component or membrane selectivity, which can be easily monitored (Dewettinck and Le, 2011).

An indirect way to monitor the size and uniformity of pores in the membrane is through integrity testing procedures (e.g. bubble point, diffusive flow, forward flow, water intrusion). These tests are related to the ability of the membrane to retain microorganisms.

Monitoring

Filtration time, flow rate and trans-membrane pressure must be monitored throughout the filtration process. Integrity of the membrane shall be confirmed before and after the filtration step to ensure its effectiveness in removing microorganisms from the process stream.

Hurdle Technology

Principles

Briefly, the hurdle concept relies on the combination of techniques that act upon food and process intrinsic and extrinsic factors with the aim of controlling all forms of quality deterioration (Leisner and Gould, 2002). As the worst form of quality deterioration from the human standpoint is the presence or growth of infectious or toxigenic microorganisms, the main priority is the minimization of such risks and, consequently, this section will only discuss aspects related to microbial safety. However, it should be borne in mind that hurdle technology could go further – it could even be used to better preserve quality aspects of the product such as microbial stability or sensory and nutritional food properties (Tapia de Daza et al., 1996).

The hurdle approach is not new, only the term is recent. The technology has been in use for a long time, as fermented foods and other kinds of food commodities like cured meats, fruit preserves or jams demonstrate. Actually, it is necessary for the vast majority of food products to use it to meet consumers' expectations. Other names such as "multi-target preservation," "combined methods" or even "minimal processing" have been suggested and used to describe this technology.

The main difference between traditional and novel food products is that historically the knowledge used to produce foods in a safe way was achieved following trial-and-error experimental methodology. The current knowledge on microorganisms and the ecology of food products allows not only understanding the mechanisms and factors affecting the shelf-stability of food products, but also optimizing the different hurdles for quality improvement.

There are families of food products that traditionally use a specific set of hurdles. Cured meats typically have to use a combination of preservatives and reduced water activity to be safe for long periods of time. Processed meat products such as sausages introduce mild thermal treatments and/or need to be stored under refrigeration. Recently developed food products such as ready-to-eat fruits and vegetables require a combination of chemical preservatives, low temperature and modified atmospheres to maintain product safety over the whole product shelf-life (Martín-Belloso and Soliva-Fortuny, 2010).

Consumers are currently demanding these types of convenient products, so mild non-thermal technologies such as described here are studied so that they can be applied in combination with traditional preservation methods (Soliva-Fortuny et al., 2011). Some review reports are available regarding the state-of-the-art application of hurdle technology on other important goods such as fresh meats (Zhou et al., 2010) or dairy products (Sobrino-López and Martín-Belloso, 2008), for example (Table 18.9).

Critical Factors and Critical Control Points

Critical factors of food products processed by hurdle technology depend on the combination of chosen technologies. The election of the technologies to preserve a food product is influenced basically by its nature as there are multiple hurdles that kill microorganisms and avoid microbial proliferation. The most commonly used are pH, water activity, use of preservatives, electric potential, competitive flora, physical barriers, modification of atmospheric conditions and physical treatments, either thermal or not. To add more complexity

TABLE 18.9 Example of Combined Effect of Gamma Irradiation and Modified Atmosphere (Map) on Enterobacteriaceae Populations in Chopped Chicken Meat Stored at 4°C (Choulíara et al., 2008)

Storage Time (day)	Air Packaging (control)	Air packaging +2 kGy	MAP 1	MAP 2	MAP 2 + 2 kGy
0	2.28 ± 0.13 Aa	2.28 ± 0.13 Ab	2.28 ± 0.13 Aa	2.28 ± 0.13 Aa	2.28 ± 0.13 Aa
3	3.99 ± 0.24 Bb	<1.00	3.28 ± 0.21 Bb	2.76 ± 0.24 Ab	<1.00
6	6.15 ± 0.48 Cc	<1.00	4.85 ± 0.36 Bc	3.27 ± 0.17 Ac	<1.00
9	7.48 ± 0.51 Cd	<1.00	5.98 ± 0.39 Bd	4.08 ± 0.27 Ad	<1.00
12	ND	<1.00	6.42 ± 0.46 Bde	5.29 ± 0.51 Ae	<1.00
15	ND	1.29 ± 0.06 Aa	7.02 ± 0.52 Be	6.71 ± 0.49 Bf	<1.00
20	ND	2.88 ± 0.14 Bc	ND	ND	<1.00
25	ND	ND	ND	ND	1.91 ± 0.15 Aa

MAP 1: 30% CO_2 + 70% N_2; MAP 2: 70% CO_2 + 30% N_2; ND: not determined.
Different capital and lowercase letters in the same row and column respectively are significantly different ($p < 0.05$). Measures expressed as mean values and standard deviation in log cfu/g.

each hurdle can be modified with different agents usually in close relation with other hurdles. Thus, organic acids reduce pH as well as acting as chemical preservatives. A reduction of water activity of a product can be achieved by drying, freeze-drying, heating or by adding fat, salts or sugars to the raw product.

As already stated, hurdle technology requires an accurate case-by-case study in order to select the appropriate critical factors to be controlled. As a general rule of thumb, at least all the critical process factors of every technology used should be considered.

Regarding the decision to select critical limits for the critical parameters, there are tools that can help in such hard task due to the multiple possible combinations. Predictive microbiology attempts to provide mathematical models of microbial growth under a variety of environmental conditions (e.g. temperature, pH, a_w and the effect of preservatives). The current discussion focuses on whether the effects of a combination of hurdles are independent or interact with each other (Biesta-Peters et al., 2010). However, as prudence suggests a specific analysis for the particular combination of technologies on a certain product, the data gathered in such analysis will resolve any discussion (Figure 18.2).

If the monitored variables are the same as used for each technology the monitoring procedures should obviously be the same. Even so, during the analysis of a particular combination of technologies it would be possible to find some repetitions of the measurements. For example, in the preparation of a ready-to-use vegetable soup, it seems reasonable, *a priori*, to consider acidity a critical variable because it will prevent *a posteriori* microbial growth due to cross-contamination, even though it is thermally processed before packaging. Consequently, a measure of the pH of the media is decided. The designed preparation could also require that a natural preservative and potassium sorbate are selected. The preservative concentration can be related to a pH measurement. So, both variables could be controlled by monitoring only the pH of the media at the end of the process before aseptic bottling. It is part of the

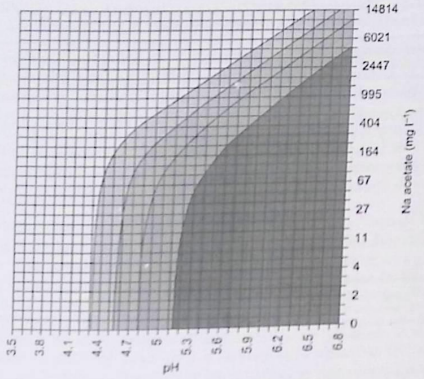


FIGURE 18.2 Example of a product stability map of total sodium acetate and pH for a cocktail of *Enterobacter sakazakii* developed using predictive microbiology (Lambert and Baldas, 2007).

tasks of the safety management group to decide the best solution to such particular issues as well as whether other factors should be controlled and at what stage.

VERIFICATION AND VALIDATION METHODS FOR NON-THERMAL TECHNOLOGIES

Current quality management systems are flexible enough to allow the same tools to be used to achieve both goals product safety and product quality without compromising the efficacy of the system. Actually, product safety can be considered, from a certain point of view, as the most basic aspect of product quality. Furthermore, a quality system can achieve its objectives irrespective of the area where it is applied, the processed product and the technologies used in the manufacturing process when it is properly designed and implemented. There are particular issues with specific technologies. For example, irradiation allows processing packaged products and differences between unprocessed and processed products are not easily appreciated. This point evidences the importance of the complementary measures that stakeholders should implement such as GMP, hygiene plans, preventive maintenance systems aimed at avoiding equipment failures or, in this case, an inventory system that should prevent release of non-irradiated goods.

Process verification implies a comparison of the current process variable values with the established critical limits of each critical variable of the non-thermal preservative

technology. Process verification method is now highly automatic thanks to the recent advances in computers. It is quite possible to follow the manufacturing process via online physical measurements over chemical and microbiological ones. The latter methods are more suitable to confirm the relationship between the live or logged measures and the real values. This step corresponds to process validation.

In summary, the election of particular verification and validation solutions should be taken after a careful analysis of the specific requirements of the regulatory requirements as well as product quality specifications. Conversely, economic aspects should be evaluated while considering each technology to ensure a proper balance between financial goals and the production of safe products.

FINAL REMARKS

Non-thermal food preserving technologies should not add any complexity to a well-implemented quality and safety management system. Such systems are based on scientific knowledge and the critical factors of each technology have been, in most cases, already clearly determined. The main safety concern arises from the natural variability of biological systems that hinders the election of the critical limits for these variables.

The best way to solve such problems is to obtain specific data of each combination of product and process so the appropriate decision is made while defining the criticality of process variables (e.g. process limits). Meanwhile, food processors must consider the limitations associated with non-thermal processes.

Consumers are aware of the pros and cons of thermal processes and ask manufacturers for better products. This usually means more convenient foodstuffs with the added value of reduced nutritional and sensory losses because safety must be inherent in a food product. However, the novelty of non-thermal technologies and the fact that they are, by far, more specific than thermal technologies, gives consumers a feeling of insecurity. Therefore, stakeholders should provide their customers with proper information about the safety and added benefits of the products manufactured using non-thermal technologies if they want to promote their social standing (Olsen et al., 2010).

Last but not least, there is currently a concern within the scientific community, and also among food processors and legislators, that the application of sublethal stress factors could induce cross-resistance mechanisms in the surviving populations and change their virulence characteristics (Capozzi et al., 2009). This concern should motivate food industry stakeholders not only to design proper safety (quality) management systems but to implement them adequately. Such management systems provide the tools (validation) to monitor any possible deviation from what can be considered a normal microbial behavior irrespective of the preservation technology used.

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CHAPTER

19

Acids and Fermentation

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OUTLINE

INTRODUCTION: ACIDITY AND PH

Acidity is one of the fundamental taste characteristics of food. The term itself derives from the Latin *acere*, meaning to taste sour, and consumers can readily detect acidity in foods as well as quantify it in terms of the degree of sourness.

In chemical terms, an acid, as defined by Arrhenius in 1884, is a substance that yields hydrogen ions (protons)* in solution while a base yields hydroxyl ions. This definition was later broadened independently by Brønsted and Lowry in 1923 to encompass non-ionic reactions by defining an acid as a proton donor.

When dealing with food materials we are primarily concerned with aqueous systems. In pure water a very small proportion of the water molecules dissociate into protons and hydroxyl ions:

$$H_2O \leftrightarrow H^+ + OH^-$$

The concentration of the two ionic species is equal (10^{-7} mol/L) and their product (the dissociation constant or ion product of water) is constant at 10^{-14}. If an acid is dissolved in

*Strictly speaking it is not a free hydrogen ion or proton but a solvated hydronium ion (H_3O^+).

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water then the equilibrium changes and the concentration of hydrogen ions increase acidity of the solution increasing with the level of hydrogen ions, while that of hyd ions decreases correspondingly to maintain the ion product at 10^{-14}.

While it might be preferable in some respects to describe acidity in terms of hydroge concentration, the huge range over which it can vary means that in practice a logarit scale is more useful. This is the pH scale, proposed in 1909 by Sørensen who was wor appropriately enough, in a food-related laboratory at the Carlsberg Brewery in Denm He defined pH as the negative logarithm of the hydrogen ion concentration, c_{H^+}:

$$pH = -\log c_{H^+}$$

From the above, it follows that the pH of pure water is 7 (at 25°C). A pH below 7 i cates acidic conditions where the concentration of H^+ exceeds that of OH^-, and a above 7 indicates alkaline conditions where the concentration of OH^- is more than that H^+. Thus a very acidic solution with a H^+ concentration of 1 mol/L would have a pH o For most practical purposes the pH scale normally ranges between 0 and 14, although can extend beyond that, and most foods have a pH on the acidic side of neutral rang between 2.0 and 7.0 (Figure 19.1).

In practice pH is generally measured in the form of an electromotive force generat in an ion selective glass electrode and is a response to the activity of hydrogen ions rath than their concentration. Activity is related to concentration by a proportionality constan the activity coefficient γ. The activity coefficient is affected by factors such as temperatu and ionic strength. In very dilute solutions γ approaches 1 and activity and concentrati become equal.

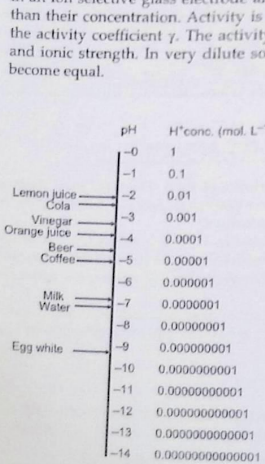

FIGURE 19.1 Most foods have a pH on the acidic side of neutral ranging between 2.0 and 7.0.

Strong acids such as hydrochloric and sulfuric dissociate completely in water to produce protons and the negatively charged counter ion but many of the acids encountered in food are described as weak acids which only partially dissociate:

$$HA \leftrightarrow H^+ + A^-$$

The extent to which acids dissociate, and hence their strength, is defined by the position of this equilibrium:

$$K_a = \frac{[H^+][A^-]}{[HA]}$$

the larger the equilibrium constant K_a, the greater the degree of dissociation and the stronger the acid.

As with hydrogen ion concentrations and pH, the range of values taken by K_a is very large so that a logarithmic scale of pK_a is used for convenience where:

$$pK_a = -\log K_a$$

Some representative values of pK_a for acids frequently encountered in foods are presented as Table 19.1.

The dissociation behavior of weak acids is described by the Henderson–Hasselbalch equation:

$$pH = pK_a + \log\frac{[A^-]}{[HA]}$$

TABLE 19.1 pK_a Values of Some Common Food Acids and Preservatives

Acid	pK_a
Acetic (ethanoic)	4.75
Propionic	4.87
Lactic	3.86
Sorbic acid	4.75
Citric	3.14, 4.77, 6.39 (tribasic)
Benzoic	4.19
Parabens	8.5
Phosphoric	2.12, 7.21, 12.67 (tribasic)
Carbonic	6.37, 10.25 (dibasic)
Nitrous	3.37
Sulfurous	1.81, 6.91 (dibasic)

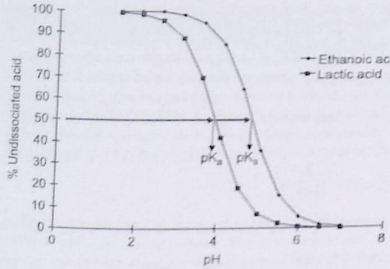

FIGURE 19.2 Dissociation of lac and ethanoic acids as a function of pH.

This equation relates the strength of an acid and the pH of the solution with the re tive concentration of dissociated and undissociated forms of the acid. It can be represent graphically for individual acids as shown in Figure 19.2 for ethanoic acid and lactic ac This shows that as the pH of a solution decreases then the concentration of the undisso ated acid will increase for all acids, and that for weaker acids, the undissociated proporti at any given pH will be higher than for stronger acids, i.e. those with a lower pK_a. A simp rule to remember is that when the pH is equal to an acid's pK_a, then the concentration dissociated and undissociated forms will be equal; as the pH decreases below this then th level of undissociated acid increases.

ACIDITY AND FOODS

Acids are common components of food systems. Citric, malic and tartaric acid, among others, occur naturally in fruits and vegetables. Lactic acid produced by endogenous enzymatic activity is responsible for the postmortem acidification of meat. Adipic, citric, ethanoic, fumaric, gluconic, lactic, malic, succinic and tartaric acids are available commercially and are permitted for use as food acidulants, and acid preservatives such as benzoic acid and sorbic acid can be added to a range of food products such as jams, bread and cakes. Phosphoric acid, a relatively strong acid, is an important ingredient in soft drinks such as colas.

Lemon and lime juice, which contain citric acid, are used in products such as ceviche, some salad dressings and pickles, but traditional procedures to acidify foods and confer keeping quality and safety usually employ acids of microbial origin. The preserving power of vinegar is due to its high content of ethanoic acid. It is produced by a double fermentation process in which sugar is first converted into ethanol by yeast and a second aerobic stage in which acetic acid bacteria oxidize the ethanol to ethanoic acid.[†] Vinegar can be

[†]Edible grade acetic acid produced from petrochemical sources can also be used as an alternative to vinegar in some products. In contrast, citric acid used as a substitute for lemon juice in some circumstances is produced by a microbial fermentation.

produced with ethanoic acid concentrations in excess of 10% (most table vinegars would contain 4–5% w/v) and was the strongest acid known in antiquity. Addition of vinegar to a food material can thus considerably reduce its pH, inactivate some of its indigenous microflora and restrict the growth of those that survive.

The efficacy of acid solutions, such as vinegar, added to foods will be reduced by the diluting effect of the food's water content and by its intrinsic buffering capacity.

In many traditional products the effect of the former is mitigated by osmotic dehydration (salting) or drying of raw materials prior to pickling. While it is relatively straightforward to calculate the effect on pH of dissolving known concentrations of an acid in water and, knowing the pH, to calculate degree of dissociation of a weak acid using the Henderson–Hasselbalch equation, it is not possible to make such simple calculations of the pH resulting from addition of a weak acid such as ethanoic to the complex and ill-defined buffering system in a food. In addition to the presence of a range of buffering components such as proteins and amino acids, the issue may be further complicated by the presence of oil or fat into which the acid might partition preferentially. This would have the effect of decreasing the acidity in the aqueous phase in which microbial growth occurs and thereby the anticipated antimicrobial effect. The problem can be resolved on a purely empirical basis using test formulations but a more *a priori* approach has been described to both the problem of pH prediction and phase partitioning based on an acid titration of the food material and knowledge of the dissociation constant and the phase partition constant of the acid being used (Wilson et al., 2000).

ACIDITY AND MICROORGANISMS

The acidity of a medium will affect chemical and physicochemical reactions, the stability and activity of enzymes and other cellular components and as a consequence will affect the activity, growth and survival of microorganisms. A particular microorganism will be capable of growth over a range of pH usually spanning 2–5pH units but will grow best over a much narrower range, typically 1–2pH units. Different microorganisms will grow best at different pH values, but in general bacteria grow fastest in the pH range 6.0–8.0, yeasts 4.5–6.0 and filamentous fungi 3.5–4.0, although there are some notable exceptions to this.

In practical terms, the reduction of pH and an increase in acidity can have a profound effect on the microflora associated with a particular food, its shelf-life and safety. It is a commonplace observation that acidic foods such as yoghurt or fruit juices spoil as a result of the activity of more acid tolerant organisms such as yeast and molds. This effect is also seen in the greater prevalence of bacterial spoilage in vegetable products when compared to more acidic fruits where yeast and mold spoilage predominate.

Microbial susceptibility to acidity is not simply a function of the external pH but a result of the acidification of the microbial cytoplasm. Although microorganisms may tolerate external pH values that are lower than their optimum, most will strive to maintain a higher pH in their cytoplasm to ensure that the complex network of processes that comprise metabolism and growth continue to operate efficiently. The microbial cell membrane is relatively impermeable to protons and this is an important factor in maintaining the cell's intracellular pH, but microorganisms also have a battery of homeostatic mechanisms to neutralize or expel protons that enter the cell and thus help maintain a favorable internal pH.

Acids differ in their ability to acidify the cytoplasm so microbial inhibition will de
the particular acid present as well as the pH. It is well established that weak organic
much more effective at inhibiting microorganisms than strong acids. This is a conse
of the physicochemical properties of weak organic acids. They only partially disso
solution giving a mixture of undissociated acid, protons and the acid anion. In their
sociated state they are often relatively lipophilic and can diffuse through cell mem
down a concentration gradient from high levels outside the cell to lower levels inside
inside the cell, where the pH is higher, the acids dissociate releasing protons and acid
the cytoplasm. This imposes a burden on the cell's homeostatic mechanisms, and e
has to be expended to maintain the intracellular pH. At low levels of acidity, this dra
of resources results in slower growth, but the burden may become excessive in which
growth is no longer possible and the cell will eventually die.

Viruses only multiply after they have infected a susceptible cell therefore those of
cern to human health will not grow in foods. They can be inactivated (killed) by low p
a food material but are more resistant than bacteria since they are structurally much sim
and do not show the enhanced sensitivity to weak acids displayed by bacteria and other
lular microorganisms.

CONTROL OF PATHOGENS BY PH AND ACIDITY

Table 19.2 presents the minimum recorded pH values for a number of important bac
rial pathogens. Because pH values below 4.5 will stop or severely curtail the growth of all th
major bacterial pathogens and will, depending on the conditions, lead ultimately to their death
inactivation, food safety concerns tend to be much reduced when considering acidic foods. This
is particularly true since the production of such foods often also includes a step equivalent to
pasteurization such as hot bottling which is used primarily to control spoilage organisms. It is
mostly where there is no pasteurization step that safety problems can arise (see later).

Acidity and pH play an important role in the safe production of shelf-stable heat-
processed (commercially sterile) products such as canned foods. The major safety concern
here is that spores of *C. botulinum* will survive the heat process, germinate and grow in the
product during storage at ambient temperature producing the neurotoxic botulinum toxin.
It has long been recognized that *C. botulinum* spores will not germinate and grow at pH
values below 4.6 and this is enshrined in various codes of practice. Acidity is used as a basis
of classifying canned foods since those with a pH below 4.6 will require a less severe heat
process to assure safety (e.g. CAC, 1979).

Levels of acidity which do not kill pathogens or stop their growth entirely can still
improve food safety. The risk from infectious pathogens such as *Salmonella* will be lower if
growth and thereby numbers of the organism are restricted and, at suboptimal pH, toxigenic
organisms such as *Staphylococcus aureus* may not grow to levels sufficient to produce a biologi-
ically effective concentration of toxin in the food. This is exemplified in EU regulations where
food safety criteria for milk powder and some cheeses specify that only when levels of coag-
ulase positive staphylococci exceed 10^5 cfu g^{-1} is there a requirement to test for enterotoxin.

At acidic pH levels where growth is still possible predictive models such as Combase
(http://www.combase.cc/index.php/en/) or the Pathogen Modelling Programme

TABLE 19.2 Minimum Recorded pH Values for a Number of Important Bacterial Pathogens

Pathogen	Minimum Growth pH[1]	Optimum Growth pH
Bacillus cereus	5.0	6.0–7.0
Campylobacter jejuni	4.9	6.5–7.5
Clostridium botulinum		
Group 1	4.6	–
Group 2	5.0	–
Clostridium perfringens	5.5–5.8	7.2
Escherichia coli	4.4	6.0–7.0
Listeria monocytogenes	4.4	7.0
Salmonella	3.8	7.0–7.5
Shigella	4.9–5.0	9.2–9.3
Staphylococcs aureus	4.0	6.0–7.0
Vibrio cholerae	5.0	7.6
Vibrio parahaemolyticus	4.8	7.8–8.6
Vibrio vulnificus	5.0	7.8
Yersinia enterocolitica	4.2	–

[1]Data from ICMSF (1996).

(http://pmp.arserrc.gov/) can give predictions of the rate of growth under different pH conditions (as well as the effect of interaction with other factors such as temperature and water activity). These models are designed to be fail-safe so that they tend to overpredict the growth that will occur under any given set of conditions. While valuable, labor-saving tools to the food microbiologist in setting critical limits, these should be used with caution where food safety issues are concerned. Confirmation of predicted safety, particularly at the growth/no growth boundaries, may often be required using the gold standard technique of a challenge trial.

The Committee of the Mayonnaise and Condiments Sauce Industries of the EU (CIMSCEE) published formulae that predict the level of acid, salt and sugars necessary to inhibit microorganisms in cold-filled acid-preserved pickles and sauce products. One of these predicts stability, i.e. the levels of acid, salt, etc. required to inhibit the growth of spoilage organisms and confer shelf stability, while the other predicts safety. It is impossible to predict safety in any absolute sense; where this is attempted it is done on the basis of a food safety objective (FSO) that gives what is regarded as an acceptable level of protection. Ideally these should be based on some form of quantitative microbiological risk assessment which determines the level of risk and the effect of various interventions on that risk. Although not supported by such a rigorous analysis, in the CIMSCEE formulation a safe product was designated as one in which viable numbers of *E. coli* will decline by more than 3 log cycles (a factor of 10^3) in less than 72 hours at 20°C.

The formula is:

$$15.75(1-\alpha)(\%\text{ total acetic acid}) + 3.08(\%\text{ salt}) + (\%\text{ hexose}) + 0.5(\%\text{ disaccharide}) + 40(4.0 - \text{pH}) = \Sigma_s$$

where $(1-\alpha)$ is the proportion of undissociated acetic acid and α is the proportion of sociated acid given by the Henderson–Hasselbalch equation:

$$pH = pK_a + \log\frac{\alpha}{(1-\alpha)}$$

If $\Sigma_s > 63$ then the product would be regarded as intrinsically safe, i.e. it would deliver least the designated reduction in *E. coli*.

Though generally a very reliable guide to product formulation and the setting of cr cal limits, experimental studies and evidence from outbreaks have shown that survival greater at low temperatures (chill stored products) and that higher levels of salt and sug can also sometimes be protective (Mullan, 2009).

FERMENTED FOODS

A huge range of foods rely on the endogenous production of organic acids by lactic acid bacteria (LAB), principally lactic acid but often with lower concentrations of ethanoic acid. Although LAB produce a number of other antimicrobials such as bacteriocins which may be significant in some circumstances, the number of different species active in lactic fermentations indicates that the principal antimicrobial effect is something common to all lactic acid bacteria. This common factor is that the main mode of energy generating metabolism in these organisms is the fermentative conversion of sugars into acids, principally lactic acid. Acid production and a simultaneous reduction in pH are inevitable consequences of LAB growth and acidity levels in some fermentations can exceed 100 mM, reducing the pH to below 4.0 in weakly buffered systems (Adams, 2001).

Bacteriocins are polypeptide antimicrobials produced by bacteria which are bactericidal to other, normally closely related, organisms. Lactic acid bacteria produce a number of bacteriocins and considerable efforts have been devoted to their discovery and investigation in recent years. Despite this attention, the most effective and useful bacteriocin in food use remains nisin, a lantibiotic bacteriocin produced by some strains of *Lactococcus lactis* and first discovered as long ago as 1928. Its pre-eminence derives from its relatively broad spectrum of activity. Unlike many other bacteriocins from lactic acid bacteria, it is active against most Gram-positive bacteria and is particularly effective at inhibiting the outgrowth of bacterial endospores. In terms of its potential contribution to food safety, it can inhibit the outgrowth of spores of pathogens such as *Clostridium perfringens*, *Clostridium botulinum* and *Bacillus cereus* but also (at higher concentrations) has some inhibitory effect on vegetative pathogens such as *Listeria monocytogenes* and *Staphylococcus aureus*. However, where a nisin-producing strain is used in production of a fermented food its contribution to overall safety may be relatively minor. It will have no effect of Gram-negative pathogens. Vegetative Gram positives such as *Listeria monocytogenes*

are known to acquire resistance to nisin quite readily and *S. aureus* is among the most inherently resistant Gram-positive species. It is more likely to be useful where there is a risk of *C. botulinum*, although usually this organism can be well controlled by efficient acid production. Nisin production may also have a detrimental effect on fermentation by inhibiting other nisin-sensitive lactic acid bacteria present and adversely affecting acid production.

For *in situ* production of lactic acid by fermentation to have a significant antimicrobial effect there must be high levels of active lactic acid bacteria present and a substantial numerical superiority over competing organisms. To ensure this, large numbers of active starter must be introduced either in the form of commercial deep frozen or freeze dried concentrates, a pre-grown starter culture or by using techniques such as back-slopping where material from a previous successful batch containing high levels of organism is retained and introduced to initiate a new fermentation. A starting level of at least 10^6 cfu g^{-1} is required to guarantee a successful fermentation. Anything that interferes with this, such as the presence of antibiotics, santizer residues or bacteriophage active against the starter will inhibit the fermentation and possibly give rise to a food safety threat.

The rate of pH drop and its final value in lactic acid fermentations depend on a number of factors such as the buffering capacity and water activity of the medium, the temperature and duration of fermentation and the activity of the lactic culture. Ideally the target pH would be around 4.5, although this in not achieved in many common fermented foods such as cheese. Even in very weakly buffered media the pH would tend to bottom out around 3.8 as lactic acid production produces a lactate buffer. Maximum effect will also be achieved if the pH drop occurs rapidly, within hours, to prevent any pathogen growth occurring, but this is less important if the raw material has been pasteurized or if other inhibitory factors are present to restrict the development of pathogens.

FOOD SAFETY PROBLEMS WITH ACIDIC FOODS

Acidic products are not immune from safety concerns; failure to achieve critical limits for pH/acidity can permit the growth/survival of pathogens and there have been some notable outbreaks of foodborne illness involving acid foods.

The most common scenario when problems arise can be viewed, in some respects, as an apparent violation of the hurdle or multiple barrier concept where two antimicrobial factors antagonize rather than supplement one another. A barrier used to slow or arrest growth – nearly always low-temperature storage – reduces the lethal effect of acidity. In mildly acidic foods chill storage will act in concert with the reduced pH to inhibit growth but some form of pasteurization may be necessary to prevent survival and assure safety. In more acidic foods where there is no pasteurization step and the acidity is potentially bactericidal, the survival time of a pathogen can be extended by low temperatures. There have been several examples of where this situation has applied over the years.

Fermented meats contain a high-risk raw material and have been associated with several outbreaks of illness. In the 1990s outbreaks associated with verotoxin-producing *E. coli* in the United States and Australia led the US Food Safety Inspection service to require any fermented sausage process to assure a 5log reduction in the final product. Numerous studies showed that processes as applied in the USA achieve a 1–3log reduction although this could

be increased by ambient storage or by a heat processing step. This reinforced obser made after an outbreak that occurred in England in 1987/1988 when 101 people were a by *Salmonella* Typhimurium DT 124 in a salami stick product. The subsequent invest found that the fermentation process itself did not reduce the numbers of surviving Sal cells even though the pH dropped below 5.0. Numbers of survivors dropped durin sequent storage, the rate increasing appreciably the higher the temperature of storag product had a 6-month shelf-life at ambient and this is how it was generally stored else in Europe where no cases were reported. In England, however, the product was gen stored along with other cold meats at chill temperature and it was hypothesized that pe the lower storage temperature had allowed the salmonella to survive.

A similar scenario is apparent in outbreaks of illness associated with fruit juices: sa nellosis in unpasteurized orange juice and *E. coli* O157 in unpasteurized apple juice (U cider). The initial contamination originated with the fruits used to express the juices, the pH <4.0 would generally be sufficient to inactivate the organism but low-temperature age was essential to give the unpasteurized product a reasonable shelf-life. It also permit the survival of the enteric pathogens sufficiently long enough to cause illness.

A number of outbreaks of salmonellosis caused by home-made mayonnaise w reported during the epidemic associated with *Salmonella* Enteritidis and poultry towards end of the 20th century. The product was made using citric acid or vinegar, oil and eg contaminated with *Salmonella* Enteritidis. Mindful that it is generally advised to keep read to-eat foods chilled, the product was refrigerated soon after production thus prolonging t survival of the *Salmonella* cells and increasing the risk of transmitting illness.

Unlike products such as fermented meats, the textural properties of cheese are n unduly affected by pasteurization of the raw material (milk), though many would claim tha the flavour of raw milk cheeses is superior. Pasteurization to eliminate vegetative pathogens in the milk is therefore an important critical control point in assuring production of a safe cheese. It has, however, been associated with numerous outbreaks of foodborne illness over the years (see Table 19.3 for some examples) and in many cases inadequate pasteurization or use of/contamination with raw milk has been a factor.

A pH protective against the growth or survival of pathogens will be ineffectual in situa tions where a pH-stable toxin is produced elsewhere and added to the acidic product. This was the case in an outbreak of botulism caused by hazelnut yoghurt where *C. botulinum* had grown and produced toxin in the hazelnut purée used to flavor the yoghurt base (see Table 19.3). It is easy to envisage how similar situations could arise elsewhere and serves as a plangent reminder of the need for vigilance with the safety of ingredients.

Raw fish marinaded in lime juice (ceviche) was associated with the spread of pandemic cholera in South America in the early 1990s. Laboratory studies on the ability of *Vibrio cholerae* to survive in ceviche were contradictory and would clearly vary with factors such as the level of acidity, the temperature and the elapsed time between preparation and consumption. Involvement of ceviche in the pandemic could well reflect, in part, a similar variability in the method of production used.

Many parasites (helminths and protozoa) have complex life cycles involving stages that show marked resistance to adverse environmental conditions. They can occasionally be foodborne when they are acquired mainly through consumption of raw or undercooked foods. Processes such as fermentation or pickling are usually insufficient to prevent their

TABLE 19.3 Examples of Foodborne Disease Outbreaks Associated with Fermented Foods

Implicated Food	Causative Agent	Cases	Reference
Plant products			
Paste of soybeans and wax gourds	*Clostridium butyricum*	6	Meng et al. (1997)
Pruno	*C. botulinum*	5 (2 outbreaks)	Vugia (2009)
Fermented milks			
Yoghurt	*C. perfringens*	167	MOH (1993)
Hazelnut yoghurt (hazelaut purée was contaminated)	*C. botulinum*	27	O'Mahoney and Mitchell (1990)
Süzme (condensed yoghurt, Turkey)	*C. botulinum*	10	Akdeniz et al. (2007)
Fermented meats			
Semi-dry sausages	*E. coli* O111:NM	23	CDC (1995a)
Nahm (Thai fermented pork)	Trichinella	27	Khamboonruang and Nateewatana (1975)
Fermented goat (Korea)	*C. botulinum*	5	Tseng (2009)
Salami stick	*Salmonella* Typhimurium	85	Cowden et al. (1989)
Salami	*E. coli* O157	23	CDC (1995b)
Fermented fish			
Seal flipper	*C. botulinum*	1	Shaffer et al. (1990)
Salmon fish heads	*C. botulinum*	8	Shaffer et al. (1990)
Salmon eggs	*C. botulinum*	15 (7 outbreaks 1971–1984)	Hauschild and Gauvreau (1985)
Salmon eggs	*C. botulinum*	4	CCDR (2002)
Cheeses			
Soft cheese	*Salmonella* Berta	82	Ellis et al. (1998)
Cheese	*S.* Enteritidis	~700	CCDR (1999)
Goats' milk cheese	*S.* Paratyphi	273	Desenclos et al. (1996)
Soft cheese	*S.* Dublin	42	Maguire et al. (1992)
Cheddar cheese	*S.* Heidelberg	339	Fontaine et al. (1980)
Mozzarella cheese	*S.* Typhimurium	321	Altekruse et al. (1998)
Cheese	*E. coli* O157	22	The Pennington Group (1997)
Cheese (Brie, Camembert)	*E. coli* O27 H20	170	Altekruse et al. (1998)
Cheese (Brie, Camembert)	*C. botulinum*	27	Pourshafie et al. (1998)

(*Continued*)

TABLE 19.3 (Continued)

Implicated Food	Causative Agent	Cases	Reference
Mexican-style soft cheese	*Brucella melitensis*	31	Altenkruse et al. (1998)
Hand-pressed direct set cheese	*Staphylococcus aureus*	16	Altenkruse et al. (1998)
Cheese	*Shigella sonnei*	50	Sharp (1987)
Hard cheese	*S. Typhimurium*	>200	Van Duynhoven et al. (20
Cheese	*Staphylococcus aureus*	23	Ostyn et al. (2010)

(Adapted from Motarjemi, 2001).

transmission but data on the incidence of parasitic infections associated with fermen or pickled products are sparse. There is, however, some association between, for exam salami and trichinosis and the Thai fermented fish product som-fak and *Gnathostoma*. Ma parasites are susceptible to freezing and, in the absence of cooking, frozen storage is a re ognized control measure to eliminate, for example, *Trichinella* in pork destined to be used fermented meats and *Anasakis* in fish to be lightly pickled or fermented.

CONCLUSIONS

Acidity can be a potent factor in ensuring safe food. Depending on the level, it can inhibit both the growth and survival of pathogens, and there are several useful predictive tools that can help us assign critical limits for acidity. Care must be exercised, however, when there is reliance on the inactivation of contaminating pathogens by low pH and this is combined with hurdles that slow or arrest microbial metabolism such as chilling, salting or drying. In such situations unacceptable survival of a pathogen may occur.

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CHAPTER

20

Chilling and Freezing

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OUTLINE

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INTRODUCTION

There is no strict definition of what constitutes a chilled food. In general, it covers any food in which the temperature of the food is reduced to, and maintained at, a temperature below that of the ambient temperature; but above the temperature where any of its water content will change from a liquid to a solid (i.e. begin to freeze). In many foods the initial freezing point will be around −1 °C; however, in food with a high salt content (such as bacon) or sugar content (such as desserts) the initial freezing point may be as low as −10 °C or even lower. At chilled temperatures (generally between −1 °C and +14 °C) the growth of microorganisms occurs only slowly and food spoilage and deterioration reactions are inhibited to such an extent that food quality is preserved for extended periods. This can range from a few days to many weeks. However, chilled foods are perishable and they deteriorate progressively throughout their life. For many foods the maximum chilled shelf-life will be achieved at a temperature close to their initial freezing points. However, for some foods, such as bananas and other tropical fruit, low temperatures cause damage, and the optimum temperature can be as high as +14 °C.

Below the initial freezing point of a food detrimental reactions that promote food spoilage and limit quality shelf-life are significantly retarded, and in the case of microbial growth will be inhibited at temperatures below −12 °C (for the large majority of foods). Providing the food is of a safe quality prior to freezing, as long as the temperature remains below −12 °C during storage, there will be no growth of pathogenic microorganisms so the food will remain safe. Frozen storage life will be limited by physical and biochemical reactions, which although slow will continue to take place at frozen temperatures, and which ultimately affect the quality of the frozen product. The rates of these reactions are a function of temperature, so the frozen storage life will generally be longer at lower temperatures. Many of these changes will be accentuated if recommended conditions of handling, production and storage are not maintained. A frozen food has a "safe" storage and distribution life that can be measured in years when compared to the days or months of a chilled product. Once thawed, however, any microbes present can again become active, and under the right conditions will multiply to levels that can lead to food-borne illness. The production of safe frozen foods requires the same attention to good manufacturing practices (GMP) and hazard analysis and critical control point (HACCP) principles as the chilled or fresh counterpart.

The cold-chain (Figure 20.1) consists of two distinct types of operation. In processes such as primary and secondary chilling or freezing the aim is to change the average temperature of the food. In others, such as chilled or frozen storage, transport, and retail display, the prime aim is to maintain the temperature of the food. The basic requirements for the production and supply of safe chilled and frozen foods are no different to those needed for other foods. The first is that operations must be operated according to the principles of GMP or GHP (good hygiene practice). The second is the application of HACCP to assure product safety. The third is the application of all verification measures to ensure that the first two are effective. Finally, these measures should be applied in the framework of the quality management systems, such as the ISO 9000 series, to ensure that overall management complies with business excellence (see Chapter 1).

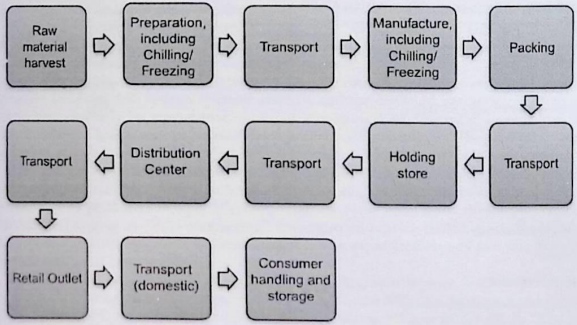

FIGURE 20.1 A typical cold chain.

EFFECT OF CHILLING ON FOOD SAFETY

The microbiological safety and rate of spoilage of chilled foods depends on what biological hazards (pathogens, etc.) are present, what other microflora are present, at what numbers they are present, whether they are on, or in, the food in question, the rate of growth of those microorganisms, the conditions of storage (temperature and gaseous atmosphere), and the characteristics (pH, a_w) of the food. Temperature is by far the most important of these factors.

The principle of chilling as a preservation process is that all biological systems are controlled by enzymatic reactions including those that control microorganisms and cause quality degradation. The rate of these reactions is directly related to temperature. Reducing temperatures below the optimum growth range of a microorganism increases its generation time. The main group of microorganisms of concern in chilled foods are psychrophiles. These organisms (such as *Pseudomonas* and *Entrococcus*) grow well at chill temperatures and cause spoilage on food at temperatures of 5 to 7°C. The optimum temperature growth range of mesophiles is 25 to 30°C and with many the minimum growth temperature is about 10°C. Since most chilled food is kept below this temperature mesophiles are not usually of concern in chilled distribution. However, some organisms (such as *Enterococcus faecalis*) can grow over a temperature range from 0 to >40°C.

Although microorganisms can grow at low temperatures, they grow more slowly as the temperature is reduced. Thus the generation time for a pseudomonad (a common form of spoilage organism) might be 1 hour at 20°C, 2.5 hours at 10°C, 5 hours at 5°C, 8 hours at

TABLE 20.1 Minimum and Optimum Growth Temperatures for Pathogens Associated with Foods

	Minimum Temperature (°C)	Optimum Temperature (°C)
Infective		
Campylobacter spp.	30	42–43
Pathogenic *Escherichia coli* strains	7	35–40
Escherichia coli O157:H7	6–7	42
Salmonella spp.	5	35–43
Aeromonas hydrophila	−0.1–1.2	15–20
Listeria monocytogenes	−1–0	30–37
Yersinia enterocolitica	−2	28–29
Toxigenic		
Clostridium perfringens	12	43–47
Clostridium botulinum proteolytic	10	35
Staphylococcus aureus	7	35–40
Bacillus cereus	4	28–35
Clostridium botulinum non-proteolytic	3	30

2°C or 11 hours at 0°C (Harrigan and Park, 1991). As temperatures are reduced below 10°C, fewer strains can grow and cause spoilage. In general, food will spoil about four times as fast at 10°C and twice as fast at 5°C, as at 0°C. Chill temperatures also have a marked effect on the type of spoilage microflora present on food by altering the microbial community. For example, raw milk stored at temperatures close to 0°C tends to putrefy because of the activity of pseudomonads, rather than to sour due to the activity of lactic acid bacteria.

Pathogenic bacteria such as *Listeria*, *Salmonella*, *Bacillus cereus* and *Yersinia* are of particular concern in chilled foods because they are capable of growth at low temperatures (Table 20.1). Many of the organisms that compete with pathogens at ambient temperatures will not grow at low temperatures, thus low temperatures may preferentially favor the growth of these pathogenic organisms. However, most will not grow, or produce toxins, below 4°C, with the exception of *Listeria* and *Yersinia* (*Yersinia* grows below 0°C).

Investigations (García de Fernando et al., 1995) into the effect of different storage atmospheres on pathogenic growth at low temperatures appear to show that carbon dioxide (CO_2)-enriched atmospheres produce the greatest inhibitory effect on psychrotrophic pathogens (*Y. enterocolitica*, *Aeromonas hydrophila* and *L. monocytogenes*).

EFFECT OF CHILLING RATE ON FOOD SAFETY

Whether "rapid" chilling offers any clear advantages to product safety will depend on what biological hazards (pathogens, etc.) are present, and at what numbers they are present,

whether they are on, or in, the food in question, and how "rapid" the rate is in comparison to other rates. There is no definition of "rapid" and "slow" rates. The size of product will also have a big effect on relative rates of chilling, since conduction through the product will become the rate-limiting factor as product size increases.

Rapid chilling has been shown to be an important control measure in reducing histamine formation in at-risk fish species (pelagic species, such as mackerel, sardines, pilchards and certain tuna species) by preventing/reducing the growth of histamine-forming bacteria. High histamine levels are associated with scombroid poisoning. It is generally recommended that such fish is chilled to between 4 and 0°C in less than 12 h post-harvesting.

There are instances where excessively rapid chilling rates, or too low a chilling temperature, can cause quality problems in foods. For example, a serious defect known as "woolly texture" can be produced in rapidly cooled peaches. Substantial textural problems due to a phenomenon known as "cold shortening" can occur in rapidly chilled meats (particularly beef and lamb), although electrical stimulation before rapid chilling will mitigate this problem (Chrystall and Devine, 1983).

There is little international legislation that specifies chilling rates. Legislation tends to suggest rather than define, for example the EC Regulation 852/2004 contains a requirement for the cooling of foodstuffs. Annex II, Chapter IX, 6 states: "Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature, which does not result in a risk to health."

However, there are many guidelines and recommendations, particularly for chilling cooked/pasteurized food products (Table 20.2). The aim of a pasteurization process is to ensure destruction of vegetative stages of any pathogenic microorganisms. The minimum recommended cooking temperature requirements are related to the most thermally resistant pathogen that may present a risk in such products. For many products, such as ready meals, this is *Listeria monocytogenes* and a minimum temperature of 70°C for not less than 2 minutes in the center of the food, or the equivalent, is recommended (Gaze et al., 1989). For other products, including some soups, non-proteolytic *Clostridium botulinum* or *perfringens* are of most concern. There is always the possibility that some microorganisms that produce spores will not be killed by the cooking process. Therefore the temperature of the product should be rapidly reduced between 60 and 7°C to prevent multiplication of any surviving organisms. Further reduction to 3°C is required to reduce growth of spoilage bacteria and prevent the growth/germination of any surviving pathogenic organisms/spores. Although the guidelines were produced specifically for cook–chill catering operations they are often used by the producers of chilled ready meals for retail sale.

Some examples of food poisoning outbreaks directly attributable to poor temperature control are:

1. An analysis of 1000 general outbreaks in England and Wales between 1970 and 1979 by Roberts (1982) identified that inadequate cooling was a contributory factor in 32% of outbreaks and inadequate thawing in 6%.
2. An analysis of 530 general outbreaks in England and Wales between 1992 and 1996 by Panisello et al. (2000) identified that improper storage (including foods either left at room temperature, or warm outdoor temperatures, for several hours or refrigerated in devices

TABLE 20.2 International Chilling Time Guidelines/Recommendations for the Cooling of Cooked Food

Country	Chilling Range (°C)	Time (h)	Chilling Rate (°C/minute)	Storage Temperature (°C)	Reference
Australia	60–21	≤2	0.33	5	de Jong et al. (2004)
	21–5	≤4	0.07		
Canada	60–20	≤2	0.33	4	CFISIG (2004)
	20–4	≤4	0.07		
Codex Alimentarius	60–10	≤2	0.42	–	Codex Alimentarius Commission (1997)
Denmark	65–10	≤3	0.31	<5	Evans et al. (1996)
France	70–10	≤2	0.50	0–3	Evans et al. (1996)
Germany	80–15	≤2	0.54	2	Evans et al. (1996)
	(15–2)	≤24			
Ireland	70–3	≤2.5	0.45	3	FSAI (2004)
The Netherlands	60–7	≤5	0.18	–	de Jong et al. (2004)
	7–4	≤24			
Sweden	80–8	≤4	0.30	3	Evans et al. (1996)
UK	70–3	≤1.5	0.74	3	UK Department of Health (1989)
USA	60–5	4 to 6	0.23–0.15	–	de Jong et al. (2004)

with deficient temperature control for long periods of time) was a contributory factor in 32% of outbreaks and inadequate thawing in 2%.

3. HPA analysis of general foodborne outbreaks in England and Wales in 2011 (Health Protection Agency, 2012) showed that of the 83 general outbreaks inadequate chilling was a contributory factor in 14% (12/83), while storage of food for too long was a contributory factor in 19% (16/83).

EFFECT OF FREEZING ON FOOD SAFETY

Microorganisms vary in their ability to tolerate freezing and frozen storage. Survival is affected by the type and age of microorganism. In general, Gram-negative bacteria (which include pathogens such as *Escherichia* and *Salmonella* spp.) are more susceptible to freezing and frozen storage than Gram positives, with bacilli being more susceptible than cocci. Yeasts and molds are more resistant than bacteria, in part due their tolerance to reduced water activity (a_w). Psychrophilic and psychotropic microorganisms are generally more

tolerant to freezing and frozen storage due to their ability to synthesize larger amounts of enzymes to compensate for reduced enzymic activity at low temperatures, and their reduced susceptibility to cold shock in comparison to thermopiles and mesophiles.

Spoilage microorganisms do not grow below ca. −10 to −12°C and pathogens below −1°C, thus the growth of pathogenic microorganisms is only normally relevant to handling before freezing or during thawing. In these contexts, frozen foods behave like their unfrozen counterparts, if surface temperatures are reduced rapidly during freezing this allows less time for any microorganisms to grow, although growth rates may be faster after thawing due to increased drip. Also thawing may take a long time and on large objects subjected to long uncontrolled thawing cycles, surface spoilage can occur before the center regions have fully thawed.

Repeated freeze–thaw cycles have been shown to disrupt and destroy bacteria; however, the effects of cyclic freezing on most microbial pathogens are not well documented.

Although *Salmonella*, *Staphylococci* and other potential pathogens can survive freezing and frozen storage, spoilage bacteria tend to inhibit their growth. During freezing and thawing of food, the temperature favors the growth of psychrophilic organisms, most of which are spoilage organisms. Hence, in nearly all cases, if a frozen product is mishandled, spoilage is apparent before the food becomes a health hazard.

Freezing and crust-freezing has been suggested as a means to reduce numbers of *Campylobacter* organisms on poultry carcasses. It is one of a number of measures taken to reduce the incidence of campylobacteriosis in Iceland, although the exact impact of this measure is unclear. This work in Iceland (Stern et al., 2003) has been very influential and many risk assessment models have incorporated freezing as an import factor due to this work. Freezing to ~−20°C has been reported by a number of studies to result in an initial fall in numbers of *Campylobacter* organisms, followed by a slower decline during storage. The European Food Safety Authority (EFSA) has recommended freezing as a control measure for reducing *Campylobacter*. The mechanism of damage during freezing has been attributed to mechanical damage caused by ice crystals, desiccation due to the reduced water activity, and oxidative damage.

Freezing generally has little effect on viruses. For example, the H5N1 virus (avian influenza H5N1), if present in poultry meat, is not destroyed by freezing. Food contaminated with hepatitis A is a common vehicle transmitting the virus and each year approximately 30–50,000 cases of hepatitis A-related illnesses occur in the United States (CDC, 2007). In 2012 imported frozen strawberries contaminated with hepatitis A were believed to be the source of an outbreak of food poisoning in 11,000 children in Germany (Herriman, 2012).

Freezing has been shown to be a control measure in reducing histamine formation in at-risk fish species (pelagic species such as mackerel, sardines, pilchards and certain tuna species), both by preventing the growth of histamine-forming bacteria and by reducing the activity of preformed histidine decarboxylase. However, while freezing may limit histamine formation, it has no effect on histamine that has already been formed prior to freezing.

Higher organisms, such as nematode parasites, are very susceptible to freezing and freezing is a control measure for inactivating trichinae in pork, tape worms (*Taenia saginata*) in beef and nematode parasites in seafood (particularly for lightly processed seafoods that will receive no cooking before consumption) (Archer, 2004). The USDA recommended holding times for pork to inactivate *Trichinella spiralis* range from 106 hours at −18°C to 0.5 hours at −37°C. Freezing

is used as a control measure for inactivating tape worms (*Taenia saginata*) in beef carcasses w localized infections in the EU by holding at −10°C or less for 14 days or more.

Most frozen fruits and vegetables are subjected to a mild heat treatment known blanching before freezing. Blanching is carried out to inactivate various enzymes that c lead to quality deterioration over time. Typically, blanching is done by treating the pro uct with steam or hot water for 1–10 minutes at 75–95°C, the time–temperature combinatio depending on the specific product. Such treatment times and temperatures are also capab of reducing, to varying extents, the numbers of viable microorganisms on the food.

EFFECT OF FREEZING RATE ON FOOD SAFETY

Whether "rapid" freezing offers any clear advantages to product safety will depend o what biological hazards (pathogens, etc.) are present, at what numbers they are present whether they are on, or in, the food in question, and how "rapid" the rate is in comparison to other rates. There is no definition of "rapid" and "slow" rates. Size of product will also have a big effect on relative rates of freezing, since conduction through the product will be the rate limiting factor.

CHILLING AND FREEZING PRINCIPLES

Chilling and freezing is a process of removing heat and can only be achieved by four basic mechanisms: conduction, radiation, evaporation or convection.

Conduction requires a good physical contact between the food to be chilled/frozen and the cooling medium, and this is generally achieved only with foods that can be shaped into regular shapes, such as blocks of meat or fish, etc.

Radiation does not require any physical contact but a large temperature difference is required between the surface of the food being cooled and that of surrounding surfaces to achieve significant heat flow. In primary chilling/freezing, radiation is only important in the initial stages of the process in a system where the food is not surrounded by other products. Again, in the initial stages of the chilling/freezing of cooked food products (e.g. pies and other pastry products, meat joints, baked cakes, etc.) radiant heat loss can be substantial if the products are surrounded by cold surfaces.

Evaporation from a food surface reduces yield and is not desirable in most food refrigeration operations but can be useful again in the initial cooling of cooked food products and is used in the immediate post-harvest cooling of many fruits and vegetables. However, as soon as the surface of the food is close to that of the cooling medium then any heat loss due to evaporation is minimal.

Convection is by far the most important heat transfer mechanism employed in the majority of food chilling/freezing systems. In most cases, refrigerated air is the transfer medium; however, in some cases a liquid or a cryogenic gas may be used. The rate of heat removal from the surface of a food depends on:

1. The surface area of the food available for heat flow.
2. The temperature difference between the surface of the food and the cooling medium.

3. The surface heat transfer coefficient (h). The value of h will depend on the shape of the food and its surface roughness, the type of cooling medium, the velocity of the cooling medium, and the flow regime. The higher the surface heat transfer coefficient the faster the rate of surface cooling. Air is a poorer heat transfer medium than a fluid (such as water or brine). Increasing the air flow or agitation around a food will increase the rate of surface cooling.

Heat must also be conducted from within the food to its surface before it can be removed. Since most foodstuffs are poor conductors of heat this imposes a severe limitation on attainable cooling times for either large individual items (such as meat carcasses) or small items cooled in bulk (such as a pallet of boxed product).

CHILLING/FREEZING METHODS/EQUIPMENT

There are many different types of chilling/freeing equipment, but generally all use a gas or a liquid as the cooling medium. Equipment is classified according to the method of chilling/freezing into:

- Direct methods, where the energy is extracted directly from the food into the heat transfer medium (in such cases the heat transfer medium needs to be food safe, such as air or liquid nitrogen), for example air blast chillers/freezers.
- Indirect methods, where the cooling is generated externally and then applied to the food through heat exchangers, for example plate freezers.

Chilling/freezing may be carried out as a batch (Figure 20.2) or continuous system (Figure 20.3). Generally, batch systems are used to refrigerate small quantities of food, whereas continuous systems become economic with large throughputs.

From a food safety-based approach, prepacking the food prior to chilling/freezing will lower the risk of contamination/cross-contamination during the chilling/freezing process; however, it will significantly reduce the rate of cooling, and this may allow the growth of any microorganisms present. Although there has been (and remains) a great debate regarding the virtues of "dry" air vs. spray or immersion methods for chilling products such as poultry, there is no clear scientific evidence that air chilling is hygienically better than spray or immersion (James et al., 2006). Provided the cooling medium (air, water, etc.) and refrigeration equipment used is kept clean, no one cooling method can be said to be intrinsically more hygienic than any other. The potential for the fans used in air chilling to disseminate molds and bacteria has been identified in a number of reviews but very little work has been carried out to evaluate whether this is in fact the case. A study carried out in the UK found high levels of bacterial contamination of evaporator coils in industrial chilling systems but very few pathogens (Evans et al., 1997; James et al., 1998). Further laboratory studies showed that bacteria did not grow on clean coils. It is therefore important that food refrigeration systems should be properly constructed and maintained. The design of chillers/freezers, especially drip trays, should facilitate effective cleansing and disinfection.

FIGURE 20.2 Simple batch air-cooling system for cooling trays of product.

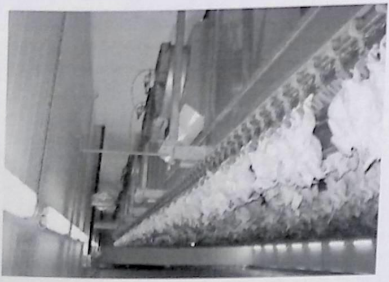

FIGURE 20.3 Continuous air-chilling system for whole poultry.

Air Chillers/Freezers

Air is by far the most widely used method of chilling and freezing food as it is economical, hygienic and relatively non-corrosive to equipment. The big advantages of air systems

are their cost and versatility, especially when there is a requirement to cool a variety of irregularly shaped products.

Three different types of air-blast (forced air) systems are used: batch (cabinets or rooms), tunnel and spiral freezers. Batch blast chillers/freezers usually consist of a room or large cabinet into which the product is loaded directly onto shelves or via trolleys that are wheeled into the chamber (Figure 20.2). These chillers/freezers are sometimes called batch-continuous systems if the trolleys are periodically removed trolley by trolley on a "first in-first out" basis. The tunnel chiller/freezer, in its simplest form, is a straight, continuous link-belt carrying product through a chamber (Figure 20.3) or tunnel. Spirals are essentially tunnel chillers/freezers in which the belt travels in a spiral (helical) motion through a near-cube-shaped room. The airflow direction in a spiral may be horizontal, vertical or some combination of these, as it flows over the product riding along on the belt. Spirals perform the same function as tunnels but require less floor space; however, they are usually more expensive. Both tunnels and spirals are best suited to small products with relatively short chilling/freezing times of less than an hour.

Operating temperatures and air speeds depend on the requirements of the product. If the risk of surface freezing is to be avoided (in the case of chilling) air temperatures will need to be above −2°C (depending on the freezing point of the product).

In general, relatively low rates of heat transfer are attained from product surfaces in air-cooled systems. In standard systems air speeds are seldom faster than 6 ms^{-1}, but far higher air speeds (up to 30 ms^{-1}) are achievable, with higher surface heat transfer rates, in impingement systems. Impingement chillers/freezers are best suited for products with high surface area to weight ratios (for example, products with one small dimension such as hamburger patties, pizzas, etc.). Testing has shown that products with a thickness less than 20 mm chill/freeze most effectively in an impingement heat transfer environment.

High heat transfer rates do not offer advantages for thick products where heat transfer within the product is the rate-limiting factor. For example, while increasing the air velocity during chilling of beef sides substantially reduces chilling times at low air velocity, the effect is smaller at higher velocities. Also the power required by the fans to move the air within a room increases with the cube of the velocity. Thus while a fourfold increase in air velocity from 0.5 to 2 ms^{-1} will result in a 4.4 h (18%) reduction in chilling time for a 140 kg side, it requires a 64-fold increase in fan power. In most practical situations, where large items are being cooled it is doubtful whether an air velocity greater than 1 ms^{-1} can be justified.

Even when a system has been designed to distribute the air through the product, poor management and/or poor understanding of the requirement of the plant commonly leads to uneven cooling. Products stacked or racked irregularly will leave channels around the stacks that are larger in cross-sectional area than those within the stacks and channels of differing area through the stacks. Air leaving and returning to the refrigeration coil will take the path of least resistance through the largest gaps, instead of passing evenly through or over the product.

One of the principal disadvantages of air-cooling systems is their tendency to dehydrate unwrapped products. One solution to this problem is to saturate the air with water. Wet-air cooling systems recirculate air over ice-cold water so that the air leaving the cooler is cold (0 to 1°C) and virtually saturated with water vapour (100% RH).

Immersion/Spray Chillers/Freezers

In immersion/spray systems products are either immersed in or sprayed with a cold uid. When water is used as the heat transfer medium the process is often called "hy cooling." Systems range in size from 2 to 3 m^3 tanks used to cool small batches of cook products to large continuous chilling systems capable of cooling 10,000 poultry carcas per hour. They produce high rates of heat transfer due to the intimate contact between pr uct and cooling medium. They offer several inherent advantages over air-cooling in ter of reduced dehydration and coil frosting problems. Clearly if the food is unwrapped t heat transfer medium has to be "food safe." Cooling using ice or cryogenic substances i essentially immersion/spray processes. The freezing point of the cooling medium used d tates the temperature it can be used at. Heat transfer medium temperatures <0°C necessita the use of non-toxic salt, sugar or alcohol solutions in water, or the use of cryogens or effe refrigerants. Calcium chloride solutions are capable of temperatures as low as −55°C.

Chilling with crushed ice, or an ice/water mixture, is simple, effective and common used for the cooling of fish (Figure 20.4), turkeys (Figure 20.5) and some fruits and vegeta bles. Cooling is more attributable to the contact between the fish and the cold melt wate percolating through it (i.e. hydrocooling) than with the ice itself. The individual fish ar packed in boxes between layers of crushed ice, which extract heat from the fish and conse quently melt. Ice has the advantage of being able to deliver a large amount of refrigeration in a short time as well as maintaining a very constant temperature, 0 to −0.5°C (where no water is present).

Solid carbon dioxide pellets or "snow" can be used in much the same way as ice for some applications, for example during sausage manufacture to remove the heat generated during chopping and mixing. Solid carbon dioxide has the advantage over ice that it rapidly sub limes to gas leaving no residue and not wetting the product.

FIGURE 20.4 Ice/water immersion cooling of whole fish.

FIGURE 20.5 Immersion cooling of turkey carcasses.

Cryogenic Freezers

The term cryogenic simply means very low temperature. Cryogenic cooling uses refrigerants, such as liquid nitrogen or solid carbon dioxide, directly. Cryogenic freezing is often treated as a specific type of freezing method on its own; however, it is essentially an immersion/spray system, depending on how the cryogen is utilized.

Although it is common in laboratory studies to freeze samples with liquid nitrogen by direct immersion, few commercial liquid nitrogen freezers employ this technique. One reason for this is that many foods will shatter and split if frozen in this way, due to rapid gas expansion; it is also inefficient. Cryogens are typically employed as sprays in tunnel, spiral or batch cabinet systems.

Cryogenic freezing is often cited as the fastest method of freezing a food. Rapid freezing in comparison to other methods is principally due to very low operating temperatures. In general, commercial cryogenic freezers do not provide substantially higher surface heat transfer coefficients between the product and medium than other refrigeration systems, unless the cryogen comes in direct contact with the product. Cryogenic systems are best suited to freezing thin products with high surface area to weight ratios in which heat conduction within the product is not rate limiting. Although running costs of cryogenic systems can be expensive, capital investment is low, with cryogenic suppliers often renting the equipment to users. Also, installation and maintenance costs are lower than mechanical refrigeration systems.

Vacuum Chillers

Vacuum cooling systems work by boiling some of the water in/on the food under vacuum conditions (typically operating at between 530 and 670 Nm^{-2}); the low pressure lowers the boiling point of water. The food cools due to the evaporation of this moisture. Evaporative cooling is quite significant, the amount of heat released through the evaporation of 1 g of water is equivalent to that released in cooling 548 g of water by 1°C (Fennema, 1975). In general terms a 5°C reduction in product temperature is achieved for every 1% of water that is evaporated. Food products that have a large surface area to volume ratio and an ability to readily release internal water are the most amenable to vacuum cooling. Suitable products, such as lettuce, can be vacuum cooled in less than 1 hour. Since vacuum cooling requires the removal of water from the product, prewetting is commonly applied to prevent the removal of water from the tissue of the product. Traditionally, this method of cooling has been relatively common for removing "field heat" of leafy vegetables immediately after harvest, but it is also suitable for many other foods, such as baked products, sauces, soups, particulate foods and meat joints (James and James, 2002; Zheng and Sun, 2005). It is particularly good for cooked fillings, stews, sauces and casseroles since pressure cooking and vacuum cooling can be combined in the same vessel, reducing both cooking and cooling times and saving space (Figure 20.6).

Vacuum cooling is rapid and economical to operate because of low labor costs, but the capital cost of the large vacuum vessels is very high and it is usually a batch process; this limits its widespread use.

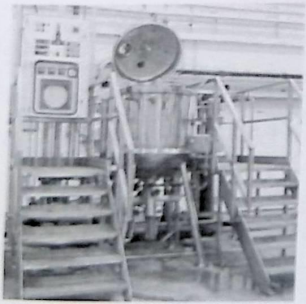

FIGURE 20.6 Combined pressure cooker/vacuum cooler.

Plate Chillers/Freezers

Modern plate cooling systems differ little in principle from the first contact freezer patented in 1929 by Clarence Birdseye. Essentially product is pressed between hollow metal plates containing a circulating refrigerant. A hydraulic cylinder is used to bring the plates into pressure contact with the product. These plates can be either horizontal or vertical.

Plate coolers are more commonly used to freeze solid foods, but can be used for chilling. Contact cooling offers several advantages over air-cooling, for example better heat transfer and significant energy savings. However, the need for regularly shaped products with large flat surfaces is a major hindrance.

Belt Freezers

Belt freezers employ a similar contact method of freezing to plate freezers.

Simple belt freezers consist of an endless steel belt (around 1 mm thick), the underside of which is cooled directly with brine, glycol or cryogenic sprays, or by sliding over a stationary cold surface. Since only one side of the product is in contact with the cooling surface relatively thin products are required, such as hamburgers, fish fillets or liquid and semi-liquid products such as purées and sauces.

In double-band systems the product is frozen between two endless belts of which the top is flat and the lower belt corrugated. The product is spread into the corrugations, the top belt enclosing the exposed surface thus freezing the product as IQF (individually quick frozen) pellets. Liquids and semi-liquids are often frozen into pellets using this method.

Scraped Surface Freezers

Scraped surface, or cylindrical, freezers are designed for freezing liquid products either on the inner or the outer surface of a cooled cylinder. The layer of frozen product formed on the surface of the cylinder is continuously scraped from the cylinder surface, thus achieving high heat transfer and a rapid freezing rate. Scraped surface freezers are used for manufacturing ice creams and similar products.

Stirred Jacketed Vessels

Stirred jacketed vessels are essentially a scraped surface heat exchanger (also called swept surface heat exchanger). The 'blades' rotation causes an increase in the product mixing, and also leads to film removal as they continuously scrape the walls through which heat is being transferred. This type of heat exchanger is particularly useful for high viscosity products, since the heat transfer is increased by the produced turbulence.

Liquid Heat Exchangers

Liquid heat exchangers can be classified in four main categories according to construction features: tubular, plate-type, extended surface and regenerative exchangers. Tubular heat exchangers consist of one single tube or more, enclosed within a larger tube. The

product flows through the smaller tubes, with the cooling medium flowing over the tub within the larger tube.

Plate heat exchangers consist of a series of thin plates clamped together on a fra and separated by spacing gaskets. The spaces form channels in which the two fluids for exchanging heat through alternate plates. Suitable gaskets and channels control the flo and allow parallel or counter-current flow in any desired number of passes. The plates us ally have a corrugated pattern in order to increase the available surface area for heat tran fer, provide greater system support and enhance the turbulence present in the process.

Chilled Storage

Publications such as the International Institute of Refrigeration (IIR) *Recommendations fo the Chilled Storage of Perishable Produce* (2000) provide data on the storage life of many food at different temperatures.

Three factors during chilled storage – the storage temperature, the degree of fluctuation i the storage temperature and the type of wrapping/packaging in which the food is stored – are commonly believed to have the main influence on chilled storage life. The storage life of most chilled foods is limited by the growth of spoilage microorganisms. However, with unwrapped food, dehydration of the surface layers may lead to unacceptable quality changes. In general, for many foods the longest chilled storage life will be achieved by storing the food at a temperature just above its freezing point.

Most unwrapped meat, poultry, fish, fruit and vegetables and all types of wrapped foods are stored in large rooms with circulating air. To minimize energy consumption and to unwrapped foods weight loss/appearance changes associated with desiccation, air movement should be the minimum required to maintain a constant temperature. However many storage rooms are designed and constructed with little regard to air distribution and localized velocities over products. Horizontal throw refrigeration coils are often mounted in the free space above the racks or rails of product and no attempt is made to distribute the air around the products. Using a false ceiling or other form of ducting to distribute the air throughout the storage room can substantially reduce variations in velocity and temperature.

There are some cases where maintaining a particular food at temperatures that severely limit if not completely stop chemical changes does not achieve the desired final product quality. Examples of this are in the maturing of meat, ripening of fruits and flavor development in cheese. In all these cases, the time–temperature history of the food must be carefully controlled so that periods are provided at temperatures where the desired changes can occur. However, the combination of time and temperature needs to be controlled such that undesirable and especially unsafe changes do not occur.

Controlled atmosphere storage has been developed for specialized fruit stores. In addition to the normal temperature control plant these stores also include special gas-tight seals to maintain an atmosphere that is normally lower in oxygen and higher in nitrogen and carbon dioxide than air. Additional plant is required to control the carbon dioxide concentration, generate nitrogen and consume oxygen. There is growing use of controlled atmosphere and modified atmosphere retail packs to extend the chilled storage and display life of red meats, poultry, fish and vegetables. Since the packs tend to be large and insulate the

products efficient precooling before packaging is especially important if product quality is to be maintained. Provided that temperatures during chilled storage are sufficient to prevent or inhibit the growth of any pathogens present on the food in question, in general the food will spoil before unsafe pathogen growth occurs.

Frozen Storage

Publications such as the IIR *Recommendations for the Processing and Handling of Frozen Foods* (2006) provide data on the storage life of many foods at different temperatures. Storage lives for food can be as short as 3 to 4 months for individually quick frozen, polybag-packed shrimps at −18°C. On the other hand, lamb stored at −25°C can be kept for over 2.5 years.

Most of the mechanisms of quality loss in frozen foods are determined by storage temperature and are accelerated with time spent above the recommended value. They are also promoted by temperature fluctuations. Traditionally the frozen food industry was interested in two problems that were detrimental to the appearance of the frozen food: "freezer burn" and "in-package frosting" – both of which may occur during storage. Freezer burn is caused by water loss from the surface of the frozen food due to sublimation. The resulting desiccation produces a dry fibrous layer at the surface that has the appearance of a burn. It is irreversible. It only occurs in unwrapped, or poorly wrapped, foods and its development is fastest at high storage temperatures and high air movements. It occurs during storage and not during the freezing process (unless the freezing process is excessively long); it is not caused by fast freezing. In-package frosting results from a combination of water loss from the surface, loose packaging and temperature fluctuations during storage. The water lost from the surface is deposited and frozen on the inner surface of the packaging. The use of suitable packaging and good temperature control should eliminate both problems. Neither has an effect on food safety.

THAWING (DEFROSTING) AND TEMPERING SYSTEMS

Frozen raw material as supplied to the industry ranges in size and shape, although much of it is in blocks packed in boxes. Thawing (defrosting) is usually regarded as complete when the center of the block has reached 0°C, the minimum temperature at which most of fish can be filleted or cut by hand and fruits and vegetables hand sorted. Lower temperatures (e.g. −5 to −2°C) are acceptable for produce that is destined for mechanical chopping, but such product is "tempered" rather than thawed. The two processes should not be confused because tempering only constitutes the initial phase of a complete thawing process.

Inherent in thawing is a major problem that does not occur in a freezing operation. The majority of the bacteria that cause spoilage or food poisoning are found on the surfaces of food. During the freezing operation, surface temperatures are reduced rapidly and bacterial multiplication is severely limited, with bacteria becoming completely dormant below −10°C. In the thawing operation these same surface areas are the first to rise in temperature and bacterial multiplication can recommence. On large objects subjected to long

uncontrolled thawing cycles, surface spoilage can occur before the center regions have fully thawed.

Most systems supply heat to the surface and then rely on conduction to transfer that heat into the center of the foodstuff. A few use electromagnetic radiation to generate heat within the food. In selecting a thawing system for industrial use a balance must be struck between thawing time, appearance and bacteriological condition of the product, processing problems such as effluent disposal and the capital and operating costs of the respective systems.

TRANSPORTATION

Chilled/frozen foods are transported around the world and locally via a range of transportation systems. All these transportation systems are expected to maintain the temperature of the food within close limits to ensure its optimum safety and high-quality shelf-life. It is particularly important that the food is at the correct temperature before loading since the refrigeration systems used in most transport containers are not designed to extract heat from the load but to maintain the temperature of the load. In the large containers used for long distance transportation food temperatures can be kept within ±0.5°C of the set point.

Control of the oxygen and carbon dioxide levels in shipboard containers has allowed fruits and vegetables, such as apples, pears, avocados, melons, mangoes, nectarines, blueberries and asparagus, to be shipped (typically 40 days in the container) from Australia and New Zealand to markets in the USA, Europe, Middle East and Japan. Even longer shelf-lives (over 20 weeks) can now be achieved for meats, particularly beef and lamb.

Air-freighting is increasingly being used for high-value perishable products, such as strawberries, asparagus and live lobsters. Although air-freighting of foods offers a rapid method of serving distant markets, there are many problems because the product is usually unprotected by refrigeration for much of its journey. Up to 80% of the total journey time is made up of waiting on the tarmac and transport to and from the airport. During the flight the hold is normally between 15 and 20°C. Perishable cargo is usually carried in standard containers, sometimes with an insulating lining and/or dry ice but is often unprotected on aircraft pallets.

Overland transportation systems range from 12m refrigerated containers for long distance road or rail movement of bulk chilled or frozen products to small uninsulated vans supplying food to local retail outlets or even directly to the consumer. The rise in supermarket home delivery services, where there are requirements for mixed loads of products that may each require different storage temperatures, is introducing a new complexity to local overland delivery.

CHILLED RETAIL DISPLAY

The temperature of individual consumer packs, small individual items and especially thin sliced products responds very quickly to small amounts of added heat. All these products are commonly found in retail display cabinets and marketing constraints require that they have maximum visibility. Maintaining the temperature of products below set limits while they are on open display in a heated store will always be a difficult task.

The required display life and consequent environmental conditions for wrapped chilled products differ from those for unwrapped products. The desired chilled display life for wrapped meat, fish, vegetables and processed foods ranges from a few days to many weeks and is primarily limited by microbiological considerations. Retailers of unwrapped fish, meat and delicatessen products (e.g. sliced meats, pâté, cheese and prepared salads) normally require a display life of one working day. The introduction of humidification systems can significantly improve display life of unwrapped products.

Average temperatures in chilled retail display cabinets can vary considerably from cabinet to cabinet, with inlet and outlet values ranging from −6.7 to +4.0°C, and −1.5 to +7.8°C, respectively, in one survey (Lyons and Drew, 1985). The temperature performance of an individual display cabinet does not only depend on its design. Its position within a store and the way the products are positioned within the display area significantly influences product temperatures. External factors such as the store ambient temperature, the position of the cabinet and poor pretreatment and placement of products substantially affect cabinet performance. Warm and humid ambient air and loading with insufficiently cooled products can also overload the refrigeration system. Even if the food is at its correct temperature, uneven loading or too much product can disturb the airflow patterns and destroy the insulating layer of cooled air surrounding the product. One in-store survey of 200 prepackaged meat products in chilled retail displays found product temperatures in the range −8.0 to 14.0°C, with a mean of 5.3°C and 18% above 9°C (Rose, 1986). Other surveys have shown that temperatures of packs from the top of stacks were appreciably higher than those from below due to radiant heat pick-up from store and cabinet lighting. It has also been stated that products in transparent film overwrapped packs can achieve temperatures above that of the surrounding refrigerated air due to radiant heat trapped in the package by the "greenhouse" effect. However, specific investigations have failed to demonstrate this effect (Gill, 1988).

FROZEN RETAIL DISPLAY

No frozen food, with the possible exception of ice cream, should be unwrapped when in a retail display cabinet. Traditionally frozen food was displayed in a "well-type" cabinet with only the top faces of food packs being exposed. In many cases the cabinets were fitted with a see-through insulated lid to further reduce heat infiltration. There is marketing pressure to display an increasing amount of frozen food in open multi-deck display cabinets. Maintaining the temperature of products below set limits while they are on open display in a heated store will always be a difficult task. Radiant heat gain on the surfaces of exposed packs can result in the food thawing in extreme cases. During display, temperature, temperature fluctuations and packaging are the main display parameters that control quality.

Temperature fluctuations can increase the rate of weight loss from wrapped frozen food. Higher rates of dehydration have been measured in a retail cabinet operating at −15°C than in another cabinet operating at −8°C. Fluctuations in air temperature in the −15°C cabinet ranged from −5 to −21°C compared with ±1.5°C in the −8°C cabinet. Successive evaporation and condensation (as frost) caused by such a wide temperature differential resulted in exaggerated in-package dehydration.

The extent of temperature fluctuations will be dependent upon the air temperature the product, the product packaging and the level of radiant heat. Retail display packs a relatively small thermal mass and respond relatively quickly to external tempera changes. These can be from store and display lighting, defrost cycles and heat infiltra from the store environment. In products where air gaps exist between the packaging the food, sublimation of ice within the product leads to condensation on the inside of packaging, resulting in a build-up of frost. This dehydration causes small fissures in the face of the food, allowing the ingress of any packaging gases into the food. This can al acceleration of oxidative rancidity within the product. Minor product temperature fluctu tions are generally considered to be unimportant, especially if the product is stored bel −18°C and fluctuations do not exceed 2°C.

DOMESTIC HANDLING

When removed from display cabinets the temperature of chilled and frozen foods ris rise rapidly if exposed to ambient conditions. Surveys have shown that the majority consumers do not use insulated bags or boxes to transport chilled and frozen food their homes. Once the food has warmed during transportation it can take many hours in domestic refrigerator and freezer for the food temperature to fall below a safe temperature It is also common for consumers to purchase chilled products and freeze them at home Studies have shown that it can take over 6 hours for the temperature of a chicken portion cool from 0 to −5°C in a domestic freezer.

Generally the range of recommended refrigerator temperatures are below 8°C throughout the world, with many countries (including the UK) recommending below 5°C. The numerous surveys on the domestic storage of refrigerated foods show remarkable simi larities in consumer attitudes and handling of chilled foods and the performance of their fridges. Perhaps even more remarkable is that despite numerous recommendations on han dling and storage temperatures, consumer use and the performance of refrigerators remain remarkably unchanged throughout the world over the last 30 years. Numerous surveys show that mean temperatures range between 5 and 7°C, with 50 to 70% of domestic refrigerators operating at temperatures above 5°C (James et al., 2008). It is clear that many refrigerators throughout the world are running at higher than recommended temperatures. Since even these recommended temperatures are higher than the 0 to 1°C that is usually the recommended temperature range for storing fish and seafood, meat and many chilled products, the current situation is even more detrimental to maintaining the high-quality life of chilled foods. At present domestic storage of chilled foods would appear to be the weakest link in the entire chill chain.

After a frozen product has reached the operating temperature of a domestic freezer it is very unlikely that its temperature will rise above −12°C during domestic storage, unless there is an electricity cut. In a New Zealand survey (McIntyre et al., 2007) mean temperatures in domestic freezers ranged from −11.5 to −23.3°C with an overall mean value of −16.6°C. Only 28% of freezers operated at −18°C or lower, with 68% operating between −15 and −18°C. Temperature control in freezers does not appear to have improved over the last 20 years. Freezers ≤10 years old and freezers ≥21 years old had similar mean temperatur

values. The mean air temperature recorded in the top sections of surveyed freezers was on average 2 to 2.5°C warmer than the middle and bottom sections, respectively, which suggests that freezing could be slightly slower in the upper areas of the freezer compartment.

SPECIFYING REFRIGERATION SYSTEMS

In the authors' experience, the poor performance of new refrigeration systems used to maintain the cold chain can often be traced back to a poor, non-existent or ambiguous process specification. In older systems it is often due to a change in use that was not considered in the original specification. There are three stages in obtaining a refrigeration system that works:

1. Determining the process specification, i.e. specifying exactly the condition of the product(s) when they enter and exit the system and the amounts that have to be processed.
2. Drawing up the engineering specification, i.e. turning processing conditions into terms that a refrigeration engineer can understand, independent of the food process.
3. The procurement and commissioning of the total system, including any services or utilities.

The first task in designing a system is the preparation of a clear specification by the user of how the facility will be used at present, and in the foreseeable future. In preparing this specification the user should consult with all parties concerned: these may be officials enforcing legislation, customers, other departments within the company and engineering consultants or contractors – but the ultimate decisions in forming this specification are taken by the users alone.

The process specification must include, as a minimum, data on the load(s) to be refrigerated, in terms of size, shape and throughput. The maximum capacity must be catered for and the refrigeration system should also be specified to operate adequately and economically at all other throughputs. The range of temperature requirements for each product must also be clearly stated. If it is intended to minimize loss, it is useful to quantify at an early stage how much extra money can be spent to save a given amount of weight. All the information collected so far, and the decisions taken, will be on existing production. Another question that needs to be asked is: Will there be any changes in the use of the refrigeration system in the future?

The refrigeration system chiller, freezer, storeroom, etc. is one operation in a sequence of operations. It influences the whole production process and interacts with it. An idea must be obtained of how the system will be loaded, unloaded and cleaned, and these operations must always be intimately involved with those of the rest of the production process. There is often a conflict of interest in the usage of a chiller or freezer. In practice, a chiller/freezer can often be used as a marshaling yard for sorting orders, and as a place for storing product not sold. If it is intended that either of these operations are to take place in the chiller/freezer the design must be made much more flexible in order to cover the conditions needed in a marshaling area or a refrigerated store. In the case of a batch or semi-continuous operation, holding areas may be required at the beginning and end of the process in order to even

out flows of material from adjacent processes. The time available for the process will b part dictated by the space that is available; a slow process will take more space than a process, for a given throughput.

Other refrigeration loads, in addition to that caused by the input of heat from the pr uct, also need to be specified. Many of these, such as infiltration through openings, the of lights, machinery and people working in the refrigerated space, are all under the c trol of the user and must be specified so that the heat load given off by them can be in porated in the final design. Ideally, all the loads should then be summed together o time basis to produce a load profile. If the refrigeration process is to be incorporated w all other processes within a plant, in order to achieve an economic solution, then the lo profile is important. The ambient design conditions must be specified. These are general the temperatures in areas adjacent to the refrigerated equipment and the temperatures the outside ambient to which heat will ultimately be rejected. In stand-alone refrigerati processes this will often be the wet and dry bulb temperatures of the outside air. If th process is to be integrated with heat reclamation then the temperature of the heat sink must be specified. Finally, the defrost regime should also be specified. There are times w any process where it is critical that coil defrosting and its accompanying temperature ris does not take place, and that the coil is cleared of frost before commencing the specifie part of the process.

Although it is common practice throughout the food industry to leave much of this speci fication to refrigeration contractors or engineering specialists, the end user should specify all the above requirements. The refrigeration contractors or engineering specialists are in a position to give good advice on this. However, since all the above are outside their con trol, the end user, using their knowledge of how well they can control their overall process should always take the final decision.

The aim of drawing up an engineering specification is to turn the user requirements into a specification that any refrigeration engineer can then use to design a system. The first step in this process is iterative. First, a full range of time, temperature and air velocity options must be assembled for each cooling specification covering the complete range of each product. Each must then be evaluated against the user requirements. If they are not accept able then another option is selected and the process repeated. If there are no more options available there are only two alternatives; either standards must be lowered (hence cooling specifications will not be met) or the factory operation must be altered.

A full engineering specification will typically include: the environmental conditions within the refrigerated enclosure, air temperature, air velocity and humidity; the way the air will move within the refrigerated enclosure; the size of the equipment; the refrigeration load profile; the ambient design conditions; and the defrost requirements. The final phase of the engineering specification should be to draw up a schedule for testing the engineering specification prior to handing over the equipment. This test will be in engineering and not product terms.

The specification produced should be the document that forms the basis for quotations and finally the contract between the user and his contractor, and must be stated in terms that are objectively measurable once the chiller/freezer is completed. Arguments often ensue between contractors and their clients from an unclear, ambiguous or uninformative specification. Such lack of clarity is often expensive to all parties and should be avoided.

MANAGING/PRODUCTION PRINCIPLES FOR REFRIGERATED FOODS

Two principles control the safety and quality of chilled and frozen foods: PPP (product-process-package) factors and TTT (time–temperature-tolerance) factors.

PPP factors that need to be considered at an early stage in the production of chilled and frozen foods are:

- Product: High-quality chilled and frozen foods require high-quality raw materials and ingredients.
- Process: The speed and effectiveness of the chilling/freezing operation and the use of additional processes, e.g. heating, pasteurization.
- Package: The packaging must provide a physical/chemical barrier to protect the food; "advanced packaging," including modified atmosphere packaging.

TTT factors maintain quality and safety during storage. For different foods, different mechanisms govern the rate of quality degradation and the most successful way of determining practical storage life is to subject the food to long-term storage at different temperatures. TTT relationships should also be able to predict the effects of changing or fluctuating temperatures on high-quality shelf-life.

TEMPERATURE MEASUREMENT AND MONITORING

Temperature measurement and monitoring are integral parts of any food cold-chain management system; as well as being, in many areas of the cold chain, a legislative requirement. Monitoring the cold chain requires detailed information on food product temperatures. Temperature monitoring includes both measurement and recording. Like any food safety system, an effective temperature measurement and monitoring system should be:

- Practical to apply.
- Results oriented.
- Cost effective.
- Useful to meet applicable regulations or food safety policy.
- Applied consistently and equitably.
- Verifiable and verified.

It is important to clearly know the difference between monitoring and verification. Codex Alimentarius Commission (2008) defines them as: "Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control." "Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended."

When designing a temperature monitoring system there are three clear stages:

1. Identify what has to be measured and why it needs to be measured.
2. Select optimum measurement/monitoring method/system.
3. Develop a suitable method of analyzing the data gathered.

Temperature measurement can be achieved using a variety of instrumentation as as bimetal style thermometers, thermistors, thermocouples, infrared thermometers. Typically, in the food industry, temperature measurement is achieved using calibrated th mocouples and data loggers, while many temperature control systems use Pt100 platinu resistance sensors. Due to the variety of available equipment, manufacturers and suppli are best positioned to give advice to the food business on the choice of temperature mea urement equipment for specific purposes and food products. Further advice can be fou in publications such as the *ATP Handbook* (2012), *IIR Recommendations for the Processing a Handling of Frozen Foods* (2006) and Evans and Woolfe (2008). The following questions are useful aide-mémoire when choosing equipment:

- What is the required temperature range and likely operating temperature range for the instrument?
- Is there a need to measure product temperatures? Ambient temperatures? Package temperatures?
- Is there a need to continuously record the temperature (temperature history), or are spot checks acceptable?
- If a temperature history is required, what sampling frequency is required?
- Does the system need to provide a permanent record of temperatures, or just act if outside limits?
- What is the required accuracy?
- What is the required response time?
- If electronic, does the battery life compromise the application?
- What shape of probe is required? For example, a flat probe to reach between packages, a sharp long robust probe to reach the deep (core) temperature of a beef side, etc.
- Is water proofing of the probe/electronics required?
- Can the temperature data be imported into commercial data analysis spreadsheets or software packages?
- Does the system allow ease of calibration?

One possible aid in the future may be the widespread use of time–temperature indicators/integrators (TTI) throughout the cold chain (Taoukis and Labuza, 2003; Evans and Woolfe, 2008; Hobday et al., 2010). Time–temperature indicators, or integrators (TTIs) are simple and potentially inexpensive devices that are capable of reporting a visual and straightforward summary of either the temperature (indicators) or time–temperature exposure history (integrators) of the product. Indicator or threshold indicators show that a product has exceeded, positively or negatively, a given temperature, while integrators monitor both time and temperature during a given period and show the cumulative effect of temperature fluctuations during the history of the product.

Recommended Temperatures

Currently, the Agreement on the International Carriage of Perishable Foodstuffs (ATP Agreement) specifies maxima for transportation of chilled and frozen foods, as shown in Table 20.3.

TABLE 20.3 Maxima for Temperature of Chilled and Frozen Foods

	Maximum Temperature (°C)	
Chilled foods:	7	Red meat and large game (other than red offal)
	6	Raw milk
	6*	Meat products, pasteurized milk, fruit dairy products (yoghurt, kefir, cream and fresh cheese), ready cooked foodstuffs (meat, fish, vegetables), ready to eat (RTE) prepared raw vegetables and vegetable products, concentrated fruit juice and fish products not listed
	4	Poultry, game (other than large game) and rabbits
	3	Red offal
	2*	Minced meat
	0**	Untreated fish, molluscs and crustaceans
Frozen foods:	−20	Ice cream
	−18	Frozen or quick (deep)-frozen fish, fish products, molluscs and crustaceans and all other quick (deep)-frozen foodstuffs
	−12	All other frozen foods (except butter)
	−10	Butter

*Or at temperature indicated on the label and/or on the transport documents.
**At temperature of melting ice.

These temperatures are also a good guideline to be followed during storage and retail display of such foods. It should be noted that the recommended temperature of −18°C for frozen storage is rather arbitrary and based on the historical reason that −18°C is approximately equal to 0°F. There is little evidence that frozen food is any safer at −18°C than −12°C, provided good temperature control is maintained throughout the cold chain. Data on the importance of frozen storage temperatures on shelf-life and quality are conflicting. There is a growing realization that storage lives of several foods can be less dependent on temperature than previously thought. Since research has shown that many food products, such as red meats, often produce non-linear time–temperature curves there is probably an optimum storage temperature for a particular food product. Improved packing and preservation of products can also increase storage life and may allow higher storage temperatures to be used.

Publications such as the IIR *Recommendations for the Chilled Storage of Perishable Produce* (2000) and *Recommendations for the Processing and Handling of Frozen Foods* (2006) also give indications of recommended storage life and temperatures for different foods. Specific temperatures for certain foods may also be required by national legislation.

Recommended Controls

There is much published guidance for the processing and handling of chilled and frozen foods to help ensure product safety, including many Codex texts. It is important to

ensure that proper cold-chain management and control incorporates good hygienic and good manufacturing practices (GMP) and the application of the HACCP, as described in the Codex text *General Principles of Food Hygiene* (CAC/RCP 1-1969). Many Codes texts contain appropriate guidance that can be used in developing management procedures, including the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985), codes of hygienic practice (e.g. *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food* (CAC/RCP 47-2001), *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005)), codes of practice (e.g. *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)) as well as the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008). Guidance can also be found in the *ATP Handbook* (2012) and International Institute of Refrigeration (IIR) *Recommendations for the Chilled Storage of Perishable Produce* (2006) and *Recommendations for the Processing and Handling of Frozen Foods* (2006).

The following general factors are important in relation to achieving the necessary temperature control for chilled and frozen foods:

In raw materials selection:

- Remember that high-quality chilled and frozen foods require high-quality raw materials and ingredients.
- Stocks should be rotated to ensure that the products leave the cold store on a "first in-first out" basis or shortest durability date.

In chilled/frozen food production:

- Use product temperatures–time as parameters to monitor at the critical control points (CCP) in the HACCP plan.
- In blast-air chillers and freezers poor product loading and placement can disrupt the flow of cool air around the product adversely affecting the rate of cooling.
- Iced-up cooling coils in chillers/freezers will have an adverse effect on air flow and indicate the need for proper defrosting regimes and correct setting of thermostats.

In chilled/frozen food storage:

- The temperature of the cold store may be an essential quality provision and/or a CCP monitoring parameter to avoid a critical temperature abuse situation that may jeopardize food safety.
- Use product temperatures–time profile as a CCP monitoring parameter in the HACCP plan.
- Introducing warm products into chilled/frozen food storage rooms can cause a general temperature increase: it should be noted that storage rooms are intended only for holding and are not designed for cooling foods.
- Stocks should be rotated to ensure that the products leave the cold store on a "first in-first out" basis or shortest durability date.
- Product and environment temperatures should be closely monitored and recorded during storage. Systems available include dataloggers (both *in situ* and portable).
- Iced-up cooling coils in store rooms indicate the need for proper defrosting regimes and correct setting of thermostats.

In chilled/frozen food transport:

- The product time–temperature profile during transport and distribution may be an essential quality provision and/or CCP monitoring parameters to avoid a critical time–temperature abuse situation that may jeopardize food safety.
- The product should be at the appropriate temperature prior to loading. Unless the transportation container has been specifically designed for that purpose, distribution should never be considered a cooling operation.
- Prior cooling of the distribution vehicle container is necessary to achieve the appropriate temperature during the entire distribution process.
- Ensure that products are transferred in a continuous operation (no stopping or delays) between temperature-controlled areas, e.g. holding store to delivery truck, delivery truck to holding store.
- Product and environment temperatures should be closely monitored and recorded during the distribution process. Systems available include dataloggers (both *in situ* and portable).
- Distribution of quick frozen foods should be carried out in such a way that any rise in product temperature warmer than −18°C be kept to a minimum within, as appropriate, the limit set by competent authorities and should not in any case be warmer than −12°C in the warmest package to ensure quality of the products. After delivery, the product temperature should be reduced to −18°C as soon as possible.

In chilled/frozen food retail display:

- Introducing warm products into chilled/frozen food cabinets can cause a general temperature increase: it should be noted that retail display cabinets are intended only for holding and are not designed for cooling foods.
- Cabinets should never be stocked beyond the load line. Poor cabinet stocking and stacking arrangements and inadequate servicing can cause significant problems with maintaining low temperatures.
- Do not overload cabinets.
- Iced-up cooling coils in cabinets indicate the need for proper defrosting regimes and correct setting of thermostats.
- Interference with cabinet design can disrupt the flow of cool air through the cabinet and cause a rise in temperature.
- Cabinets should be located so that the open display area is not subject to draughts or abnormal radiant heat (e.g. direct sunlight, strong artificial light or in direct line with heat sources).
- Stocks should be rotated to ensure that the products are sold on a "first in-first out" basis or shortest durability date. In no case should products be stored beyond their specified shelf-life.

Problem Areas

Transfer points, e.g. chiller/freezer to cold store, factory to distribution vehicle, retail cabinets to consumers' refrigerators, are well-known problem areas. A useful concept is

that of the "relay system," where the baton (the food product) is transferred safely from one responsible person to another, and where a signing-over system includes information on product temperature and history. Such a system necessitates thorough education and training of staff likely to come into contact with the food product.

In many air-based refrigerated systems the evaporator coils operate at temperatures below the freezing point of water in order to achieve the required air and product temperatures. During operation water vapor that is present in the air that circulates over the evaporator coil condenses and eventually freezes on the coil surface. Over time frost and ice will accumulate on the coil surface leading to a decrease both in the air flow rate and in the overall heat transfer coefficient, causing air temperatures to rise. In order to maintain satisfactory performance, evaporator coils are defrosted periodically. This is achieved by warming the coil to melt the ice. This warming can cause a brief rise in both air and product temperatures. Legislation/guidance usually allows for such brief changes, for example ATP guidance permits "a brief rise of the temperature of the surface of frozen foodstuffs of not more than 3°C in a part of the load, e.g. near the evaporator, above the appropriate temperature." Defrosting is usually controlled by a preset time cycle; however, such control may cause a number of unnecessary defrost cycles which reduces the energy efficiency of the refrigeration system as well as causing unnecessary fluctuations in air temperatures. Implementing defrosts only when they are needed, or on "demand," would reduce the number of defrost cycles, lead to savings in energy and improve product quality and safety.

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Official site for the European Chilled Food Federation
http://www.frperc.com
Food Refrigeration and Process Engineering Research Centre site

CHAPTER

21

Detection of Physical Hazards

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OUTLINE

INTRODUCTION

Foreign bodies are a major reason for consumer complaints in the food industry. They represent either a quality defect affecting company and brand reputation or a food safety hazard, due to potential injury or choking. Hard and sharp foreign bodies, named physical hazards, can lead to serious illness.

Foreign bodies are an emotive subject for consumers and should be given special attention, in particular when the product is consumed directly from the packaging (e.g. ready to drink, confectionary, ice cream) or while feeding a third person (e.g. babies or the elderly).

The product is susceptible to contamination from raw material to final consumption. Its transformation process is often responsible for introducing foreign bodies (e.g. metal particles or human hairs) but the raw material itself might also contain foreign bodies, for example fish bones or grit in mushrooms.

The application of good manufacturing practice (GMP) and hazard analysis (HACCP) through the whole food supply chain, "from plant to plate," is the most effective way to prevent and reduce contamination and thereby protect the consumer; this includes, for example, hygienic design of buildings and machinery, training of factory employees, eradication of pests or certification of raw material suppliers. In addition, separators and sorters (e.g. filters, sieves, magnets, lasers) might be placed on production lines to improve foreign body reduction.

Unfortunately, due to technical and operational limitations, the above-mentioned control measures can only mitigate the risk. This is why detection equipment, typically a metal detector or X-rays, are part of the foreign body management system, working in combination with upstream control measures to minimize the likelihood of product contamination. They act like an alarm to warn about weaknesses in control measures. However, these tools are not absolute barriers and cannot ensure "zero risk" for the consumer, and overconfidence in detection technology may create a false sense of security.

Foreign bodies might be differentiated from the product by any of their physical characteristics: magnetic or electrical conductivity, density, color, shape or dimension. Despite the emergence of new detection technologies (ultrasonic, near infrared or magnetic resonance), metal detectors and X-rays are still today the most commonly employed technology in food inspection due to reasonable cost and good detection performances on physical hazards. Both of these technologies are also supported by a mature industry providing efficient turnkey solutions, maintenance and spare parts services.

Detection equipment is a competitive market with dozens of suppliers. Significant gaps exist between manufacturers in terms of detection capabilities, product handling, reject units, human interfaces or service level. Complex integration remains the preserve of a few specialists. Given the high cost of false rejection over several years or repeated efficiency losses, it would be unreasonable to try saving money during the machine selection process.

This chapter presents the basic working principles of metal detectors and X-rays and some key rules to select the most adequate equipment according to needs. A second part introduces concepts necessary for the optimal management of the detection equipment.

SORTERS AND DETECTION EQUIPMENT (FIGURE 21.1)

Foreign body separation equipment (hereafter called sorter) and detection equipment are often incorporated into a same classification, however, there is a significant difference in their purpose:

- Sorters (e.g. sieves, filters, magnets, manual sorting) remove foreign bodies from a product identified as a known contaminate (e.g. agricultural material, nuts, cacao or green coffee beans).

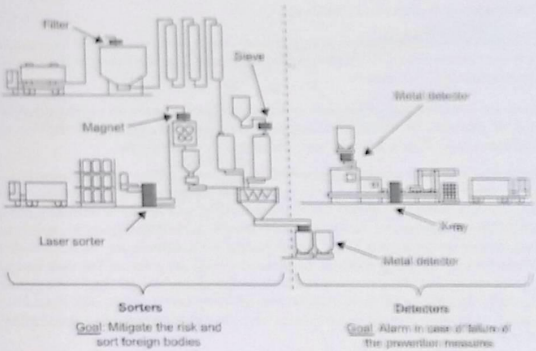

FIGURE 21.1 Sorting and detection equipment on a fictional process.

- Detection equipment (e.g. metal detector, X-ray, near infrared) is usually installed at the last stage of the process to control foreign body hazards prior to dispatch to consumers. Potential imperfections are highlighted in the upstream preventive measures.

There are also fundamental differences between the management of sorting and detection equipment. For sorters, usually no corrective actions are taken when foreign bodies are found, except in the case of abnormally high contamination or if a non-conventional type of material is discovered. However, all rejects from detection equipment should be carefully inspected and any foreign body discovered should invoke thorough investigation and batch retention (when justified) as this might be a potential failure of the preventive measures upstream (e.g. equipment maintenance, failure of sorter, hygienic design, worker's practices). In addition, most of the sorter technology does not have warning or reject mechanisms, for example a filter or a magnet will not notify when a contaminant is collected.

Sorters should be installed:

- On incoming raw materials.
- After hazardous process steps, often involving metal–metal contact, like rotary valves, grinding, mixing or cutting.
- Before some processes where foreign bodies might be broken up into smaller parts or could damage the equipment itself, generating more contamination.
- Upstream of a metal detector or X-ray as a last barrier to reduce the likelihood of an alarm.

Detection devices should be installed:

- At the end of the process, at or after packing, when no contamination is expected
- At important intermediate process steps, for example at the filling or discharging of intermediate bulk containers.

There are countless sorting technologies, some very specific to certain types of industry. Almost all physical, chemical or biological characteristics can lead to the development of sorting techniques. Here is a brief overview of the most common:

- **Sieves and filters** are efficient, cost effective and used on free-flowing powders, granulates or liquids. The separation is based on the geometric dimensions of the contaminants. Setup might vary from a simple grid to a rotary or vibratory configuration using different mesh sizes. Sieves are often combined with magnets to capture large and small ferrous contaminants. Good build quality is vital to ensure the sieve itself does not become a source of foreign bodies. Perforated sieves are preferred to wire sieves for their hygienic design, but the clearance rate will be lower and might hinder the product flow (especially for powder). Edges must be free of sharp wires, and welds should be avoided as much as possible. For the same reason, scraping elements, such as brushes, are not recommended.
- **Magnets** attract ferromagnetic and some paramagnetic materials. They are built with permanent magnets or electromagnets. In food applications permanent rare earth magnets are the strongest available. Magnets can be configured as magnetic plates, pipeline traps, magnetic conveyors, grid or rod magnets. They are a good counterpart to remove small particles and wires that are sometimes difficult to be detected by metal detectors. They are often used upstream of equipment such as mills or cutters to prevent mechanical damage. As a drawback magnets can only remove magnetizable materials. Magnets are ideal to attract thin and flat particles; however, spherical or larger fragments may prove harder to catch.
  A point of safety: strong magnetic fields could also be a danger for people with heart pacemakers; therefore all magnets must be labeled with warning signs.
- **Optical and laser sorters** (Figure 21.2) are complex systems adapted to bulk sorting, using various types of lights and cameras to segregate contaminants according to their shape, size and color. Of the two sorts laser sorters are more complex and expensive, allowing for structure recognition. Therefore two elements with identical color can be differentiated thanks to their different outer structure. Even chlorophyll content, water content and biological characteristics may be distinguished. The product is inspected during free fall by a number of broad spectrum lasers simultaneously (infrared, ultraviolet, red, green, blue, etc.). While passing through the scan zone, the signals from the reflected lasers are evaluated. A few milliseconds later the defects are hit by timed, high-speed air jets into a reject chute.
  Both, optical and laser sorters are surface scan only. They are used on items such as vegetables, fruits, seafood or dry foods (e.g. nuts, hazelnuts).
- **Manual sorting** remains a valid solution where automatic methods are still not efficient enough or only available at prohibitive costs. This is an ideal choice for small and various operations.

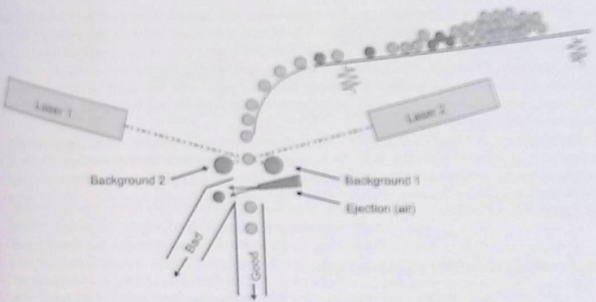

FIGURE 21.2 Laser sorter working principle.

METAL DETECTION

Working Principle

A metal detector generates a magnetic field through an emitting coil. Receiving coils constantly monitor this magnetic field for variations. Any magnetically permeable or electrically conductive materials that pass through the detector generate a disturbance of the magnetic field. Ferromagnetic metals impact on the magnetic field by both effects, which makes them easy to detect. Non-ferrous metals are non-magnetic, so more difficult to detect as the disturbance comes only from the induced magnetic field (due to the eddy current). Stainless steel is the most difficult to detect as it is usually non-magnetic and a poor conductor (usually metal detectors will catch a stainless steel piece 1.5 to 2 times larger than a ferrous piece). Note that for a metal detector the material density is not a relevant factor.

The product itself might disturb the magnetic field when passing through a metal detector, a condition called the "product effect." The amplitude of this signal depends on the conductivity of the product; this is particularly the case for products containing a high level of moisture (e.g. bread, jam or cheese) or ferrous elements (e.g. cocoa). Frozen foods are usually conductive too, but below a certain temperature (deep frozen) this electrical conductivity disappears.

Product effect is a drawback for metal detector detection capabilities. An efficient detection will therefore avoid false rejects by reducing the product effect, but without decreasing the detection capabilities: a rudimentary solution consists of moving the sensitivity threshold just higher than the product signal, reducing in the same ratio the detection sensitivity. Better results can be obtained by reducing the inspection frequency or by applying signal filtering algorithms.

Metal detector size, geometry and position of coils can be arranged in various ways walk-through gantry at an airport, a hand-held soil search as used by the military or a surface bar for webbing. In the food industry detectors typically have a cylindrical or rectangular aperture. Principal configurations are the horizontal flat belt (a conveyor is passed through the aperture to handle the bulk or finished product), the vertical gravity fall (used for inspection of bulk powder or product in free fall) and the pipe inspection (for pumped liquids or pastry products).

Performance between equipment and manufacturers might vary significantly; so when benchmarking performances, it is useful to remember that detection capability is proportional to the mass of the contaminant when using spheres; therefore, a detection limit of a diameter of 0.8 mm is about two times more difficult to obtain than a diameter of 1.0 mm.

How to Ensure an Efficient Detection

A high raw signal quality will always give better results than using post-processing filtering on a poor signal; some design characteristics have a significant impact on the signal quality:

- **Aperture dimensions.** Aperture dimensions should be kept to a minimum since the larger the aperture the lower the sensitivity. In practice, it is recommended to place detection equipment where the package/product is the smallest and the most homogeneous (e.g. individual pouches before grouping), rather than after grouping (e.g. shipping carton). Sensitivity is minimum at the center and maximum at the edges of the aperture.
- **Coil spacing.** Tighter coil spacings are available when geometrical constraints cannot be overcome. By bringing the coils closer together, detection quality is slightly reduced; often the shielding will also be smaller, creating more sensitivity to external electromagnetic disturbance. Such a configuration might be selected when no other can be found.
- **Operating frequencies** are referred to in kHz. The lower the detector's frequency, the lower the product effect and sensitivity. Fixed frequency detectors are built for simple applications (low product effect); a multi-frequency system offers the choice between several frequencies to optimize the inspection (often done automatically during auto-setup). Some high-end solutions generate several frequencies simultaneously and apply filters independently for each.

In addition to the above design features, some installation rules must be ensured to achieve best in class performances, in particular:

- **The metal-free zone.** This is the required area free from conductive material (especially moving parts). The dimensions for the metal-free zones are given by the suppliers and can vary from 1 to 1.5 times the largest dimension or diameter of the search head (to be confirmed by the supplier).

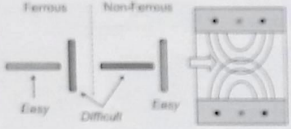

FIGURE 21.3 Orientation effect on a metal detector

- **Power supply.** Metal detectors are sensitive to power supply quality. Use of electrical power stabilizers might be necessary in some countries.
- **Environmental conditions.** Vibrations (engines, forklift trucks) or electromagnetic interference (variable speed drives) or temperature fluctuations may affect the stability of the detection. A mechanical isolation of the detection head with anti-vibration elements is recommended. Often the reject unit itself is a source of vibration.

During operation some other aspects must be respected to minimize false rejects and ensure the best possible performance:

- **Product spacing.** Adequate spacing between products is usually calculated as half of the tunnel length plus half of the largest dimension of the aperture. If this rule is not respected the wrong pack might be detected and rejected.
- **Ensure the minimum product effect.** If the product characteristic is given, some parameters, such as temperature, may increase the product conductivity.
- **Cleaning.** Wet cleaning might disturb the metal detector if the belt or other elements are not dried correctly before restart.

Technical Limitations

As mentioned before, the product effect is the main limiting factor of metal detector capabilities, but in addition:

- The orientation of straight wire contaminants passing through the aperture might reduce the detection sensitivity as shown in Figure 21.3. Manufacturers provide equivalence tables between sphere diameter and wire length for the worst-case orientation.
- Metal detectors cannot inspect packaging containing metal parts, for example tin cans or glass jars with aluminum membranes. However, for product packed in foil (aluminum or metalized), some manufacturers propose "search in foil" technology. To do this, inspection frequencies are drastically reduced and high-power magnets might be used to increase the detectability of ferrous materials prior to inspection. This technology gives acceptable results on ferrous materials but is not very efficient for non-ferrous materials and stainless steel.

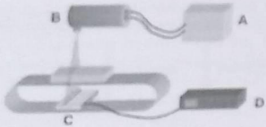

FIGURE 21.4 X-ray equipment working principle.

- Gravity fall and pipe inspection are efficient solutions but difficult to set up and test. Reject units are difficult to adjust and might generate a significant amount of rejected product to ensure the contaminant has been excluded. It is recommended to work closely with manufacturers on this topic.

X-RAY DETECTION

Working Principle

Referring to Figure 21.4, in the X-ray tube (B), electrons are accelerated between cathode and anode under strong electrical potential produced by a high-voltage generator (A). The moment the electrons hit the surface of the anode, X-rays are produced (99% of the kinetic energy of the electrons is transformed into heat, hence the importance of cooling systems). Passing through the product, X-rays are partially absorbed. The remaining radiation reaches a detector (C) where X-rays are converted into light by a scintillator and converted to a grayscale value by an array of photodiodes. A computer (D) constructs an image line by line, using the motion of the product passing in front of the detector. Some other solutions use a matrix sensor that works like a camera, taking a picture produced by a "flash X-ray" generated in milliseconds. The detection of foreign bodies is ensured through image processing software.

X-rays can penetrate all common packaging materials, which makes this method suitable for scanning glass jars, plastic bottles or tin cans. X-ray detection quality is defined by density, thickness and X-ray absorption coefficient of materials; the X-ray intensity transmitted through the material is given by the following law:

$$I = I_0 e^{-\mu x}$$

where I is the transmitted X-ray intensity, I_0 is the incident X-ray intensity, μ is the attenuation coefficient and x is the thickness of the material. The attenuation coefficient μ typically increases with material density.

Numerous image processing algorithms identify contaminants; this task becomes very complicated the more blurred the picture (some examples are shown in Figure 21.5). What might be obvious to the human eye, through the complex filtering of the brain, could be

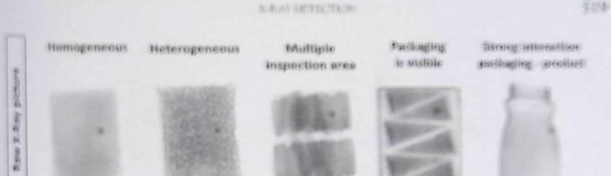

FIGURE 21.5 X-ray picture complexity.

extremely difficult, even impossible, to detect by automatic routine (which is why airports still require humans skills to analyze the X-ray scans of luggage). Basic detection work on a simple grayscale threashold. Fixed masks/frames are then applied where packaging shadows or a specific zone must be excluded from the inspection (e.g. promotional items). More complicated applications use active contour alogrithms to differentiate packaging from product. On high-speed applications, the processing time of complex algorithms still remains a constraint.

X-ray technology allows machine design flexibility; customized configurations might be developed according to the application by placing one or more views with different inspection angles. Flat belt is the most common application, usually a single view from the top or from the bottom crossing the conveyor belt to inspect packed, unpacked and bulk product. A similar configuration is used for the pipe inspection, scanning pumped product through a plastic pipe transparent to X-rays. Stand-up products that cannot lie on their side are usually inspected by lateral view with the tube and the detector positioned on each side of the conveyor.

Rigid container inspection is notable because the packaging appears omnipresent and intertwined with the product. It is therefore necessary to dissociate the product from the packaging. Rigid container by single view offers good results on simple packaging shapes, but multiview X-ray (between two and four combining lateral and top views) increases significantly the volume coverage.

Glass container inspection is a typical area where multiview X-ray is widely used. Due to the density and thickness of glass, the bottom and sides of the packaging will appear blurred, limiting the inspection on a single view. Using a second view, for example crossing at 90 degrees, the areas difficult to inspect in one view are then visible in the other, as explained in Figure 21.6.

X-rays can also be used to perform further picture analysis in addition to foreign body detection, for example: filling level control, control of missing item or product, fat analysis, broken parts control or mass evaluation. However, these techniques have limitations and cannot replace dedicated tools like a checkweigher or vision system.

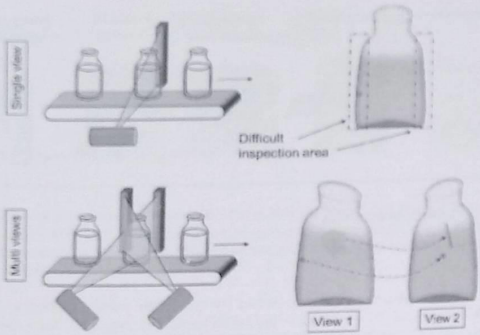

FIGURE 21.6 Double view detection advantages on rigid containers.

How to Ensure an Efficient Detection

As with metal detectors, the first priority is to ensure a superior raw signal quality (picture contrast and resolution) instead of applying ineffective post-processing on a picture of poor resolution. Therefore the following need particular attention:

- **X-ray tube power and voltage.** The voltage indicates the penetration force of the photons while amps define the image brightness. Some filters might also be applied according to the application to fine-tune the energy profile of the X-ray spectrum.
- **Focal spot size** (area where the X-rays are generated) influences the image sharpness together with the distance between tube, object and detector (as illustrated in Figure 21.7). An ideal situation is to have a small focal spot, a long distance between tube and object and a small distance between object and detector. Note that the smaller the focal point, the more important the cooling, as all the energy is concentrated in one point.
- **Scan resolution.** As known from digital cameras, the higher the number of pixels, the better the resolution. Usually for food inspection the pixel dimension should be in the range 0.4 to 1.2 mm. The resolution of the picture is the result of scan frequency in conjunction with conveyor speed. To obtain, for example, a 0.4 mm resolution at a conveyor speed of 25 m/min, a rate of 1042 scans/min is required.
- **Sufficient contrast** between the product and the contaminant is dependent upon product thickness as illustrated in Figure 21.8. As a consequence, it is recommended to inspect the smallest and thinnest possible unit. For example, detection performance will be better on a single sachet than on a shipping case.

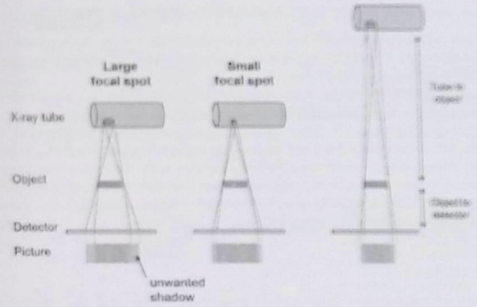

FIGURE 21.7 Scan resolution and unwanted shadow effect.

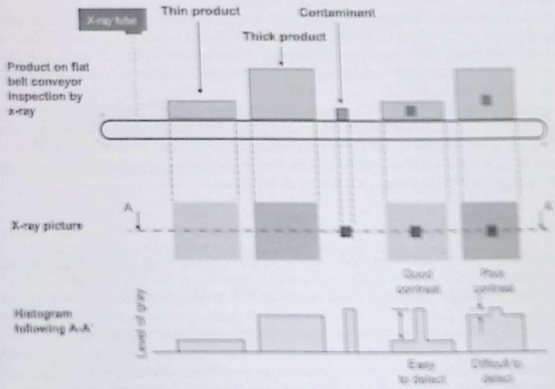

FIGURE 21.8 Product thickness influence on image contrast.

There are many rules for efficient X-ray installation and operation:

- **Precise product handling** reduces image variability and provides a greater precision of the inspection area. Protection against radiation (curtains, baffle system) can often be a source of disruption to product flow.
- **Frame accessibility.** Protection against radiation requires the use of a shield which sometimes restricts the accessibility of the transport and inspection area. Ensure the unit is easy to open and access for cleaning and maintenance is straightforward.
- **Software.** This is probably the most important aspect. The software might become extremely complex and unmanageable for a factory with limited engineering resources. Manufacturers provide remote control solutions, but this is of limited support in many situations. The software must be easy to use with a limited number of parameters to ensure manageable setup and traceability.

Technical Limitations

- **Awareness of contaminant shape and orientation** (Figure 21.9). A contaminant might appear more or less dark on the picture depending upon its orientation. This is especially limiting for flattened shapes and low density material.
  It is necessary to be vigilant when comparing the detection performance between metal detectors and X-ray. Indeed the use of a sphere or a cube is always preferable for X-rays because it concentrates the mass at a point. Multiview X-ray improves the situation by projecting the contaminant from different angles.
- **Blind area on rigid container** (Figure 21.10). Masks exclude part of the picture and therefore part of the product, where shadows generated by the packaging disturb too much of the image. This has to be considered when benchmarking X-rays on rigid containers against metal detectors before filling, where with metal detectors 100% of the product is always inspected.
- **Limitation with aluminum.** Aluminum density ($d = -2.7$) is lower than other common metals, three times lower than stainless steel ($d = -7.9$) and therefore more difficult to detect by X-ray. Density is not the only limiting factor; chemical elements up to atomic number 12 (magnesium) have light interaction with X-ray photons. This interaction increases gradually only from number 13 (aluminum).

Safety

Industrial X-ray for food inspection uses an electric X-ray tube, containing no radioactive sources. When turned off no residual radiation is produced. During operation the operator is protected by the lead shielding of the machine. The leakage can be measured by a gamma survey meter. There are no common international norms; each factory should refer to its local radiation protection entity to ensure compliance with local regulations.

Note that humans are constantly exposed to X-ray radiation, mainly from nature (cosmic radiation, radon in earth) and to a smaller degree from human activity (medical X-ray or air travel). For example, the average dose received by a French citizen is about 2400 microsievert per year, where a return flight from Paris to New York will generate a dose of

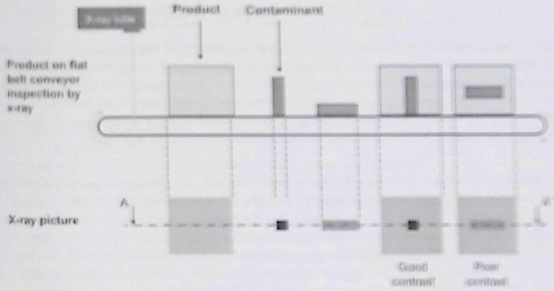

FIGURE 21.9 Contaminant orientation influence on image contrast.

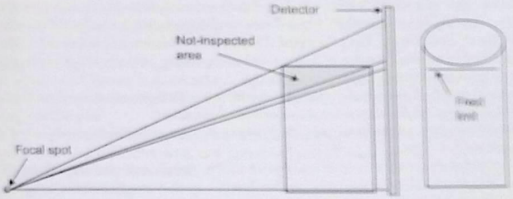

FIGURE 21.10 Limitation on rigid container.

60 microsievert and a chest X-ray about 3000 microsievert. Working in proximity to industrial X-rays might not generate any significant increased yearly irradiation.

Some recommendations:

- Leakage measurements should be carried out regularly by a radiation protection trained person on site.
- Never try to manually remove product from an X-ray device without switching off the power.
- Do not modify any machine parts, in particular do not cut the shield curtain to help product flow. If the product stream is disturbed by the curtains, another method must be discussed with the supplier, e.g. baffles or elongated tunnel.

EQUIPMENT SELECTION

There is no unique configuration and several aspects will determine the choice of detection equipment, such as contamination risk (material, shape), packaging and product characteristics, line layout, environmental conditions or process speed. No detection technology is able to detect all types of physical hazards and, according to the risks, one might install complementary technologies. Direct dialog with suppliers every so often is the best solution for professional advice. The following selection process is recommended:

1. **Determine the source and nature of physical hazards all along the production line**, based on the HACCP study and factory records. Maintenance reports or consumer complaints are an efficient way to determine the main hazards.
2. **Apply all possible prevention measures** to ensure the best reduction of foreign bodies: GMP, hygienic design, best practices and sorters according to the principle "first prevent, then detect." Working on the hygienic design of equipment with the supplier to eliminate the source of contamination in a process will deliver better results than using a metal detector and retaining the source of contamination.
3. **Select the most appropriate technology and location** according to the type of product and the packaging. This step might require modifications to the line layout. For example, the installation of a metal detector before filling instead of an X-ray device on packed product due to higher detection capabilities might require a redesign of the filler infeed or height of the building. Keep in mind that metal detectors and X-ray technology are more effective on small products (e.g. bulk before filling or individual packaging), rather than on grouped products or shipping cases.
4. **Select a shortlist of potential suppliers**, based on selection criteria, for example:
   a. Best detection performance for the specific application.
   b. Capability of the supplier to provide turnkey solutions (infeed, product handling, reject, etc.).
   c. Support level available from the supplier in the installation country. This is essential for complicated installations like multiview X-ray that might require frequent modification to settings and specific maintenance.
   d. Coherence with other equipment brands already installed in the factory to optimize maintenance and operational cost.
5. **Build the user requirement specification (URS)**, see below.
6. **Send URS together with products and contaminated test samples to the preselected suppliers to handle detection capabilities trials.** It is recommended to build your own sets of contaminated test samples to ensure a fair performance benchmarking between suppliers (with spheres and real fragments). Indicate the testing procedures to follow. Ideally the client should be present during the trials.
7. **Build a selection matrix** to make the choice, assessing the key elements of the URS. Equipment with slightly inferior performance might be chosen for its ease of cleaning and hygienic design.
8. **Handle a detailed performance qualification with the selected supplier** to assess and document the detection capabilities for each relevant foreign body type, according to the detection equipment selected.

User Requirement Specification (URS)

The URS is integral to the success of detection equipment. This is the reference document that links supplier and factory by defining all key aspects of the installation. The URS is a working document that should be developed and agreed with the supplier during the project. It should contain at least the following elements:

- **General project information**
  - Country, address, contact person
  - Project objective, type of equipment (metal detector, X-ray)
  - Confidentiality level
  - Project timeline (factory acceptance test, commissioning, start-up)
- **Product characteristics**
  - Type (powder, liquid, dry, wet, sticky, frozen, etc.)
  - General characteristics (density, flowability), particularly important for pipe or gravity fall application
  - Inspection product conditions (temperature)
- **Packaging characteristics**
  - Type and material (carton, glass, pouch, tin can, etc.)
  - Max dimensions for each format (width, height, weight)
  - Foreseen inspection orientation
  - Pictures and technical drawings
- **Production line characteristics**
  - Line speed (kg/h, m/min, pack/min)
  - Line layout and constraints (available space, accessibility, etc.)
  - Accessible power: electrical (V/Hz) and pneumatic pressure
- **Working conditions**
  - Room atmosphere (temperature, humidity) and hygiene level
  - Type of cleaning (wet cleaning, dry cleaning) and IP requirements
  - ATEX protection requirements
- **Expected performances**
  - Foreign body hazardous material foreseen on the line (material, density)
  - Maximum acceptable false reject rate
  - Expected detection limits (see Further Reading)
  - Reject unit requirements
- **Additional requirements**
  - Communication requirements (Ethernet, wireless)
  - Key items to be included in the offer: test kit, check of the rejection unit, training modules, test samples spheres and gamma survey meter
  - Training modules and documentation (language, number of copies)
  - Maintenance contract
- **Installation and commissioning procedures**
  - False reject setup procedures
  - Detection limit assessment procedure
  - Test samples definition, drawings or sketches
  - Necessary test pieces material and dimensions to be provided by supplier

TABLE 21.1 Summary of Detection Capabilities for X-ray and Metal Detector

	Material	Metal Detector	X-Ray
Metal	Ferrous	Excellent	Good
	Non-ferrous	Excellent	Good
	Stainless steel	Good	Good
	Aluminum	Excellent	Fair
Non-Metal	High density (e.g. Glass, stones)	Not possible	Fair
	Light density (e.g. Insects, wood)	Not possible	Not possible

Metal Detector or X-ray?

Testing the product on trial equipment remains the best method to evaluate the highest detection performances between a metal detector and an X-ray device. Nevertheless some basic rules will guide the choice in the early stage:

- **Non-metal hazards only:** On dense materials (e.g. glass or stone), usage of X-ray is obvious.
- **Metal hazards only:** Promote the use of a metal detector if there is no contraindication due to the packaging or product itself. While benchmarking between both technologies, remember spheres represent a favorable shape for X-ray. Therefore it is recommended, in addition to traditional spheres, to benchmark both equipments with real contaminants.
- **Aluminum hazards risk:** A metal detector is the most appropriate technology (as explained previously).

Table 21.1 gives a rough summary of material detection capacities.

In addition to the above technical considerations, investment cost, layout, maintenance complexity and difficult environment might drive the choice too, for example:

- Investment cost is usually cheaper for metal detectors. In particular, multiview X-ray costs can be prohibitive. The maintenance costs are also higher for X-ray equipment due to expensive spare parts (X-ray tube, detector, high voltage generator) with limited lifetime.
- While a metal detector has only a few parameters to adjust (amplitude, frequency and phase), X-ray machines need tens of algorithms with many parameters and are difficult to master and trace in case of modification. Factories might evaluate the complexity they are able to manage, in particular if no local support is available from the supplier.
- If the contamination risk on a tin can line is only metal particles from the process and the filler is evaluated not hazardous, a metal detector before filling to regularly check the filler integrity is a more efficient solution than a multiview X-ray alone on the tin can after filling.

Choice of Reject Unit

Reject systems are an integral part of detection equipment and must always be part of validation and monitoring processes. Faultless efficiency and synchronization with the

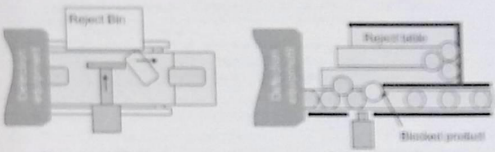

FIGURE 21.11 Reject unit malfunctioning examples.

detector must be ensured to avoid issues like mis-ejection, uncontrolled ejection or a jam (Figure 21.11).

Some key rules should be followed:

- The rejection motion should be quick enough so as not to disturb the next product and create consecutive rejections.
- If rejection is actuated by air jet, install a pressure control gauge to indicate insufficient air pressure, ensure the system has enough pressure to handle multiple rejects (air buffer tank might be needed) and carefully test the rejection unit with all products' weight and dimensions.
- Install a sensor to confirm the rejection. This control should stop the line if rejection is not effective. For flat belts this is often done by a laser barrier at the entrance of the rejection table; for gravity fall or pipe inspection it may be done by placing a second metal detector with a smaller aperture (for higher sensitivity) on the reject pipe. Install a sensor level for the rejection bin.
- Conveyor application should be equipped with an encoder to ensure automatic regulation of timing according to the conveyor speed. In the case of a long product, a synchronization photodiode should be used to detect the exact position of the product.
- For combined systems such as a checkweigher and metal detector, the rejection device should separate faulty weights from contaminated packs. The reject logic should be clear: any contaminated product should be rejected in the detection reject bin, with correct or incorrect weight.
- The line should stop automatically or an alert given in the case of a large amount (e.g. over five) of consecutive rejection during normal production.
- For rigid containers, in particular for glass jars, it is recommended to use progressive/multi-finger reject units. These rejection systems allow a smooth rejection of fragile products, like glass jars to avoid breakage that could lead to potential foreign body contamination on the line. It also allows for rejection of fallen containers or successive rejection.
- Reject units for gravity fall or pipe inspection are complex and need to be designed, installed and regulated by specialists. The relationship between the pipe size, the rejection response time and the free fall distance between the dropping point and the rejection valve must be considered. A locally made solution is not recommended.

DETECTION EQUIPMENT MANAGEMENT

Detection equipment is often the last defense against physical hazard contamination before the product reaches consumers, and warns in the case of failure of upstream measures. Detection equipment must be treated as an alarm: it has to be inactive most of the time and warn only when necessary leading to further investigation of the source of contamination. The trust placed in this equipment by the operator, engineer or quality manager will contribute to the efficiency of this alarm: in particular, a too large amount of false rejects (too sensitive settings) and insufficient level of detection are both responsible for a loss of confidence in the equipment.

This is why a detection limit cannot be decided in advance, it can only be measured once the parameters have been set for an acceptable false reject rate. Indeed, increasing the detection sensitivity results almost inevitably in an increase in the number of false rejects.

Some concepts and terminology necessary to ensure adequate detection parameter adjustment are presented below.

Product Classification

During production, the rejected product should be a contaminated product, but often the detection equipment rejects products for no apparent reason; this is the notion of **false reject** and **correct reject** as described in Figure 21.12.

False rejects are defined as products that have been ejected by the detection unit for no acceptable reason. They are mainly due to:

- Inadequate sensitivity setup. Often due to too sensitive parameters leading to the ejection of good packaging and/or good product within acceptable specification.
- Environmental disturbances (e.g. magnetic or electrical field, vibration, unstable power supply).
- Operational issues (e.g. vibration on metal detectors, wrong setup after format changeover, dust, poor cleaning, packaging with incorrect orientation/handling/spacing).
- Incorrect layout/installation (e.g. inappropriate product/packaging handling system, fallen jars on conveyor or deformed packaging, not respecting the metal-free zone area).
- Detection unit malfunctioning due to internal technical failure (electronic issues or unbalanced coil for metal detectors. Arc in X-ray tube, tube aging, software bugs or overheating of X-ray equipment.

Beside the false reject, some non-contaminated items might be rejected due to products or packaging being interpreted by the detection unit as a defect. This occurs because it is not always possible to differentiate foreign bodies from some products or packaging deviations. A metal detector might reject a product with an abnormal moisture content level or an X-ray machine might reject an overweight pack. Some typical examples are:

- Glass jar inspection by X-ray: Some metal inclusions present in the side wall of a glass jar have identical appearance to metal contamination in the product. These jars are therefore often rejected, but in this case the detection equipment should not be blamed.

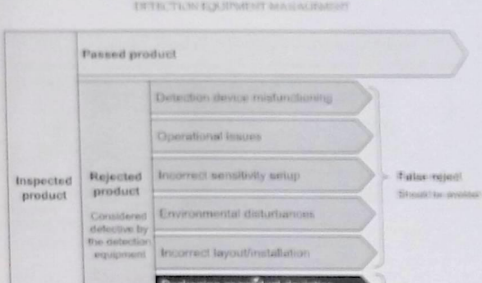

FIGURE 21.12 Reject categories.

- A tin can might have deformed during transport, and is interpreted by X-ray as not acceptable. Again this should not be considered a false reject, unless it is relevant to the factory to produce such defects; in this case the detection sensitivity might be reduced to accept a wider packaging defect range.

The False Reject Rate (FRR)

This is the ratio of "false reject/inspected product." The FRR should be calculated on an extended period of time or quantity, after the rejected product has been sorted and classified into categories. A detailed examination of each reject is necessary to define if it is a false or correct reject.

In order to ensure a realistic workload and to maintain confidence of operators in the detection equipment, FRR should remain at an acceptable rate, ideally close to 0%. A good value recognized in industry is a maximum of 5/10,000, but it is up to each business to define the acceptable level of reject that can be manageable. However, no false reject at all (0%) might also indicate the equipment settings are not sensitive enough.

It is recommended to set the detection equipment at the higher sensitivity and to reduce it step by step once the FRR is acceptable. The sensitivity of the detection equipment is then fixed.

Representative Samples

As discussed, some product characteristics will influence the detection and generate a false reject, for example the density, humidity, temperature, mass distribution of the product or packaging tolerances.

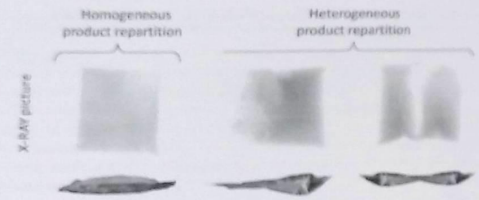

FIGURE 21.13 Heterogeneous product repartition.

Representative samples simulate the foreseen, but acceptable, industrial variations of the product and/or packaging. These samples can be hand-made or collected. They are used to set the sensitivity of the detection equipment when a large amount of product is not available. Indeed, to ensure an acceptable false rejection rate, it is more efficient to ensure that a dozen representative samples are not rejected rather than inspecting a thousand identical products.

Some examples are given below:

- For pouch inspection by X-ray, some extreme cases should be prepared, for example heterogeneous product repartition in the pack (see Figure 21.13), or over- and underweight parts.
- For conductive products inspected by a metal detector (e.g. wet, frozen, cocoa based), the standard variation range should be tested and not rejected.
- Tin cans might be artificially slightly damaged to reproduce some of the usual damage found after transport.

Probability of Detection (POD)

Foreign body occurrence is a "rare event" following Poisson's law. Detection capability is assessed by passing a contaminated test sample through the detection equipment several times. The associated probability of detection (POD) is the likelihood of a contaminant of a given size, nature and position with a defined confidence level.

In theory, a POD of 100% cannot be demonstrated by testing. Statistically, by increasing the number of passed test samples, the corresponding POD will increase. At the same time, by increasing the numbers of successfully detected test samples, the limit of detection will generally increase too. An increase in the POD is usually associated with a size increase of the corresponding test sample contaminant diameter.

A minimum number of passes must be performed to have an acceptable POD. In practice (realistic workload), a contaminated sample detected 30 times over 30 passes (POD = 30/30) ensures a statistical POD of 90.5% at 95% confidence level as per the binomial distribution law (Figure 21.14).

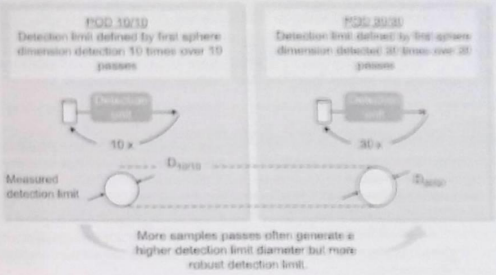

FIGURE 21.14 Impact of number of passes on detection limit.

It is important to understand that increasing the POD level will not modify the sensitivity of the equipment, but will give a more faithful representation of the real detection sensitivity.

Limit of Detection

Detection equipment performance is measured by the smallest test piece detected for a defined POD level (e.g. 30/30). For practical reasons, only spheres are used in contaminated test samples to establish the detection limit (no influence due to sphere orientation). This defined detection limit assesses, by a statistical method, the best possible machine performance in good working conditions for the spherical contaminant in a given position.

The testing procedure to establish the detection limit is:

1. Start with the equipment set up for the highest sensitivity.
2. Step by step reduce sensitivity until the FKR is not higher than expected. When a large quantity of product is not available, representative samples (see below) are used to simulate the production variability. None of them should be rejected.
3. When the settings ensure an acceptable FKR, they should be fixed, saved and not modified until the end of the procedure.
4. Pass each contaminated test sample, for each sphere dimension, the number of times required at the selected POD, starting with the smallest dimension. The detection limit is defined by the smallest dimension achieving the required POD (e.g. 30 detections on 30 passes). Always put the test pieces together with the product.

Note: Equipment should be designed and installed in order to ensure that several passes are easily managed. In particular, suppliers should propose test kits to ensure easy access for test sample handling on gravity fall and pipe metal detector (access/retrieval gate). This aspect might be described in the URS.

5. Pass some test samples with real contaminants (fragments, wires, shavings, etc.) to document the detection capabilities on real contamination. These samples cannot be used to determine a detection limit because they are not reproducible, but they are essential documentation (qualitative information).

The above measured detection limit has, however, severe limitations:

- A sphere is not a true representation of usual contaminants such as wire, shavings or fragments.
- A sphere is a favorable shape for the detection equipment (mass concentration).
- Material composition used for the spherical contaminant might differ from the real hazard material composition.
- Risk of overestimated detection performance by the use of a unique test sample, even passed several times, cannot ensure the contaminant has been tested at the worst position in the product or packaging (a typical case for gravity fall or pipe inspection metal detector is where the trajectory of the contaminant cannot be controlled to pass always in the center of the aperture).

Consequently, the detection limit measured statistically at a given POD on a unique test sample (e.g. 90.5% chance of detection) is optimistic. The statistical approach always associates a risk of non-detection too. If this limit is used for frequent routine equipment checks, there is still some chance that this will not be achieved all the time. Failure in the routine check might generate operational complications (such as batch blocking, rework or waste) and loss of confidence in the equipment.

A solution to increase the POD level is to pass more samples; an alternative solution with a similar effect is to artificially counterbalance the relatively low POD by introducing higher test sample sizes (e.g. using spheres with a diameter of 0.1 or 0.2 mm larger than the detection limit) for the routine equipment checks by operators. A check of the detection limit should, however, be performed on a regular basis.

Whatever the solution selected, the effective detection performance will remain the same. Checking the equipment with a slightly larger test piece dimension than the detection limit measured during the POD test does not influence the quality of detection. Detection equipment parameters are defined during the FRR assessment and are not modified.

Detection Limitations and HACCP

Metal detectors and X-ray equipment cannot ensure removal of all foreign bodies. The detection efficiency of these two technologies is heavily influenced by factors such as material, shape, size, location and orientation of the foreign bodies. They are also limited to sharp and hard physical hazards and will not be adequate to detect common biological contaminants (for example, insects or hair).

Detection limits are measured for each material by statistical methods, using spherical contaminants and a limited number of tests. They are not absolute and only associated with a probability of detection. Therefore detection equipment cannot always guarantee 100% removal of all contaminants bigger than or equal to these detection limits.

As a consequence, detection equipment can be identified either as a control measure or a verification measure depending on local HACCP assessment, but they should not be the

only measures to reduce the hazard to an acceptable level and should be used in combination with upstream control measures.

Finally, it is important to remember that all rejects must be investigated and root cause analysis and corrective actions taken when a foreign body is discovered.

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SECTION III

FOOD SAFETY ASSURANCE SYSTEMS

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CHAPTER

22

Principles and Systems for Quality and Food Safety Management

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OUTLINE

PRINCIPLES, SYSTEMS AND SCHEMES

Background and Working Definitions

In this chapter we will first look at the scope and meaning of "quality and food safety management" and then discuss principles and their relationship with systems and schemes.

Quality and safety in food are best considered together in this context. While for some purposes (for example, HACCP) we will want to make clear distinctions between them, they also share a number of common elements, especially from a perspective of their management.

For our current purposes, therefore, we will consider the management of food in terms of the goals we aim to achieve: safety, legality, consistency and consumer acceptability.

Food businesses all around the world must build and maintain management systems around these aspects.

There are many definitions of "principles," but for our purposes we might view them as headings under which we bring together all methods, techniques and background knowledge necessary to manage a particular (sub) aspect of food quality and safety. The principles therefore all relate back to one or more of the goals listed above, and together they cover our needs. Whether the list is exhaustive will remain debatable, but it should suffice to cover our needs and relate to the "systems" (see below).

"Systems" can be understood as management tools, aimed at operationalizing the principles. Of all the methods, techniques and background knowledge associated with a principle, a system typically selects those that "must" be used to fulfill appropriate requirements in a particular context, to make them as concrete and measurable as possible and provide a defined endpoint where possible. As an example, we might take "consistency," which was mentioned above as a goal (in practice we would then need to specify targets and limits for parameters), but is also listed below as a principle (but then we need to mention related methods and techniques, and the backgrounds of statistics and metrology). 6 Sigma, for example, is a management system that operationalizes the principle of consistency: it provides steps, presents specific methods and background knowledge and defines an endpoint (in its most literal sense, that endpoint is the achievement of 6 Sigma performance for the parameter(s) in question).

We will use the term "scheme" to describe a construction where one or more systems have been enveloped in an auditing/certification format. This applies to a large degree to our current topics – management systems in the area of food quality and safety usually combine the application of various principles under one roof. The GFSI-recognized certification schemes (currently including BRC, IFS, FSSC 22000, CanadaGap, GlobalGAP, Global Red Meat Standard, Global Aquaculture Alliance Seafood Processing Standard, PrimusGFS, Safe Quality Food) are all representatives of this approach. They typically cover general quality management systems requirements, loosely based on ISO 9001, including an HACCP module (based on the Codex format), and they provide a series of "prerequisite program" requirements, which address the principles of hygiene.

These schemes provide clear advantages: they present a concrete and comprehensive format to the management of food quality and safety, their certifications can be used as the basis of acceptability within the industry and (increasingly) towards authorities, and they can be expanded and updated as necessary with the input of all stakeholders.

The disadvantages, however, relate mostly to the fact that all schemes (and their underlying systems) are compromises:

1. Specificity – in order to be widely applicable, the requirements can never be sufficiently specific to fit any particular operation and the scheme owners must strike a balance between the (commercial) scope of their scheme and the relevance of the practical guidance it provides. ISO 9001, for example, is designed to be universally applicable, and therefore contains nothing that would specifically apply to food. In contrast, one might design a standard specific to each process for each food (or raw material) product. This would lead to a totally unmanageable multitude of standards and still not be precisely applicable to every individual situation. The above-mentioned global standards have managed to strike a much more relevant balance for the food industry, but it is important to note that there will always be this balance, and it is impossible to get it "just right" for all operations and situations. The limited specificity of global standards then makes the professional judgment of the auditor the key deciding factor for the practical validity of any certificate, which represents a structural vulnerability of these approaches. The report of the Joint FAO/WHO consultation on the Role of Government Agencies in Assessing HACCP, Geneva, 2–6 June 1998 already states that it is important that the use of a checklist does not evolve into a simple "tick-box" approach where there is no critical evaluation.
2. Level of sophistication – in order to address legal and market expectations in the most developed markets, standard requirements must be set at levels that may not be easily attainable in developing markets. Any claim of global relevance then risks ending up in a compromise that is practically irrelevant everywhere. As a result, the GFSI standards now include a stepping-stone approach, the "global markets" scheme. While this clearly addresses a realistic need, it also gets us back to what are effectively local rather than global standards.

All in all, therefore, management schemes are compromises and their practical claims are critically dependent on the professional qualifications of their auditors. Still, it is probably fair to say that the world of food quality and safety management has benefited enormously from these schemes, and their development and global acceptance is likely to continue for the foreseeable future.

We will see further in this chapter the use of systems to manage food safety and quality between different elements of the value chain and between organizations, for example linking retailers with suppliers.

While IT can help structure and track processes in a system, we do not specifically tackle IT systems in this chapter. We do, however, make reference to relevant types of IT software systems, and where they are driving the adoption of overall systems to manage food safety and quality.

Conclusion

From the above it is clear that effectively and efficiently managing food safety and quality in any specific case will always have to involve the application of principles. Whether

it must also involve a formal system, or a certification scheme, will depend on the need for additional structure and/or external recognition. To make certification as meaningful as possible, the choice of the appropriate scheme is important, but even more important is the professional qualification and attitude of the auditor.

Food Safety Initiatives

GFSI

The Global Food Safety Initiative was established to continuously improve food safety management systems and ensure confidence in the provision of safe food to consumers worldwide. The initiative is business driven, bringing together leading food safety experts from global organizations to collaborate through the GFSI platform. Defining food safety requirements throughout the food supply chain, benchmarking different food safety standards against the requirements, building capacity of small or less developed businesses and focusing on auditor competency are the main activities. (See http://www.mygfsi.com/.)

HACCP

Hazard analysis and critical control points is a specific food safety-oriented method that was developed in the USA. In the meantime it has become the universally recognized and accepted method for food safety assurance, part of food safety legislation in the EU, USA and many other countries. Guidelines for the application of the HACCP system have been adopted by the FAO/WHO Codex Alimentarius Commission. HACCP certification through certification bodies is available in many countries – usually through the HACCP-based ISO 22000 scheme or the GFSI-recognized FSSC 22000 scheme, which combines ISO 22000 with Prerequisite Programs as described in ISO/TS 22002-1. (See also HACCP and its validation and maintenance in this book: www.fao.org/docrep/W8088E/w8088e.htm.)

ISO 9001

ISO 9001 (the International Organization for Standardization's standard for quality management systems, currently in the 2008 version) is internationally recognized as the authoritative standard in its field, but all its requirements are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. Because of the lack of specificity, an ISO 9001 certificate is normally not accepted as a sufficient proof of acceptable practices in the food industry. Still, the management system principles as outlined in 9001 have found their way into all food-specific quality standards. ISO 9001 certification is available from multiple certification bodies across the world. (See http://www.iso.org/iso/home.html.)

6 Sigma

6 Sigma is a methodology aimed at reducing product and process variability – if possible to a nominal level of 0.0003% failure rate. The method makes extensive use of applied statistics throughout its five steps: Define, Measure, Analyze, Improve, Control. Having started in the electronics industry, 6 Sigma has found applicability in many other branches. While 6 Sigma is supported by many consultants and training courses, it is not a "scheme"

as defined in this chapter. Companies can apply the method, but not be certified according to a defined 6 Sigma standard. (See http://asq.org/index.aspx.)

PRINCIPLES AND ASSOCIATED SYSTEMS

The management of quality and safety in food will require the application of the following principles.

Hygiene

Hygiene has been defined as "the practice of keeping yourself and your surroundings clean, especially in order to prevent illness or the spread of diseases." For our current purposes the concept of hygiene will be extended to include cleanliness issues that do not necessarily relate to illness, like foreign material prevention and basic housekeeping rules regarding chemicals including pesticides and lubricating oils. Taken together, they are usually covered by what is commonly referred to as "prerequisite programs" – PRPs – in the context of HACCP (see "Prevention and Risk Reduction," below), indicating that we normally do not rely on hygiene alone to prevent illness or the spread of diseases.

Hygiene will also include allergen management, which is related to illness, although not in all individuals. Nevertheless a system is required to manage cross-contamination, as a prerequisite to appropriate labeling. In many countries, there are strict laws requiring the declaration of allergens on packaging.

When designing and implementing hygiene management, we always need to consider the level of hygiene required for the specific purpose at hand. It seems obvious that a rule like "all food handlers need to wear a hairnet" would not logically apply to people harvesting lettuces by hand.

In all cases, however, we do need to consider requirements related to people, equipment, tools and materials (including anything from water to lubricating oils and pesticides) and the general environment in the context of the intrinsic vulnerability of the product and the intended later cleaning and processing.

The hairnet for lettuce harvesters would not be required because lettuces will receive a subsequent cleaning step which may include removing outer leaves and is meant to sufficiently remove more types of foreign materials than just hairs. Protecting the general lettuce-growing environment against, for example, EHEC (enterohemorrhagic *Escherichia coli*) contamination – through untreated organic fertilizers, water or direct animal activity – would be relevant because later treatment including food preparation might not eliminate the EHEC bacteria.

Hygiene management systems can therefore be understood to support HACCP systems by reducing the list of "realistic hazards" in a relatively simple and robust way. What can easily be prevented or eliminated is taken care of by the somewhat broad brush of hygiene management; the remaining hazards get individually named and treated through HACCP.

As a general source for the methods, standards and techniques of hygiene, Codex Alimentarius must be mentioned. It captures a very wide and internationally accepted array of hygiene standards. As such, it underpins practically all food quality and safety-related

management systems, but it is not generally seen as a system itself, and there are no widely recognized certification schemes based on Codex (sporadically, Codex certification has been offered).

For manufacturing equipment there is, for example, EHEDG and the EU legislation.

In the context of hygiene management, the 5S methodology must be mentioned. Originally it is a Japanese workplace organization method, concentrating on the elimination of "waste" in its various forms: unnecessary tools, parts and instructions, all dirt and rejects, and all forms of disarray and untidiness. The workplace needs to be standardized, clean, clear and lean at all times. Depending on the exact format adopted locally, safety, worker satisfaction and quality can be part of the 5S program. Though it has originated outside the food industry, it is easy to see how 5S can be used in support of hygiene management and reliability, and the program is being used as a firm basis for continuous improvement programs (6 Sigma, Process Variation Reduction – PVR), as well as various HACCP-based food safety-oriented schemes (GFSI certification).

For systems approaches covering hygiene, there are the globally available and recognized GFSI certification schemes as mentioned above, and in the case of FSSC 22000 there is a specific prerequisite program standard (ISO/TS 22002-1) that was developed to augment ISO 22000 to provide an all-round food safety solution. Additionally, the AIB (American Institute of Baking) scheme must be mentioned, which heavily concentrates on hygiene topics (understandable from the perspective of AIB's bakery background, where the baking process normally provides an adequate kill step for any microbiological concerns), and a veritable multitude of local standards, which often specialize on locally relevant product categories.

Food Safety Initiatives

EHEDG

The aim of the European Hygienic Engineering & Design Group is to promote the production of safe food by ensuring the hygienic design and engineering of food manufacturing equipment. EHEDG is a consortium of equipment manufacturers, food industries, research institutes and public authorities, providing training and guidelines. Started in Europe, EHEDG has now active sections in countries on all continents and guidelines are available in many languages. (See http://www.ehedg.org/.)

PRPs

Prerequisite programs address operational conditions that must be in place if a HACCP program is to be effective. They may relate to conditions in facilities and grounds, production equipment, cleaning and sanitation, personal hygiene, control of chemicals, receiving, storage and shipping, pest control and others. Most commonly used PRPs in the food industry derive from Codex Alimentarius. ISO/TS 22002-1:2009 specifies requirements for establishing, implementing and maintaining prerequisite programs (PRPs) to assist in controlling food safety hazards, typically used in connection with ISO 22000 for certification purposes (see also Chapter 24).

PVR

Process Variation Reduction is a method for isolating and identifying sources of process variation in excess of inherent, intrinsic variation (often called common cause variation),

with the intent of their removal. PVR can stand alone, or it can augment a Sigma. Its aim is removing assignable sources of variation is to create more laminar, less turbulent, process flow, thereby improving productivity and quality simultaneously. This is accomplished by gathering sufficient data, organized specifically to quantify common cause variation, structural variation (due to differences among parallel segments of processing) and additional sources of assignable cause variation such as those due to raw material, operator, environmental and other differences. The quantified sources of variation are accumulated into "performance" and "capability." Performance variation measures fluctuations experienced by the consumer, while capability measures the best the process can do. The difference between performance and capability can usually be set in financial terms, aiding the setting priorities for improvement projects.

5S

5S is the name of a workplace organization of Japanese origin. The method is about: (1) eliminating everything that is not needed in the workplace, (2) giving everything that remains a clear and permanent place, (3) cleaning the workplace, (4) standardizing all common elements of the workplace, and (5) sustaining and continuously improving the practice. The practices of 5S normally exceed food industry PRPs, but there can be significant synergies in the combination of the specifics of PRPs with the rigorous 5S approach. 5S is supported by many consultants and training courses, but it is not a "scheme" as defined in this chapter. Companies can apply the method, but not be certified according to a defined 5S standard. (See http://www.epa.gov/lean/environment/methods/five-hm.)

Prevention and Risk Reduction

Prevention and risk reduction is the one principle that is generally understood to be the exclusive domain of a single system: HACCP (hazard analysis critical control points). The HACCP system was developed in the 1960s by Pillsbury and the format was given global authority by Codex in 1993. As the Codex Alimentarius series of standards is meant to form the basis of national laws and international trade, HACCP has found its way into many countries' legal systems.

ISO 22000 is the primary international standard for the certification of HACCP, but as mentioned above, it lacks a specification of necessary hygiene conditions – the PRP's – and this is what, for example, the GFSI series of schemes addresses.

At this point it is probably relevant to mention that none of the above-mentioned standards and schemes will mention any specific hazard to be "prevented or reduced to an acceptable level" (in many cases they do mention specific hygiene precautions to be taken). It therefore continues to depend on the specific expertise of those who design, verify and validate a specific HACCP system to make the appropriate choices, and on the ability of the auditor to judge the results.

Some large food manufacturers have therefore established a two-tier system, whereby for each product/processing combination category (canned pineapple, frozen vegetables, smoked sausage, etc.) highly specific process flow and core hazard identification/reduction methods are given. It is then up to the individual manufacturing site to implement the standard plan and add any locally specific additional hazards, controls as necessary. This

approach is as robust as reasonably possible, but it does require the availability of high-level expertise and is only practicable where a relatively limited number of products are involved.

General claims relating to food safety "because we have HACCP" must therefore be viewed with a certain degree of skepticism.

To illustrate the point – we have seen cases where producers of canned food products did have multiple globally recognized certificates, awarded by internationally accredited certification bodies, but were unable to show records and reports of the validation of their retorting process. (In the USA, the FDA will require highly detailed information before approving a retorting operation – see, for example, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071581.pdf.)

In practice, the HACCP system is often abused through:

- Lack of specificity: hazards are not identified individually, but collectively (for example, "microbiological pathogens"), which leads to lack of specificity of the controls.
- Identified hazards not being real hazards (product dissatisfiers, or PRPs, rather than hazards, being managed in the HACCP plan).

The status of HACCP as a legal requirement throughout the supply chain in many countries has to a certain extent facilitated its misuse, where, for example, operations handling only packed and shelf-stable foods felt compelled to establish their own CCPs.

Where large numbers of widely varying products are involved, the use of risk matrices may help to manage complexity and assure consistency. Typically, risk matrices consider a combination of inherent product risk (for example, whether or not the product in its current form would support the growth of pathogens, as indicated through a_W or pH, or the relative frequency with which a product type is associated with a certain type of chemical contamination in the EU RASFF reports) and supplier-/origin-related risk. The latter is usually more complex and may involve certification status, geographic origin (addressing questions of the type: "is this a BSE country?"), internal layout and product portfolio (allergen risks), complaints, incidents, capability history, sales turnover, etc.

Establishing and keeping a risk matrix up to date is a major undertaking if it is used to combine all current and relevant factual information about the suppliers and their products. Where the aim is to implement a risk management strategy that is both rigorous and efficient, there may not be an alternative.

Microbiological modeling is increasingly being used in support of risk matrix approaches. Growth/death kinetics of various relevant microbiological strains are being modeled under relevant and realistic conditions, including intrinsic product parameters (including pH, a_W), processing conditions (time–temperature), packaging (vacuum, modified atmosphere), logistic conditions (time, temperature, humidity), storage and retailer shelf conditions and expected treatment/preparation by the consumer. As compared to ad hoc testing of samples, this approach has many advantages, with the assessment of any individual situation being based on a body of interrelated and systematized data and trends. The sheer complexity and the efforts necessary to build these models, however, will likely preclude their general application for the near future.

In the context of prevention the due diligence defense merits discussion. The UK sees some organizations referring to their "due diligence" systems. While the defense is an integral

element of UK food safety law we are seeing the principle appear in other European countries, for example in retail organizations, as an overarching guiding principle in managing food safety. The UK Food Safety Act of 1990 (since amended) established that a defense in case of court would be that a person can prove he or she took all reasonable precautions and exercised due diligence to prevent the occurrence in question. This would mean that in a food production environment there must be the appropriate risk assessment and HACCP backed up with procedures and documentation to demonstrate all reasonable precautions have been taken. The size of the company has a bearing on the level to which these precautions extend – the larger the organization and therefore with more access to resources, the greater the expectation.

This brings us back to the beginning of this section where we mention that no scheme requires any specifically named hazard to be prevented or reduced to an acceptable level and that we depend on the expertise of those designing such a system to manage this level.

The due diligence defense is a robust way to prevent food safety incidents and puts the burden of proof on the defendant. In doing so it prevents an often seen attitude where a company that causes an offence is simply able to pay a fine – the insurance costs of which would inevitably be reflected in the cost of running this system – and continue business unabated.

The vulnerability of the food chain and the necessity for preventive action is further recognized by the signing of the FDA Food Safety Modernization Act (FSMA). While certain details remain to be finalized, the American government's intention is clear – to proactively reduce the occurrence of foodborne illnesses. This will require food and agriculture businesses to implement preventive controls, the basis of such controls being scientifically based risk assessment, which is specifically mentioned under "Hazard Analysis and Risk-based Preventive Controls" (See http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm). We may see the introduction of such legislation having a positive effect on the adoption of certification across the supply chain – both for domestic and import suppliers.

Food Safety Initiatives

FSMA

The US Food Safety Modernization Act was signed into law on 4 January 2011 and aims to ensure the safe supply of food by preventing contamination rather than responding to it. It is said to be the most significant reform in decades. (See http://www.fda.gov/Food/FoodSafety/FSMA/default.htm.)

RASFF

The Rapid Alert System for Food and Feed (RASFF) is an online database used by European member states to quickly exchange information on consignments of food and feed where a risk to human health has been detected. The tool allows EU countries to check whether the affected product is on their market and to take necessary action, for example, to block consignments, withdraw, recall or seize. The database is also accessible by consumers and businesses. (See http://ec.europa.eu/food/food/rapidalert/index_en.htm.)

Reliability

The performance predictability of processes and equipment, reliability can be seen as another PRP underpinning food safety and consistency (see "Consistency," below). Many

food scares and incidents have been caused by reliability issues, and many could have been avoided through simple – but rigorous – preventive maintenance. Carbon filters being used beyond their capacity (filtering organic chemicals or microbes out of water), in-line sieves breaking and fragmenting after a certain throughput, pumps or air conditioning devices internally accumulating dirt, are all examples of the preventable breakdown of *a priori* capable processes and equipment. The fact that preventive maintenance is still not ubiquitous is usually due to considerations of short-term versus longer-term costs (why fix it now, when it is still working?).

Another typical cause of unreliability in the food industry is *a priori* lack of capability. In one example, we have witnessed a press plate of a cocoa press, woven from steel wire, broke down and caused an avalanche of small steel particles through a system of pipes, where they were supposed to be caught by magnets. Normally the press mat would break gradually and regular inspection would enable its timely replacement, while the magnets would keep the cocoa powder from being contaminated with steel particles. When the mat suddenly broke catastrophically (though roughly around the normal period of use), the magnets were overwhelmed. Assuming capability of the magnets to deal with any eventualities, they were simply cleaned from the metal debris and heavily contaminated cocoa powder was shipped (the situation was detected by the customer through their finished product metal detection system). This episode illustrates three points: (1) replacing only parts that have already visibly started to break down is not a reliable preventive maintenance strategy, (2) a downstream process aimed to "eliminate the hazard" (HACCP terminology) must be designed to be capable of dealing with the worst-case scenario (breakdown of a complete press mat) and (3) the process must include a point that can be used as a reference to demonstrate control. (In this case, a new setup included a "final magnet" which was required to stay clean at all times. Finding any metal particle on the final magnet would be seen as an indication that metal particles would have found their way into the product.)

Organizing reliability has been the focus of TPM (Total Productive Maintenance), which aims to achieve zero unplanned equipment failures, zero product defects, and zero accidents. The first two aspects were illustrated above; the accidents aspect fits logically with the others and can also be seen in 5S programs (see "Hygiene," above). Another key element of TPM is the involvement of the operator in the maintenance program and the explicit intention to optimize and redesign the equipment, based on ongoing in-depth performance analysis. A TPM program typically starts with a complete stripdown and cleaning of the equipment, followed by initial inspection for early signs of partial deterioration.

TPM is a very time and expertise intensive program, and many companies do not feel confident to use it, but its results in terms of productivity, hygiene and consistency are potentially very significant.

Food Safety Initiatives

TPM

Total Productive Maintenance is a participative method, where production employees take responsibility for the combined preventive and corrective maintenance of the equipment with which they are working. The goals are expressed as various elements of loss reduction: downtime, out-of-spec production, planning uncertainty and the associated stock

levels, safety issues, impact on morale and the costs associated with all of the above. TPM is supported by many consultants and training courses, but it is not a "scheme" as defined in this chapter. Companies can apply the method, but not be certified according to a defined TPM standard. (See http://en.wikipedia.org/wiki/Total_productive_maintenance)

Consistency

Consistency (and variation reduction) in this context, indicates the degree to which successive batches of) products or units processes comply with their specifications. In food this can involve any type of parameter, thermal treatment (baking, cooking, stirring), color, weight, taste characteristics, etc. While proper specification and consistent compliance is arguably as relevant in food production as it is in any other industry, it is probably fair to say that this aspect is rarely given the attention it deserves.

Proper specifications are:

- Relevant to safety, legality, customer acceptability or internal processability.
- Specific as to the exact nature of the parameter(s) and measurement methodology involved.
- Precise in defining the required targets and limits.
- Realistic in terms of the capability of the process that is being specified or that produces the product spec.

Specifications in the food industry rarely fulfill these requirements, and typical problems include:

- No target defined (which may encourage a supplier to produce in a very tight tolerance close to the economically most attractive side of the limits).
- No limits defined (in practice this means that all acceptance/rejection decisions will be arbitrary).
- Insisting on symmetrical limits around the target (for example, in a pH specification, the upper limit may reflect a very different requirement than the lower limit, and the spec may be asymmetrical).
- No regard to process capability (batches may never be in spec).
- Specifying an irrelevant parameter.
- Not specifying a relevant parameter.

In the absence of proper specifications, there can be no appropriate process control, which then may lead to noticeable issues in all relevant areas mentioned above: safety (for example, through uneven heat distribution across an oven band), legality (for example, weight or volume), customer acceptability (for example, color or texture), or internal processability (for example, the fit of exactly x cookies in a tray).

In recent years, multiple examples have demonstrated the potential of 6 Sigma approaches to increase consistency and reduce losses. At a somewhat simpler level the PVR methodology has also demonstrated the ability to improve products and processes. In its simplest form it distinguishes three types of variability: common cause (i.e. inherent in the current design of the unit operation of the process in question), structural variation (i.e. the

variability related to multiple unit operations in parallel, for example multiple parallel filling heads in a bottling plant) and assignable cause variation (related to "external" influences on the process that can be identified and eliminated or reduced).

Assignable cause variation can be normally addressed without major interference with the processing conditions or equipment. Structural variation and certainly common cause variation can only be improved through rigorous maintenance and/or redesign programs, for example TPM.

Food manufacturing is often plagued by inherent losses, and often a certain level of losses can be calculated as being "unavoidable." This may involve overfilling of weight or volume, product rejections, or when equipment is jamming because of lack of fit of product into packages, or lids to tubs or any other of a multitude of variability related causes. Frequently, the role of raw material consistency on the finished product is not considered, for example in poultry production often an inordinate amount of effort is spent in cutting and sorting different sizes of chicken pieces – leg, wing, etc. – due to variability in carcass quality. A focus on the farming methods and clear specifications for suppliers would help to reduce this effort. We could see an application of a 6 Sigma approach to identify and resolve the variation.

In all those cases a careful and systematic program to reduce variability around meaningful specifications will pay significant dividends.

Traceability

Under EU law, "traceability" means the ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all stages of production, processing and distribution. Traceability must be understood to apply both upstream (where does this product come from?) as well as downstream (where did this product go to?).

Legal requirements for traceability are formulated differently in different countries, but it is clearly essential in any food quality and safety management system. Claims of origin ("product of…region or…country") are the most obvious examples, but traceability also involves the coverage of products by a certificate (has this product actually been made at the manufacturing site that carried the certificate, or has it been subcontracted to a less well-controlled operation?), the assumption of *a priori* risk (did this batch of beef originate from a BSE country, did this tea shipment come from a country that has effective regulations and controls against chlorinated pesticides?), the age (production time, expiry date) or catch area of fish (fish species may be red listed in some catch areas but not in others).

In recall and withdrawal cases, traceability is essential to determine the scope (mostly downstream traceability) as well as the root cause (upstream traceability). Finding the exact root cause may again have an influence on the scope. The 2011 EHEC crisis in Germany presented a clear case in point – with recalls, withdrawals and import stops varying according to the then current root cause theory: vegetables from Spain and Holland and finally fenugreek seeds from Egypt.

A more demanding form of traceability is found in "chain of custody" requirements usually associated with laboratory testing of critical samples, environmental certification of critical commodities or criminal procedures. We might see this in certification of "GMO-free" maize and in ethically produced and labeled cocoa.

Implementing traceability involves barcode systems (a major international player in this field is GS1 – http://www.gs1.org), and/or in future RFID systems (radio-frequency identification – http://www.rfid.org/), which are potentially more capable but have so far not found wide acceptance in the industry, mainly for cost reasons. Simple maintenance and linking of documentation of incoming raw materials and outgoing finished products may suffice in smaller organizations. Inevitably as the size of an organization increases and is operating in a more developed market, the level of IT involved in managing such a system increases.

Food Safety Initiatives

GS1

An organization that provides a system of integrated global standards, GS1 aims to improve the efficiency and visibility of supply and demand chains worldwide. It works across sectors and is one of the most widely used supply chain standards globally. The GTIN (Global Trade Item Number) is one of the key elements of the GS1 system and is a unique number used to identify products and services that are made or sold at any point in the supply chain, for example warehouse, checkout. A key advantage of GS1 is the ability to secure traceability through the supply chain. (See http://www.gs1.org.)

RFID

Radio-frequency identification is a generic term used to describe wireless non-contact technologies that use radio waves to identify and track objects via a unique serial number. The most common technology is to embed an object with a tag that contains a microchip with electronically stored information and is attached to an antenna that transmits identification information to a reader. RFID tags can be attached to any object or being, for example livestock may have tags injected, allowing positive identification of the animal. RFID technology does not require contact or line of sight for communication which is the main difference to barcode technology. (See http://www.rfid.org/.)

Customer and/or Consumer Relevance

The question of customer and/or consumer relevance is normally a joint responsibility of the marketing and R&D functions (in retail and foodservice, quality assurance often assumes the R&D responsibilities). Methods range from the simplest forms of in-house product testing on the basis of externally supplied samples to more sophisticated product design methodologies and the use of professional panels.

QFD (Quality Function Deployment) is an example of a highly structured approach that has been used in the food industry for quality purposes and also for food safety purposes but not very widely. It aims to translate the "voice of the customer" (typically expressed through a prioritized list of achievables – the "whats") into the design characteristics, including types of raw materials, processing, packaging, distribution and presentation (the "hows") through successive stages.

QFD is designed to account for interactions, through the "roofs" of the "house of quality," but the complexity of the considerations have so far prevented widespread application of the methodology. We have seen successful application of QFD in large branded

manufacturers who typically have greater resources at their disposal and see the investment as an essential part of their brand growth.

With products already on the market, customer response systems are widely used to track complaints, claims and comments systematically. These kinds of responses are a valuable source of information for a business, but the level of sophistication of collection, analysis and response systems varies widely.

Typical challenges include trend analysis on the basis of responses per unit sold, which may be difficult for manufacturers as they do not know exactly when products are sold to the end consumer (one approach is to try to calculate an average lag period between production and consumer use, but this is inherently imprecise) and the differences in complaint behavior between different countries. The number of complaints in Europe has traditionally been highest in the UK and much lower in countries around the Mediterranean. Globally speaking, these authors have seen a two to three order of magnitude difference in complaint rates between, for example, the USA versus Costa Rica or the Philippines for the same range of food products. It is obvious that complaint rates do not simply reflect inherent product failure rates, but they also do not reflect relative indifference to product shortcomings. In our experience, consumers in low complaining countries are – equally – less likely to buy the product again after a negative experience as customers in high complaining environments.

Quality system certification – along the lines of the ISO 9001 requirements – typically requires a company to operate a system for tracking customer satisfaction, which then should be more than a design acceptance (for example, QFD including consumer testing preproduction) and complaint registration. Ongoing comparison against relevant completion and consumer requirements is then indicated, including appropriate follow-up.

All the above-mentioned aspects of and approaches to customer/consumer relevance and acceptance are not really standardized tools and are not all explicitly required by established certification formats, although the GFSI schemes do have requirements around new product development and customer feedback. All aspects, from product design through complaint tracking, are relevant and any producer or retailer implementing a food quality and safety management system must put their own mix together.

Food Safety Initiatives

QFD

Quality Function Deployment is a method for the systematic translation of customer requirements into technical product and process specifications, through a cascading series of "what" vs. "how" matrices. Started in the field of mechanical and electronic products, its influence in the food arena has for a long time been limited. The multiple and complex interactions involved in the definition and production of food products has often made the use of the "what"/"how" matrices too complex for practical product development processes. There are, however, successful examples of QFD application in foods, and its main advantage – the explicit and transparent connection between customer requirements and technology – remains unrivaled. QFD is not a "scheme" as defined in this chapter. Companies can apply the method, but not be certified according to a defined QFD standard. (See QFD quality: http://www.mazur.net/works/Mazur%20208%20QFD%20in%20

the%20Food%20Processing%20Industry.pdf – QFD food safety; http://dspace.wageningenur.nl/bitstream/1880/48177/1/Balakrishnan_Applying_Quality_IFT2010_postprint.pdf)

Transparency/Accountability

Transparency/accountability refers to the integrity of the products and materials needing to be maintained and demonstrated where food is handled, anywhere in the value chain. It means that an acceptable level of transparency must be provided about all relevant parameters and conditions, related to the principles mentioned above, batch by batch. In many cases, the schemes associated with the principles are precisely designed to provide such an acceptable level of transparency. A GFSI-recognized certificate is widely accepted as a reliable reflection of an operation's quality, safety and hygiene implementation. So auditing and certification scheme can guarantee that the conditions that were in place at the moment of harvesting, production, transport, storage or sales of a particular batch of product were exactly in line with the underlying requirements of the scheme, but the audit frequency and in-built self-check requirements of the scheme should provide a reasonable assurance. Where control over individual parameters is required, however, the customer will need to see more precise information.

For batches of products moving down the food value chain, there are two extreme examples we would like to discuss here: (1) complete vertical integration and (2) open market buying.

In the case of complete vertical integration, the final seller is part of a predefined chain of custody that has in principle fulfilled all conditions for transparency: all relevant conditions and parameters are known at all times and can be recorded as part of the batch's history. Acceptance testing should not be necessary at any point, because the available records hold all relevant information in more detail than testing could ever reveal (if no chlorinated pesticides have ever been used on a crop, there is no need to test for it later). Likewise, no later "due diligence" testing should be necessary for the same reason. Where there are a priori uncontrollable variables (for example, mercury levels in wild caught sea fish), testing can be done only once and early in the chain.

Where products are bought on the open market, traceability is typically lost and in many cases it is even uncertain whether a certain batch has actually been produced under the same conditions – as the definition requires. Having lost traceability, acceptance testing becomes the only option to determine safety and quality, and demonstrate it to the next steps in the chain. Under these conditions we are immediately confronted with two main questions:

1. What to test for? In the absence of a known history of the batch, this may be difficult. Risk matrices (see "Prevention and Risk Reduction," above) can then be used for this purpose, but this remains an approximation of product category-typical risks and may not always give us the correct answer.
2. How to sample? When the product is not intrinsically homogeneous sampling is normally carried out through AQL (Acceptable Quality Level) sampling. The exact sampling scheme will then depend on some assumptions that need to be made about the homogeneity of the batch. In our "open market" situation, these assumptions may be problematic and an AQL sampling and testing scheme may quickly become prohibitively intensive.

Vegetable oils, bought on the world market and frequently unseen aboard a vessel, provide a useful example of how difficulties can be resolved when the typical characteristics of the trade allow. International rules require ships carrying edible oils to maintain a record of previous cargoes (providing relevant information regarding potential impurities), cleaning (reducing impurities) and acceptance testing, where sampling is relatively easy (contaminants can be assumed to be homogeneously distributed) and the use of chromatography/mass spectrometry methods allows for sufficiently rapid and comprehensive screening. In this case, the main concerns regarding lack of traceability may originate from environmental considerations (for example, sustainable palm oil).

In most cases, the various participants in the chain have to generate and communicate incomplete information, resulting in the need for some level of acceptance testing. Where possible, however, the use of aggregate internal control data (process performance, see "Consistency," above) instead of acceptance testing should be preferable. For this to be successful, a transparent view of the supply chain with information on production and processing conditions must be made available.

Transparency is essential if traceability is to be effective. The nature of today's complex food chain means that this is not always achievable and it may be in the nature of certain operators to remain guarded about their sources. For this reason we see numerous multinational organizations bundling their purchasing requirements in order to go direct to the source of supply. As well as improving traceability through a simplified supply chain (removing unnecessary middlemen and a level of complexity), this enables an organization with a brand to protect – be it a manufacturer, a retailer or food service operator – to have security over the provenance of their raw materials (not forgetting the value enhancement) and in turn provide reliable information to their customers. Hence the link between transparency and accountability becomes live.

Food Safety Initiatives

AQL

Acceptance Quality Limit is a sampling and testing methodology to determine whether a batch of products meets predefined criteria with a given level of confidence. ISO 2859-1 (See http://www.iso.org/iso/catalogue_detail.htm?csnumber=1141), on Sampling Procedures for Inspection by Attributes, describes standard methods for sampling plans and acceptance criteria.

INTEGRATED SCHEMES AND THEIR LIMITATIONS

Having to assess the specific relevance and implications of all the principles above for one's operation, the prospect of having an all-encompassing certification scheme becomes very attractive for both sides: operators and their customers. One certificate to cover the totality of all relevant requirements would be worth the effort and absolve both contract partners from their responsibilities. Scheme designers and owners have pursued this ideal for many years, and the frequent updates of their schemes testify their efforts, but the "one certificate to cover all" will probably always remain elusive.

There are five main reasons for this:

1. The balance between the need to be specific and the need to accommodate very different situations, materials and processes. The wider a standard applies, the less specifically relevant it can be. A good example is ISO 9001, which is designed to be the basis for all quality systems in all types of industries, but – for that exact reason – cannot go into any relevant detail. It is perfectly possible to design a fully adequate food quality and safety system and have it certified under ISO 9001, but that would rarely have the necessary credibility for professional partners in the industry. The GFSI set of standards therefore includes HACCP requirements and prerequisite programs – but these standards still need to cover the whole gamut of food categories and cannot be specific for canning, smoking, drying, etc. operations. Time will tell whether there will ever be a comfortable balance between practical applicability to a whole branch of industry and the need to provide specifics, but we do not expect it any time soon.
2. As mentioned above, a certification scheme cannot operate at the level of detail and focus needed for the acceptance of individual batches.
3. Linked to the above is the question of auditor competence. Globally, competent food auditors are in short supply and they can realistically be expected to be experts in a few food categories or processes only. Increasingly, auditors are qualified for specific areas only, but this then effectively reduces supply further.
4. A comprehensive certification scheme should cover the entire chain, including all logistics and storage and transfer of ownership. This is not a question of wide and shallow vs. narrow and deep, but a question of vertical integration and whether multiple independent business partners can have connected systems at the same relative level of strictness which allow for often changing business arrangements. In principle the answer must be yes, but in practice there are few examples.
5. The currently most relevant systems (the GFSI-recognized schemes) are mostly privately owned. This enables them to react more quickly to emerging needs, but it also implicates an ongoing commercial competition and a barrier to true integration.

Integrated schemes therefore are both useful and limited, and while they are constantly developed further, their basic limitations will likely remain.

Systems and the Value Chain

The value chain can be seen as the totality of the various stages of product flow (the supply chain, primary processes) and those functions that serve to support and/or innovate the supply chain. For our current purposes, we recognize:

- Product and technology development
- Primary production
- Procurement
- Logistics
- Manufacturing
- Retail and delivery
- Professional food preparation
- Human resources

All principles mentioned above (hygiene, risk prevention and reduction, reliability, consistency, traceability, consumer/customer relevance and acceptance, transparency) apply in their own specific way to each element of the value chain, but systems have typically been developed to serve the needs of one particular element of the chain and find little use in other elements. As mentioned in "Reliability," above, a reliability-oriented system like TPM was developed in the context of manufacturing and finds its application exclusively there. Also, the landscape of systems has developed at a different pace in different areas. There has been an early focus on primary production and manufacturing – inspired by Codex Alimentarius and driven by the needs of international trade. Trade groups packaged and issued most of the schemes that later were combined under GFSI, but penetration of schemes applying to retail and food service themselves has been slower.

Taking the elements of the value chain one by one:

- Product and technology development – most companies use some proprietary form of an innovation funnel, designed to administratively manage the complexities of a multitude of ideas and projects, but is not a specific food quality and safety tool. QFD has been successfully used as a specific innovation tool, also for quality and safety, and it has the capability in principle to incorporate the relevant requirements of all principles (the "whats" for hygiene, traceability, etc.) in the design phase. A comprehensive use of the methodology from this perspective in the food industry is not currently known to us. The QFD methodology could potentially be used as the basis for a comprehensive certification scheme for product and technology development.

  We have seen the use of ISO 9001 to manage new product development in food service organizations; however, this is simply a way to standardize an existing process or processes and ensure a consistent approach to product development across an organization.

  If we look at IT systems, retailers in the USA and Europe are increasingly using Product Lifecycle Management (PLM) systems to manage the NPD to launch process – while this is managed using specific software, it brings a level of discipline to a process that is often run by multiple players within organizations (retailer and supplier) with different ways of managing product development. Here we see organizations linking together using IT to increase speed of the NPD process and eventually produce a safe product that adheres to an agreed customer specification.

  Increasingly research laboratories play a role in product development, using consumer panels to test products – although laboratories accredited to ISO 17025 and able to perform effective sensory assessment are rare and costly.
- Primary production – increasingly GFSI-recognized certification schemes such as GlobalGAP, CanadaGAP and PrimusGFS are being applied in primary production, be it aquaculture, crops or livestock. However, the very nature of primary producers poses a challenge to the worldwide acceptance and hence implementation of such schemes. Frequently multinational organizations and those organizations sourcing from developed countries (although OECD countries sometimes have similar issues) struggle to implement GFSI/GlobalGAP-required standards with their suppliers. With this in mind capacity building schemes have been introduced, for example the GFSI Global Markets program to serve as a stepping-stone for those primary producers with the eventual aim

to reach full certification. The risk management and prevention principle becomes live here where the involvement of an auditor who fully understands the product and related food safety hazards can bring great value to the system. Certain retailers are going further and supplementing the certifications with additional product-based checks to ensure consistency and challenge traceability.

Simple traceability systems, often using GPS and Internet-based mapping, are appearing to link the producer with the retailer or wholesaler. We have seen this implemented successfully in China with a multinational retailer. The use of IT software and hand-held devices to manage the system of checks and audits is also proliferating. We are aware of such systems being used successfully in Europe to link fruit and vegetable growers with wholesalers and retailers. Information on the produce, for example pesticides used and quality specification parameters, is relayed up the chain and stored to allow later reporting and trending.

- Procurement – We are not aware of a scheme that specifically applies to procurement, although the food safety and quality requirements tend to be pushed back down the chain to the suppliers while being monitored by the purchasing organization. Numerous private and public sector schemes are in operation, which usually require suppliers to implement food safety management systems based on HACCP and risk assessment. The due diligence defence in the UK can be regarded as a driver of food safety in any food procurement department and we see this visibly in several public sector organizations such as schools and hospitals.

  Certification requirements would be a logical next step for suppliers including brokers. Here we see the IFS broker standard, which is applied to trading activities – brokers are obliged to ensure their suppliers have appropriate food safety and quality systems. In doing this, the customer has a certain security knowing that they do not need to carry out the checks themselves. This, however, is not a final solution and on occasion additional visits by the customer to production sites with the broker may be necessary to ensure the supplier fully understands the customer requirements.
- Storage and logistics – as well as proprietary schemes, IFS Logistics and BRC Storage and Distribution standards would apply.
- Retail and delivery – IFS Cash & Carry is gaining some ground in Europe, covering the operational aspect of retail and delivery, and again, the basis of food safety is HACCP and risk assessment. This standard is seen more in the traditional bulk sales cash and carry sector rather than in mass retail. Various proprietary standards are also in use. Taking retail on its own, procurement departments often have internal documented processes that require certain standards of suppliers, for example GFSI certification (see "Procurement," above). Such procurement departments are normally linked to their technical or quality departments and product development and here we can see the proliferation of in-house systems linking the activities, sometimes using IT to track progress. Such systems can be extended to suppliers and we have seen examples where procurement, quality and NPD work together on a web-based platform allowing capture of a full picture of the product and supplier. Elements of supplier performance (test results, speed of response, complaints, etc.) are recorded and as well as monitoring supplier performance, can be used as a basis to carry out risk assessment. Certain laboratories supply online databases with information that can contribute to the risk assessment.

Assessment of product performance may be carried out, for example, using laboratory testing of finished products (see "Transparency/Accountability," above) or using informal in-house kitchen analysis where products are "cooked up" and their performance recorded. Certain organizations require their suppliers to be present at such sessions, which is seen as a valuable way to give direct feedback to the supplier for further improvement if needed.

- Professional food preparation – we are not aware of global standards for food safety and quality in this area but there are a number of proprietary and local government standards. The focus tends more towards kitchen preparation than supplier control, although for the larger national and multinational organizations, control of the supply chain is common. Traceability and accountability are again key principles in this case.

We see the larger institutional caterers and food service organizations managing food safety and quality using ISO 9001 as a structural basis, with HACCP applied to operational food safety. Such systems enable customization to local conditions. Interestingly the integration of health and safety (H&S) systems in such environments can be seen as a way of introducing PRPs – by encouraging safe working practices that have equal relevance to food safety as personal safety. In terms of supply chain practices, it is not uncommon for such organizations to have a central procurement function that organizes ingredient specifications and certificates or audit reports from their suppliers who may be wholesalers, delivery agents or cash and carry. Product development in such organizations tends to be governed by an internal system and is usually based around informal in-house kitchen trials. The multinational branded food service organizations, however, tend to have more formal systems of product development, which may be supported by in-house R&D and external customer panels.

Food Safety Initiatives

PLM

Product Lifecycle Management (PLM) is an industry term used to describe the process of managing the full life cycle of a product from its conception, through design, development and manufacture, to launch, maintenance and disposal. IT software-supported PLM is increasingly popular in the retail industry where sharing of information and collaboration across a wide range of people with different processes is necessary for the success of a project, for example in private label development. Creation and central management of all information is the basis of PLM and while it can involve specific software, the emphasis is on PLM as a business strategy. (See http://en.wikipedia.org/wiki/Product_lifecycle_management.)

THE FUTURE OF SYSTEMS

From our overview of principles and systems it may be clear that we feel there is a bright future for systems and schemes – their demonstrable results, most notably the certificates, may increasingly be treated as international "licenses to operate." The proliferation of all kinds of overlapping and redundant schemes and standards is a concern, but there is no

doubt that this rapid expansion over the last decade or so was driven by a real need and opportunity.

It may therefore be clear that we expect a number of developments:

- Systems to schemes. Where existing systems clearly have the potential to add unique value to an element of the value chain (QFD for innovation, PVR for consistency in manufacturing), we may expect a certification scheme to be developed around it. The developments around HACCP may serve here as an example – developed from a set of principles to a Codex format to an ISO standard (22000) to a GFSI-recognized scheme (FSSC 22000). Moving forward, relevant stakeholders (authorities, professional customers) may require a certified demonstration of the fact that all relevant considerations have been taken systematically into account in the design stage of a new product of technology. This may then serve as a "license to launch."
- Incorporation of additional systems into existing schemes. The current leading schemes typically do not include any mention of systematic management of reliability and/or consistency. In practice, reliability is an important factor behind many prerequisite programs as well as an economic driver. A need to establish the required level of confidence in the consistent delivery of product made under the right conditions may drive the inclusion of certain elements of TPM into mainstream certification schemes. The same holds for PVR/6 Sigma around consistency. Where legality and safety depend on strict specifications and their tolerances being upheld, a quantitative approach, linked to an ongoing improvement effort, including some of the core elements of PVR/6 Sigma underpins requirements with well-understood methodologies.
- Ongoing efforts to balance broad applicability with providing relevant detail. We may expect to see the trend set by FSSC 22000's modularity approach to PRPs – i.e. providing specific PRP packages for specific types of operations – to continue. Modularity could then also apply to the core HACCP part – specific requirements applying to canning, etc.
- Coverage of the entire value chain by schemes. As consumer awareness increases, the need to provide clear information on food safety will become imperative. Visible schemes allow consumers to make decisions and in certain environments food safety is seen as a competitive issue. We would hope that in time it would cease to do so.
- Increased attention to qualification of scheme auditors to ensure a better understanding of risk management will be proliferated throughout the value chain.

Further Reading

American Institute of Baking (AIB): https://www.aibonline.org/
Codex Alimentarius: http://www.codexalimentarius.org/
Global Food Safety Initiative (GFSI): http://www.mygfsi.com/

- BRC Global Standards: http://www.brcglobalstandards.com/GlobalStandards/Home.aspx
- CANADAGAP: http://www.canadagap.ca/
- Food Safety System Certification 22000: http://www.fssc22000.com/en/
- Global Aquaculture Alliance Seafood Processing Standard: http://www.gaalliance.org/
- GlobalGAP: http://www.globalgap.org/

- Global Red Meat Standard: http://www.grms.org/
- International Featured Standards: http://www.ifs-certification.com/index.php?en/
- Safe Quality Food: http://www.sqfi.com/
- Primus GFS: http://www.primusgfs.com/

Report of a Joint FAO/WHO Consultation on the Role of Government Agencies in Assessing HACCP Geneva, 2-6 June 1998: http://www.who.int/foodsafety/fs_management/en/haccp98.pdf

5S: http://www.epa.gov/lean/environment/methods/fives.htm

European Hygienic Engineering & Design Group (EHEDG): http://www.ehedg.org/

Food Quality and Safety Systems – A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System, FAO 1998: www.fao.org/docrep/W8088E/w8088e.htm

The Food Safety Act 1990 – A Guide for Food Business (2009 edition): www.food.gov.uk/multimedia/pdfs/fsactguide.pdf

FDA Food Safety Modernization Act: http://www.fda.gov/Food/FoodSafety/FSMA/default.htm

TPM: http://en.wikipedia.org/wiki/Total_productive_maintenance

PVR: Chicken soup for processes, Lynne B. Hare, Quality Progress, August 2001, pp. 76–79: http://asq.org/index.aspx

6 Sigma: Leading Six Sigma, Ronald D. Snee and Roger W. Hoerl, Prentice Hall (2003); Implementing Six Sigma, Forrest W. Breyfogle III, John Wiley & Sons (1999).

Traceability: http://ec.europa.eu/food/food/foodlaw/traceability/factsheet_trace_2007_en.pdf

QFD quality: http://www.mazur.net/works/Mazur%202008%20QFD%20in%20the%20Food%20Processing%20Industry.pdf)

QFD food safety: http://dspace.ucalgary.ca/bitstream/1880/48177/1/Balakrishnan_Applying_Quality_IFJ2010_postprint.pdf

Innovation Funnel:

Groupware and teamwork in R&D: limits to learning and innovation, Claudio U. Ciborra, Gerardo Patriotta (2002): http://onlinelibrary.wiley.com/doi/10.1111/1467-9310.00080/abstract

http://www.innovationexcellence.com/blog/2011/11/29/rethinking-the-product-development-funnel/

CHAPTER

23

Hygiene in Primary Production

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OUTLINE

INTRODUCTION

Food safety is defined as the assurance that food will not cause harm to the consumer when it is prepared or eaten according to its intended use (FAO/WHO 1997). Therefore, to achieve food safety all stakeholders in the food production chain should make every effort to reduce risks of contamination. As stated in EU Regulation 852/2004 on Hygiene Provisions, food business operators are to ensure that primary products are protected against contamination and must comply with provisions relating to the control of hazards in the primary production and associated operations. The control of hazards includes measures to control contamination arising from air, soil, water, feed, fertilizers, pesticides, veterinary drugs, etc. as well as measures relating to animal health and welfare.

Furthermore, as a result of foodborne diseases and mass outbreaks around the globe, public concern about food safety has increased dramatically recently. The World Health Organization estimates that there are hundreds of millions of people suffering from diseases resulting from contaminated food or water. In the past reporting these data was difficult, but nowadays with easier and more reliable reporting of data and occurrences, statistics show that both in developed and developing countries, foodborne diseases are rising. The WHO reported that foodborne diarrheal disease is one of the most common illnesses worldwide, estimated between 2.2 and 4 million cases per year. Every day, thousands of people die from preventable foodborne disease. In developing countries, 1.9 million children die under the age of 5 because of a diarrheal disease; up to 70% of these cases may be caused by foodborne and water pathogens (Larson, 2010; Motarjemi et al., 2002).

Countries with good reporting systems have documented significant increases in the incidence (number of cases) of foodborne diseases during the two last decades. It has been estimated that each year foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, 5000 deaths in the United States and 2,366,000 cases, 25,000 hospitalizations and 718 deaths in England and Wales. Data from the Netherlands indicate that out of 1.8 million cases of gastroenteritis caused by 14 infectious agents, >30% (600,000 cases) are proven to be foodborne (Motarjemi et al., 2002; Hazeleger et al., 2002). From the reported number of cases, it can be assumed that the burden of foodborne disease is probably in the same order of magnitude in most countries of the Organization for Economic Cooperation and Development (OECD) (Rocourt et al., 2003).

There are numerous sources of food contamination by pathogens. In Table 23.1 some important hazards and their related epidemiological features are summarized (Lammerding et al., 2004). In OECD countries the foods most frequently involved in outbreaks are meat and meat products, poultry, eggs and egg products, with the likely implication that these foods are associated with *Salmonella* and *Campylobacter*. Case-control studies confirmed the same food sources for sporadic cases: raw and undercooked eggs, foods containing egg and poultry for salmonellosis, poultry for campylobacteriosis and raw oysters for Vibrio illness (Rocourt et al., 2003).

In the United States, of the total reported outbreaks and outbreak-related illnesses between 1996 and 2010, excluding meat and poultry, produce accounted for 23.3% and 42.3%, respectively. These outbreaks were associated with approximately 20 different fresh produce commodities, including sprouts, leafy greens such as lettuce and spinach, tomatoes, melons such as cantaloupe and honeydew, berries such as raspberries, blueberries,

TABLE 23.1 Some Important Foodborne Hazards and their Salient Epidemiological Features[a]

Hazards	Important Reservoir or Carrier	Transmission[b] by					Comments and Examples of Foods Involved
		Water	Food	Person to Person	Multiplication in Food	Transmission by Contact with Animals	
BACTERIA							
Bacillus anthracis						+	
Bacillus cereus	Soil	–	+	–	+		Cooked rice, cooked meats, vegetables, starchy puddings
Brucella spp.	Cattle, goats, sheep	–	+	–	+		Raw milk, dairy products
Campylobacter jejuni	Chickens, dogs, cats, cattle, pigs, wild birds	+	+	+	–[c]		Raw milk, poultry
Clostridium botulinum	Soil, mammals, birds, fish	–	+	–	+		Fish, meat, vegetables (home preserved), honey
Clostridium perfringens	Soil, animals, man	–	+	–	+		Cooked meat and poultry, gravy, beans
E. coli enterotoxigenic	Man	+	+	+	+		Salad, raw vegetables
E. coli enteropathogenic	Man	+	+	+	+		Milk
E. coli enteroinvasive	Man	+	+	0	+		Cheese
E. coli enterohaemorrhagic	Cattle, poultry, sheep	+	+	+	+		Undercooked meat, raw milk, cheese
Listeria monocytogens	Environment	+	+	–	+		Cheese, raw milk, coleslaw
Leptospira						+	Flooded crops, canned food
Mycobacterium bovis	Cattle	–	+	–	–		Raw milk
Salmonella Typhi and *Paratyphi*	Man	+	+	±	+		Dairy products, meat products, shellfish, vegetable salads
Salmonella Non-typhi	Man and animals	±	+	+	+		Meat, poultry, eggs, dairy products, chocolate

Shigella spp.	Man	+	+	+	+	Potato/egg salads
Staphylococcus aureus (enterotoxins)	Man	–	+	–	+	Ham, poultry and egg salads; cream-filled bakery products; ice cream, cheese
Vibrio cholerae O1	Man, marine life	+	+	±	+	Salad, shellfish
Vibrio cholerae, non-O1	Man, marine life	+	+	±	+	Shellfish
Vibrio parahaemolyticus	Seawater, marine life	–	+	–	+	Raw fish, crabs and other shellfish
Vibrio vulnificus	Seawater, marine life	+	+	–	+	Shellfish
Yersinia enterocolitica	Water, wild animals, pigs, dogs, poultry	+	+	–	+	Milk, pork, poultry
VIRUSES						
Hepatitis A and E viruses	Man	+	±	+	–	Shellfish, raw fruit and vegetables
Calici viruses	Man	+	+	–	–	Shellfish, salad
Rotavirus	Man	+	+	+	–	?
PROTOZOA						
Cryptosporidium parvum	Man, animals	+	+	+	–	Raw milk, raw sausage (non-fermented)
Cyclospora cayetanensis	Man	+	+	? (unlikely)	–	Raspberries
Entamoeba histolytica	Man	+	+	+	–	Vegetables, fruits
Giardia lamblia	Man, animals	+	+	+	–	Vegetables, fruit
Toxoplasma gondii	Cats, pigs	+	+	–	–	Undercooked meat, raw vegetables

(Continued)

TABLE 23.1 (Continued)

Hazards	Important Reservoir or Carrier	Transmission[b] by: Water	Food	Person to Person	Multiplication in Food	Transmission by Contact with Animals	Comments and Examples of Foods Involved
HELMINTHS							
Ascaris lumbricoides	Man	+	+	–	–		Soil-contaminated food
Clonorchis sinensis	Freshwater fish	–	+	–	–		Undercooked/raw fish
Fasciola hepatica	Cattle, goats	±	+	–	–		Watercress
Opisthorchis viverrini/ felineus	Freshwater fish	–	+	–	–		Undercooked/raw fish
Paragonimus spp.	Freshwater crabs	–	+	–	–		Undercooked/raw crabs
Taenia saginata and *T. solium*	Cattle, swine	–	+	–	–		Undercooked meat
Trichinella spiralis	Swine, carnivores	–	+	–	–		Undercooked meat
Trichuris trichiura	Man	0	+	–	–		Soil-contaminated food

+ = yes, – = no, ± = rare, 0 = no information.

[a]Lederstein et al. (2004).

[b]Almost all acute enteric infections show increased transmission during the summer and/or wet months, except infections due to rotavirus and Yersinia enterocolitica, which show increased transmission in cooler months.

[c]Under certain circumstances some multiplication has been observed. The epidemiological significance of this observation is not clear.

blackberries and strawberries, fresh herbs such as basil and parsley, and green onions as well as fresh-cut fruits and vegetables. These outbreaks involved a number of pathogens, including *E. coli* O157:H7, *E. coli* O157, *Salmonella* species, *Listeria monocytogenes*, *Cyclospora*, *Shigella sonnei* and hepatitis A (FDA, 2013b).

The emergence of new foodborne pathogens as well as the recurrence of well-known pathogens over the last decades can be explained by various factors such as world changes in society and food production systems. Globalization has undoubtedly increased world trade and travel with major consequences such as faster transfer of microorganisms from one place to another, increased opportunities for contaminations, time–temperature abuse of products and hence the risk of foodborne illness. An increasing elderly world population is now exposed to a greater number of different strains and types of pathogens. A person with a foodborne illness can expose others to a new pathogen in a location thousands of miles from the original source of infection.

Advances and changes in food production at the primary level and further processing also pose new threats to global food safety. In 1996, a new variant of Creutzfeldt–Jakob disease linked to Bovine Spongiform Encephalopathy (BSE) in cattle was diagnosed in humans. Consumption of contaminated meat products from cattle is presumed to be the cause. Modern intensive animal husbandry practices to maximize production seem to have led to the emergence and increased prevalence of *Salmonella* serovars and *Campylobacter* in herds of almost all important production animals (Rocourt et al., 2003). Excessive use of veterinary drugs in intensive animal production led also to increased awareness of the health effects of high drug residue levels in animal muscle. The use of untreated manure as organic fertilizers and contaminated irrigation waters in agriculture has been associated with unusual pathogen contamination of fresh fruits and vegetables. Infections caused by *Vibrio* spp. (*V. cholerae*, *V. parahaemolyticus*, *V. vulnificus*) and intoxications due to naturally occurring toxins, e.g. various forms of shellfish poisoning or ciguatera, as well as trematodiasis, are common concerns with fish and fishery products. *Cyclospora* in raspberries, *E. coli* O157:H7 in apple juice and alfalfa sprouts, *Salmonella* in cantaloupes are just some of the many recent cases of foodborne outbreaks linked to practices in primary production (FDA, 2013a). The list of potential foodborne hazards and illnesses is long and the magnitude of the problem is enormous. The problem is greatest in the developing countries, although official reports of outbreaks are scarce and anecdotal. The high incidence of travelers' diarrhea in these countries is an indication of underlying food and water safety problems (Motarjemi et al., 2012). Over and above illnesses due to microbial agents, misuse of agrochemicals as well as naturally occurring toxins such as mycotoxins, in particular aflatoxins, causes major problems in the developing countries and are barriers to their export and development.

An effective prevention program must start with the prevention of food contamination in primary production, particularly considering the fact that many food products may be consumed raw and the predilection for such foods is increasing.

The present chapter addresses three main primary production systems and the challenges to reduce the threats to safety inherent to each. Good animal farming, fish health and good agricultural practices are described extensively so as to provide a clear picture of the complexity of the food production chains and the many factors that need to be under control to assess the safety of the products presented to consumers. This chapter is not intended to contain an exhaustive treaty on good agricultural, farming or aquaculture practices but to share experiences and propose different approaches to foster food safety.

PART 1: GOOD ANIMAL HUSBANDRY

INTRODUCTION

The human population is growing year by year. It is expected that by 2020, the number of people on Earth will increase from 7 billion to approximately 8 billion. In order to ensure a sufficient amount of food, it is necessary to use the most advanced agricultural technologies in plant and animal production. Although the agricultural technologies are highly sophisticated and activities are based on scientific knowledge, there are a number of negative impacts if they are not properly implemented. Those improper farm activities can cause environmental pollution and health problems to animals and farm workers, to neighboring wildlife, and to the consumers of their products.

Animals are exposed to constant activity factors such as air, water, soil and climate, and factors of an inanimate nature, but also by the presence of people, other animals, insects, microorganisms, pests and other factors of a living nature. All those factors can be carriers of agents that can directly or indirectly cause contamination of food produced on farms.

Almost every activity on a farm carries the risks of contamination from animal to animal, from animal to man, from man to animal; and, most important, from animal and man to farm products. Further, the composition of many animal products (meat, milk, eggs, etc.) is an ideal medium for the outgrowth of pathogenic microorganisms. Domestic animals may carry human pathogens which if present in food of animal origin may increase the risk of causing foodborne illness. Almost all foods have the potential to cause foodborne illness. There is also the potential of contamination of animal products with residues of veterinary drugs, hormones, pesticides and other chemical contaminants.

Therefore, implementing the proper procedures in agriculture, especially hygienic procedures, and control of animal products throughout the food chain are essential to ensure the safety and suitability of these foods.

This part will present potential microbiological risks at primary production level on animal farms, and give an overview of good practices that can prevent or solve problems caused by these risks.

POTENTIAL HEALTH RISKS ON ANIMAL FARMS

Microorganisms, viruses and parasites are the source of various animal and human diseases, and can, directly or indirectly, cause contamination of food produced on farms. They are widespread in the environment, in air, water and soil, inside or outside people, animals or insects, in barns, parlors, equipment and tools. For this reason, the "battle" against such agents is hard and must be carried out on a daily basis. In Figure 23.1, a selection of zoonoses and foodborne cases in human population in EU countries during 2010 is presented.

FOODBORNE DISEASES

Foodborne diseases are acute illnesses, usually affecting the gastrointestinal tract, brought on by consuming contaminated food or beverages. Various microbial agents

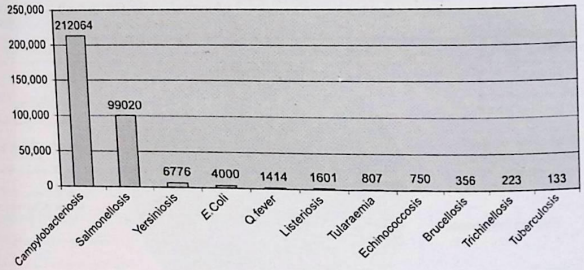

FIGURE 23.1 Number of zoonosis and foodborne cases in humans, EU countries 2010 (*data source: EFSA, 2012*).

(viruses, parasites and bacteria) can cause illness and currently more than 200 known diseases are recognized as foodborne. Contamination of food may occur at any stage in the process from "farm to fork" and can result from environmental contamination, including pollution of water, soil or air.

Despite remarkable advances in food science and technology, foodborne illness is a rising cause of morbidity in all countries and the list of potential foodborne microbial pathogens keeps increasing.

Up to 30% of the population in industrialized countries may be affected by foodborne illness each year. The global incidence is difficult to estimate, but in 1998 more than 2.2 million people, including 1.8 million children, died from foodborne diseases. In 2008, the US Center for Disease Prevention and Control (CDC) estimated that foodborne diseases caused approximately 76 million illnesses, 325,000 hospitalizations and 5,000 deaths each year. (Oliver et al., 2009).

There are significant microbiological risks associated with primary production. A wide range of agricultural products can become contaminated with microorganisms, including human pathogens. Some of these pathogenic groups come from soil and water, but for some of them, animals or humans are reservoirs from which they spread. Pathogens that live on farms are directly or indirectly recognized as risk factors in the entire commercial food chain (Tauxe, 1997). The most common foods that caused food poisoning in 2010 are presented in Figure 23.2.

EXAMPLES OF FOODBORNE PATHOGENS

Pathogens are the leading causes of foodborne morbidity and mortality. Dairy and beef cattle can harbor and shed *E. coli*. *Campylobacter jejuni*, *L. monocytogenes* and *Salmonella* spp. are carried by cattle, poultry and swine and are found in their associated farm environments

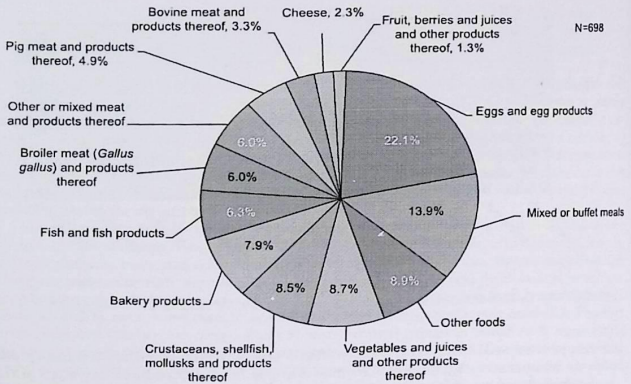

FIGURE 23.2 Distribution of outbreaks caused by food (EFSA, 2012)

(McEwen and Fedorka-Cray, 2002). *Staphylococcus aureus*, *Clostridium perfringens* and *Bacillus cereus* are also important pathogens that have origins on farms. The *Streptococcus suis* encountered in swine production is now recognized as a human pathogen. Viruses such as norovirus and hepatitis E, and parasites as *Cryptosporidium parvum* and *Toxoplasma gondii* are encountered in the farm environment and considered as human pathogens (Tauxe, 2002).

These pathogens are found in animal feces; therefore, contamination of food products by animal feces is likely to be a principal mode by which foodborne pathogens reach the consumer. Wild birds and various mammals that are common in farm environments can also be a source of these pathogens.

From the standpoint of pre-harvest food safety in general and human health in particular, *Salmonella* spp., *E. coli*, *Campylobacter jejuni* and *Listeria monocytogenes* are the most important foodborne pathogens affecting public health (Bean and Griffin, 1990).

Salmonella spp.

Salmonella spp. is the most commonly reported cause of human foodborne diseases. *Salmonella* spp. lives in the intestinal tract of various animal species and can be present on farms with absence of clinical disease. Healthy animals can become carriers and can shed *Salmonella* for long periods. Humans become infected if they consume animal products or water contaminated with feces, but direct contact with infected animals can also be a source

TABLE 23.2 Percent of Samples Positive for *Salmonella* in Various Animal Products in EU Countries during 2010

Animal Product	No. Tested Samples	% of Positive
Fresh broiler meat	21,539	4.8
RTE broiler meat	3253	0.3
Fresh turkey meat	4329	9.0
Egg and egg products	19,142	0.3
Fresh pig meat	69,005	0.9
RTE minced pig meat	11,675	0.6
Fresh bovine meat	34,236	0.2
RTE minced bovine meat	3299	0.4
Raw milk, pasteurized milk	7825	5 cases
Cheeses	34,109	0.1

Data Source: EFSA 2012

of contamination, especially for farm families. Although a great percentage of human salmonellosis occurs through consumption of raw milk or dairy products manufactured with raw milk, human illnesses are frequently linked with consumption of poultry and pork products (Besser et al., 2000).

In beef cattle, *Salmonella* was detected in 38 of 100 feedlots (Fedorka-Cray et al., 1998). In swine farms, on 58 of 152 farms, *Salmonella* was detected in 20% of broiler carcasses and 45% of ground chicken meat (Rabsch et al., 2003). Table 23.2 shows the percent of samples positive for *Salmonella* in various animal products in EU countries during 2010.

Escherichia coli

Several strains of *E. coli* cause a variety of diseases in humans and animals. *Escherichia coli* O157:H7, also called enterohemorrhagic *E. coli*, is a type associated with a particularly severe form of human disease as hemorrhagic colitis, hemolytic uremic syndrome and thrombotic thromocytopenic purpura. The majority of human outbreaks caused by *E. coli* O157:H7 were linked to the consumption of contaminated meat and raw milk (Dorn, 1993). Sources of contamination also include: feces from infected animals, use of contaminated manure as fertilizer, fecal contamination of meat at slaughter plants, raw manure and slurry from dairy farms, and cross-contamination of other food products at farm (Tarr, 1995; Banatvala et al., 1996). Cattle are currently considered a reservoir for *E. coli* O157:H7, and cattle manure is an important vehicle for spreading contamination, but this pathogen is also detected in sheep, goats, horses, dogs, reindeer, deer, birds and rabbits (Hancock et al., 1998). In 2010, the total number of confirmed human *E. coli* cases in the EU was 4000 and almost half of the reported were serogroup O157 (41.1%). Each year in the United States, approximately 265,000 cases of *E. coli* are detected, and about 36% are O157 serotype

TABLE 23.3 Percent of Samples Positive for *Salmonella* in Various Animal Products in EU Countries during 2010

Animal Product	No. Tested Samples	% of Positive
Fresh bovine meat	21,539	4.8
Raw cow milk	3253	0.3
Fresh ovine and goat meat	4329	9.0
Milk and dairy products excluding cow milk	19,142	0.3

Data Source: EFSA, 2012

(www.cdc.gov). Table 23.3 shows the percent of samples positive for *Salmonella* in various animal products in EU countries during 2010.

Campylobacter spp.

Campylobacter jejuni and *Campylobacter coli* are the most frequently identified cause of acute infectious diarrhea in developed countries and the most commonly isolated bacterial intestinal human pathogens. Between 2 and 4 million cases of campylobacteriosis occur each year in the USA, and *Campylobacter* is associated with 120 to 360 deaths (Fahey et al., 1995). Several zoonotic sources have been identified, and *C. jejuni* has been isolated from cattle, swine, poultry, dogs, cats, birds, ferrets, hamsters, wild birds, mule deer and houseflies (Altekruse, 1994). Poultry meat products are the most common foodborne source of *Campylobacter* infection in humans (Vugia et al., 2007). Symptoms are chronic gastritis, enterocolitis and septicemia. Humans become infected by ingesting contaminated foods, untreated water or contaminated nonpasteurized or improperly pasteurized milk. In 2010, *Campylobacter* continued to be the most commonly reported gastrointestinal bacterial pathogen in humans in the EU since 2005. In 2010, 266 deaths were reported due to campylobacteriosis (reported for $N = 115{,}747$). According to the US Centers for Disease Control and Prevention, during 2008 there were 2.4 million people contaminated with *Campylobacter* (www.cdc.gov). Table 23.4 shows the percent of samples positive for *Campylobacter* in different animal products in EU countries during 2010.

Listeria Monocytogenes

Listeria is a serious foodborne illness in humans (listeriosis). It is dangerous primarily for pregnant women and their fetuses, the elderly and the immunocompromised. The biggest public health concern is that it can develop resistance to antimicrobials. *Listeria monocytogenes* is an environmental contaminant whose primary means of transmission to humans is through food, which can become contaminated during production and processing. Ready-to-eat (RTE) foods that are refrigerated before consumption and do not receive substantial treatment, such as soft cheese, RTE meats, and RTE seafoods, have been implicated in outbreaks of listeriosis (Kathariou, 2002).

TABLE 23.4 Percent of Samples Positive for *Campylobacter* in Different Animal Products in EU Countries during 2010

Animal Product	No. Tested Samples	% of Positive
Fresh poultry meat	7413	29.6
Fresh pig meat	932	0.6
Fresh bovine meat	808	0.4
RTE bovine meat product	610	1.8
RTE minced turkey	142	0.7
RTE minced pig meat	289	0.0
Cow milk	1993	1.3
Cheeses	384	1.0

Data Source: EFSA, 2012

Listeria spp. is widespread in nature, can live naturally in plants and soil environments, and grows in a wide range of temperatures and pH (Bunning et al., 1988). This adaptability enables *Listeria* to grow in refrigerated raw milk, but can also survive high-temperature, short-time pasteurization (HTST). Human contamination occurs through consumption of raw milk or products manufactured with raw milk. In dairy and beef units infection of animals occurs through ingestion of contaminated feed, especially low-quality and spoiled silage. Healthy but infected animals shed *Listeria* in feces, and fecal contamination of pastures or vegetables was also implicated as a source of contamination for humans and ruminants (Murinda et al. 2004).

Control measures should be aimed at the farm and food-processing level, in order to prevent contamination of food products. Preventive measures include providing appropriate information for consumers on how to minimize the risk of ingesting food contaminated by *Listeria*.

In 2010, there were 1601 confirmed human cases of listeriosis in EU countries. In the USA, 24 confirmed listeriosis outbreaks were reported between 1998 and 2008, resulting in 359 illnesses, 215 hospitalizations and 38 deaths (www.cdc.gov). Table 23.5 shows the percent of samples positive for *Listeria* spp. in various animal products in EU countries during 2010.

Brucella abortus

Brucella spp. is also known as "contagious abortion." It is caused by infection with the bacterium *Brucella abortus*. Brucellosis infection of cattle causes abortion or premature calving of infected animals, most often between the fifth and eighth month of pregnancy. Although most countries have federal and state regulations for controlling this disease, it is still a threat. Brucellosis is spread from the vaginal discharge of an infected cow or from an aborted fetus. Breeding bulls that are infected can also transmit the disease to cows with infected semen. Milk produced by an infected cow may also harbor the organism. Such

TABLE 23.5 Percent of Samples Positive for *Listeria* spp. in Various Animal Products in EU Countries during 2010

Animal Product	No. Tested Samples	% of Positive
RTE broiler meat	1450	1.5
RTE pig meat	22,158	2.0
RTE poultry meat	3636	1.5
Soft/semi-soft cheese, raw cow milk	1674	0.3
Soft/semi-soft cheese, raw sheep and goat milk	865	0.8
Soft/semi-soft cheese, pasteurized cow milk	5548	0.9
Soft/semi-soft cheese, pasteurized sheep and goat milk	458	0.2
Hard cheese, raw cow milk	1024	0.4
Hard cheese, raw sheep and goat milk	303	0.0
Hard cheese, pasteurized cow milk	8029	0.3
Hard cheese, pasteurized sheep and goat milk	585	0.5
RTE fish and fishery products	2938	6.0

Data Source: EFSA, 2012

infected milk is a public health hazard as this is the organism that causes undulant fever in humans. There is no treatment for brucellosis. Prevention of brucellosis is vaccination of heifer calves. Although brucellosis has been eradicated from cattle in most countries, outbreaks still appear from time to time. According to the EFSA report for 2012, 10 countries with 356 confirmed cases have been reported (EFSA, 2012). So, even though the brucellosis vaccination is mandatory, there are still cases of this disease in Europe.

Helminths

Internal parasites, as tapeworms, lungworms or liver flukes, can cause significant diseases, but also economic losses at farms. Older animals that are frequently exposed to the parasites have a certain degree of immunity, but young animals are very susceptible. Adult worms that live in the animal body produce eggs that are passed in the manure. The eggs hatch, producing larvae that develop and move up onto the pasture grasses where animals consume them. These eggs are very resistant and durable. They can survive the winter and hatch out with warm weather. The most important step in the fight against worms is deworming of animals using anthelmintics before grazing season starts. There are several approved anthelmintics available such as paste, suspensions, granules, injectable or pour-on formulations, boluses or crumbles for oral use, and drench form. However, it is very important to consult a veterinarian concerning the type to use and the timing. It is also necessary to mention one of the most common internal parasites, *Trichinella*.

Trichinella spiralis is a concern when good animal husbandry is not respected. Many animals may act as reservoirs, but the most frequently involved in cases of human infections are pigs, horses and wild boars. Infested animals harbor larvae encysted in their muscles, and consumption of raw or undercooked meat products may lead to disease. After an incubation phase of about 24–48 hours, fever and intestinal symptoms may appear. A week after infection, larvae starts invasion of the muscles, followed by muscle aches and fever. Depending on the number of viable larvae consumed, symptoms will vary from hardly any to extremely severe or even fatal.

Trichinosis prevention is based on accurate, mandatory inspection of all slaughtered pigs and horses. The number of reported trichinellosis cases in humans in 2010 was 394 with 223 of them confirmed. More than 211 million tests of pigs were provided, in which 199 were positive; 36,871 wild boars tested with 26 positive; 724,640 hunted wild boar tested with 988 positive; 9569 foxes tested with 108 positive; 589 bears tested with 28 positive; 208 raccoon dogs tested with 58 positive; and 2760 other wild animals tested with 99 positive (EFSA, 2012).

Other Animal Infections

From the perspective of animal health and welfare and/or lost productivity, a range of animal infections are of concern to the food industry. Examples are scrapie, blackleg, foot rot, infestation with ticks, lice, horn flies, face flies and stable flies, etc. Some others, such as the foot-and-mouth disease, disrupt international trade in food. Certain infections, e.g. anthrax, are also an occupational disease in humans. Infections, such as leptospirosis can be the source of contamination of the environment, e.g. water supply and food and thus an indirect source of infections of human.

Control of Pathogens on Farms

The cycle of infections in animals begins with exposure to pathogens via contaminated feed, water and other environments, followed by amplification in animal hosts and fecal dissemination in the farm. Shedding of foodborne pathogens in feces and distribution in the environment where food-producing animals live leads to animal reinfection and persistence of the pathogen on the farm. This cycle makes animals constant reservoirs of foodborne pathogens. By breaking the infection–reinfection cycle, it is possible to reduce foodborne pathogen shedding and the spread of foodborne pathogens among food-producing animals and in the farm environment (Oliver et al., 2009).

Management of manure, including feces, urine and other animal secretions or excretions such as saliva, is central for the control of contamination in food-producing animals.

GOOD FARMING PRACTICES FOR ANIMAL HUSBANDRY

Biological, chemical and physical hazards may enter food-producing animals or animal production through a wide variety of exposure points in the food chain. To address the hazards, OIE recommends practices that include general farm and animal health management; veterinary medicines and biologics; animal feeding and watering; environment and

infrastructure; and animal and product handling (FAO/OIE, 2009). We will review some of these practices here.

Livestock Production

For success in livestock production farm management is essential. Very important issues for successful livestock production are (FAO/IDF, 2011):

- **Farm location** – Farms should be located in an appropriate area for good animal rearing. The environment of the farm must have minimal risks from physical, chemical and biological hazards that may affect the sanitary of animals or on-farm products. The following locations are unsuitable for animal husbandry: industrial environments, waste disposal sites, slaughterhouses, live animal markets and other farms.
- **Farm layout** – Farms should have sufficient space of suitable size, adjusted to the race and category of animals reared and designed to avoid any problem to the environment and animal health. The housing area for different categories of animals and storage area for feed and veterinary drugs should be separated and protected from pests, pets and other domestic animals that may be disease carriers. It is preferable that the farm has an open area with sufficient air flow and an appropriate pasture area with adequate shade, if necessary. Accommodation for staff and office should be located in a residential area, distinctly segregated from the rearing area.
- **Facilities** – Facilities in which the animals are bred must have enough surface area so that animals can practice their natural movements. They should be constructed using durable materials that are easy to clean and maintain. The floor should be made using non-slippery concrete and be slightly tilted with good drainage to prevent waste accumulation within the facility. For good ventilation it is necessary to elevate the roof of the facility as much as possible (e.g. for cattle at least 3 m). Appropriate and adequate water supply should be available in each facility. The facility must have sufficient daylight as well as sufficient artificial lighting for animal caring and health checks at all times. Equipment and tools for farm operation should be in good condition, adequate, easily cleaned and operated, separately stored and not cause harm to animals.
- **Feed** – Feed must be of good quality, whether produced on the farm or purchased elsewhere. Feed containers must be clean, dry, in good condition and free from contaminants. Vehicles used for feed delivery should be cleaned and dried after each use. It is necessary to check physical and chemical properties of feed, especially potential presence of molds and fungi. These microorganisms have the ability to produce mycotoxins that can be very harmful for animals and humans. Thus, such contaminated feed must be rejected and eliminated in an appropriate way. The feed should be stored in a special room that is clean, dry and free from insects, rodents and other animals.
- **Water** – Animals must have free access to fresh and clean water throughout the day and in quantities that meet their needs. Water sources should be protected from contamination by animal manure or waste water from the farm. Also, water sources should be located away from pollutants outside the farm, such as from garbage dumps, slaughterhouses or factories. If the source of water at the farm is an artesian well, it should be adequately covered and protected from atmospheric phenomena. Water for

washing and cleaning, especially water directly used to wash the animals, should be of good quality. Water containers should be clean.

- **Farm staff** – The number of farm staff should be adjusted to the size of the farm, planned daily, taking into account seasonal activities, type of housing, animal rearing system, equipment and other facilities available on the farm. All staff should have the required knowledge and skills for their tasks. Every person working on the farm should have an annual health check-up and follow good personal hygiene practices, i.e. dressing with clean clothes, washing and drying hands every time prior to any operation, and keeping hands and nails clean. It is recommended to have an assigned veterinarian responsible for animal health who can supervise animals and give proper advice on disease prevention, treatment and correct drug usage.

ANIMAL HEALTH

Prevention and Control of Diseases

To control diseases it is necessary to have means to prevent access of pathogens or their spread on the farm.

Animal Treatment

Veterinary drugs, hazardous substances and disease treatments should be under the supervision of a veterinarian. The veterinarian should recommend animal drugs and treatments with a written prescription and record all activities. Veterinarians must take into consideration the withdrawal period for drugs, defined as the interval between the time of last administration of the drug and the time when the animal can be safely slaughtered for food purposes.

BOX 23.1

PRINCIPLES FOR GOOD MANAGEMENT OF ANIMAL HEALTH

- Minimize the risk of infections through proper nutrition, grazing and housing
- Maintain hygiene of livestock, housing facilities and feed storages
- Use disinfection barriers at entrance at farm and every facility on farm
- Limit entrance to essential visitors, authorized persons and vehicles only
- Routinely test animals for specific diseases
- Carry out vaccination against specific diseases
- Carry out regular treatment for elimination of internal and external parasites
- Prevent and control pests
- Act in accordance with veterinarian advice
- Purchase, store and use only approved veterinary products
- Adequately care for injured and sick animals
- Keep accurate records of all diseases, treatments and mortality of livestock

BOX 23.2

PRINCIPLES FOR GOOD MANAGEMENT OF ANIMAL WELFARE

- Availability of feed and clean water to animals at all times
- Provide the minimum required space per animal
- Respect the maximum allowable number of animals per unit area
- Keep animals in appropriate social groups
- Avoid animal isolation, except in cases of injuries and illnesses
- Handle animals carefully and avoid use of instruments, e.g. electric scissors
- Avoid non-therapeutic and radical measures, e.g. cutting tails, beak, etc.
- Provide minimum transport and exposure to markets and animal shows

Management Procedure for Dead Animals

Infected carcasses must be destroyed in a way that prevents spreading the disease. The veterinarian should advise how to dispose of carcasses. Many countries have facilities to professionally collect, quarantine and incinerate animals that die from contagious diseases. If buried on the farm, proper disinfectants should be poured or scattered over every part of the carcass and the pit should be filled and piled up above the ground by at least 50 cm.

Animal Welfare

Animals are sensitive living beings. Their welfare must be taken into consideration (Pejanović, 2008).

PRINCIPLES OF BIOSECURITY

Biosecurity is a set of measures that are necessary to apply to keep diseases out of farms, herds and groups of animals, or to limit the spread of disease within the herd. Biosafety is one of the protective weapons for excluding pathogens from the animal's environment. The producers, herd owners and breeders are the most responsible subjects for implementing biosecurity principles on farms. The greatest risks on farms are imported new animals, farm visitors, wildlife, equipment and vehicles (David W. Snively http://www.wvu.edu/~agexten/Biosecure/Farm.pdf; Bowman and Shulaw, 2001; Gary et.al., 2001).

New Animals on a Farm

New animals on a farm present the greatest risk of introducing infectious disease. It is desirable that the breeder purchases animals from farms that have developed procedures

for animal health protection. For the purpose of avoiding spreading diseases, breeders should:

- Isolate new animals and animals returning from situations where they have been exposed to other animals, such as at fairs or shows, for a minimum of 2 weeks.
- Isolate animals showing signs of disease.
- Isolate animals in a facility separate from other animals.
- If complete isolation is not possible, provide separate pen or pasture that does not permit nose-to-nose contact or use shared feed/water supplies.
- Provide parasite control and vaccination against diseases likely to be a problem on farm.
- Do all appropriate tests and treatments under the control of a veterinarian.

Farm Visitors

Any visitor that enters the farm is a potential carrier of a disease. But not all visitors present the same level of risk.

Visitors from urban areas or others who have no contact with livestock present very little risk of carrying relevant diseases. Measures that should be taken for such visitors are:

- Wear freshly laundered outerwear and clean shoes or boots.
- Ideally provide disposable plastic boots and coveralls.
- Provide disinfectant footbaths and immerse shoes or boots in disinfectant for the adequate contact time.
- Forbid visitors to enter pens or feeding areas, to contact animals, or to bring food with them.
- When visitors leave, dispose of plastic boots in a safe way and ask visitors to wash their hands.

Salespeople, delivery people, mechanics and those who routinely visit farms but have little or no contact with animals should be subjected to the above as well as the following additional procedures:

- Wear clean or disposable coveralls and boots if there is any contact with feed, animals, soil or manure.
- Ensure personal equipment and tools are cleaned and disinfected between uses if there is any contact with feed, animals, soil or manure.
- At the end of the visit, clean and disinfect dirty boots, and remove and place coveralls in a plastic bag before visitors re-enter their vehicles.

Veterinarians, livestock-owning neighbors and anyone else who has close contact with animals and their bodily discharges are visitors presenting the greatest risk. In addition to all of the above precautions, people in this group should observe the following:

- All vehicles that enter the farm should be cleaned, free of visible dirt on tires and wheel wells, and should be disinfected prior to arriving at the farm.
- Visitors should arrive with clean clothing, boots and equipment.
- Equipment and instruments that have direct contact with animals should be cleaned and disinfected before and after use.

- Any disposable disinfectable clothing, such as sleeves and gloves, should be worn whenever there is direct contact with animal discharges or tissues.
- Dirty equipment and footwear should be cleaned and disinfected with an appropriate disinfectant before leaving the farm.
- Soiled coveralls should be removed before people re-enter their vehicles.
- Hands and forearms should be washed with antibacterial soap.

Risk from Wildlife

The presence of wild animals in a farm area should not cause alarm. However, some diseases such as rabies, leptospirosis and salmonellosis can be carried and spread by some species of wildlife including rats and mice. It is necessary to take efforts to make barnyards and buildings unattractive to wildlife by:

- Cleaning up grain spills and other sources of food.
- Cleaning up old board piles or debris piles.
- Inspecting buildings for possible hiding or denning areas.
- Inspecting hay and feed storage areas for presence of animals like cats, dogs and rats.

Risk from Farm Equipment

Equipment that has been in contact with livestock or their bodily secretions can spread diseases. Also, equipment moved from one farm unit can carry heavy pathogenic contamination to another farm unit, if not thoroughly cleaned. To help minimize this risk, it is necessary to include farm equipment in the biosecurity plan and provide activities such as:

- Remove all gross organic soiling from equipment and tools because high levels of soiling reduce the efficacy of the cleaning and disinfection process.
- Do not share manure-hauling equipment between farms unless it is thoroughly cleaned and disinfected.
- Clean and disinfect front, buckets and skid steer loaders used for manure or feed handling between each use.
- Soak and scrub equipment in a tank or pressure wash with a detergent sanitizer.
- Store used equipment where it will not be recontaminated.

Risk from Vehicles

Vehicles used for livestock haulage, feed trucks and any vehicles for animal transport are excellent vectors for disease spreading. Cleaning and washing must be carefully and thoroughly done. Procedures to reduce the potential for disease transmission are:

- Only essential vehicles may enter the farm.
- If possible, vehicles visiting the farm should be kept outside the biosecurity perimeter.
- Vehicles, especially wheels, tires and wheel arches should be cleaned and disinfected upon arrival at the farm using wheel dips or sprays.
- Personnel should use foot dips, protective clothing and observe hygiene requirements prior to entry to the premises.

GOOD HYGIENE PRACTICES ON THE LIVESTOCK FARMS

Good hygiene practices can be described as a set of procedures that provide a clean, sanitary environment for the production, processing and storage of feed and animal products. In other words, good hygiene practice determines what needs to be done regarding cleaning and hygiene, as well as when and who should carry out these tasks.

Because of the great diversity in the structure of today's farms (type, number, productivity), the emphasis has to be on prevention and crisis control, but primarily it should be on hygiene at the farm. Good farm hygiene seeks to minimize noxious external stressors that lead either to acute disease or to the exacerbation of chronic disease.

During the last decades of the 20th century, there was an increase in the number of infectious diseases that evolved into an epidemic. Almost every outbreak was associated with a lack of implementation of biosecurity and/or hygiene procedures on infected farms. Since then, hygiene has become the primary tool in the health care program.

It is very important that correct hygiene measures are routine in everyday activities.

However, before a farmer starts with the application of hygiene measures, such as cleaning and disinfection of facilities, equipment and tools, it is necessary to provide conditions on the farm that will allow hygienic measures to be effective. Attention must be given to:

- Healthy soil: hygiene must start with the soils on the farm. Healthy soil means healthy and nutritious crops.
- Manure and waste management: to reduce the risk of spreading microorganisms across the farm, special attention should be paid to manure and waste originating from sick animals that should be destroyed in a way matching principles of environmental protection.
- Grazing and harvesting programs: agro/technical measures, such as tillage and planting methods, have a direct impact on soil quality.
- Plant should be selected according to the micro-environment of the farm.
- Livestock should be selected according to the environment on the farm as well as the production and management systems.
- Water supply: sufficient quantities of clean water must be accessible to animals at all times. Slop-basins should be easily cleaned and protected from any kind of direct or indirect contact with animal excrements or animal and farm waste.
- Barns must have adequate space, water supply, ventilation and light at all times when the animals use it. If animals are kept on pasture or used outlets, the farmer must also provide adequate shelter from sun, wind, rain or snow, and those shelters must be available at all times.
- Equipment and tools must be sized for the animals being worked and must be cleaned and disinfected after each use. This is especially necessary for dairy farm equipment and tools.
- Regular vaccination is necessary to conduct in accordance with State regulations, and emergency vaccination must be provided in case of uncontrolled outbreaks.

Only if these conditions are achieved can hygiene procedures can be efficient. Maintaining hygiene on the farm should be a team approach, not the sole responsibility of one worker, especially at big farms.

Cleaning

Cleaning is one of the most important activities for disease control on a farm. Equipment, facilities, machinery, tools etc., always retain an amount of feed, litter or manure on the surface after use. Beside the corrosion that these substances can cause, they are an ideal medium for microbial growth.

Therefore, the aim of cleaning must be complete removal of manure, litter or feed, by washing, scrubbing and rinsing, or pressure washing with hot water and detergent from all kinds of surfaces, done in a dedicated separate facility to avoid spread of contaminated dirt. This is difficult to accomplish in barns with wooden walls, dirt floors, open ceilings and lack of drains. This is why, when building a new barn, it is necessary to choose a design and materials that will make cleaning easier. In barns with sand or other porous floors, it is easier and more efficient to replace sand or clay than to thoroughly clean it. Cleaning can be dry and wet.

Dry cleaning is the physical removal of manure, litter, feed and other animal wastes. The disadvantage of dry cleaning is that infective material together with dust will rise and float in the air, and after some time will cover already cleaned areas. Dry cleaning is suitable only if it represents a preparatory phase before wet cleaning. Tools for dry cleaning can be numerous types of brushes, brooms, shovels, pitchforks, etc.

Wet cleaning means using cold, temperate or hot water with or without detergents. With cold or temperate, and especially with hot water, it is possible to remove almost all organic materials from surfaces, but there is still the possibility that a so-called "organic film" will remain. To remove all traces of organic matter it is necessary to use detergents in combination with temperate and hot water.

Detergents are compounds or mixtures of compounds, organic or inorganic, used for cleaning. These are compounds that should not have an adverse effect on human health and not cause corrosion of equipment, tools, walls and floors. In general, detergents can be divided into:

- Inorganic bases and their salts:
  - sodium hydroxide, sulfates, carbonates, phosphates and silicates.
- Organic and inorganic acids:
  - nitric, phosphoric, sulfamic, citric, hydroxyl acetic, gluconic and tartaric acids.

Cleaning by using products with good detergent capacity will remove soil from the walls and floors and ensure that dirty deposits will not remain on rough surfaces, e.g. concrete and wood. Detergents also reduce the time needed to clean by up to 60%, and reduce the spread of disease in washing water.

The best way for wet cleaning with detergents is to apply a mixture using a knapsack sprayer or pressure washer. The pressure washer should be set on a low pressure setting of approximately 35 bars, and a stream of mixture should fall to the surface that should be cleaned at an angle of 45 degrees. It is also important to use the appropriate application rate of applied mixture. If it is a normal liquid mixture, it should be 500 ml/m^2, or if it is a foam mixture it should be 250 ml/m^2. It is very important to start cleaning from the apex of the roof and work down the walls to the floor, paying particular attention to corners and other areas where dirt accumulates. The same procedure, from the top to the bottom, should

be used to clean equipment or tools. Caked soiling should be brushed if necessary to aid removal.

Special attention should be paid to all water systems, most importantly the water supply systems for the animals. Water systems are likely to contain some bacterial contamination. This may enable diseases to pass from animal to animal or from one batch of animals to the next unless the bacterial growth is eliminated. To eliminate bacteria from water systems, it is necessary to:

- Drain
- Remove dirt from the system
- Refill the system with water
- Clean using a detergent
- Drain again
- Refill and add a disinfectant
- Leave in the system for 10 minutes
- Drain the system to remove all disinfectant
- Flush with fresh clean water
- Refill with fresh water

Disinfection

It is necessary to emphasize that dry or wet cleaning, even cleaning with detergent, can remove mechanical impurities and organic matter, but it is not possible to remove all microorganisms and their spores. In addition to cleaning and washing, to destroy microorganisms, it is necessary to implement methods of disinfection (sanitation) on farm facilities, equipment and tools. Disinfection is using specialized cleansing techniques that destroy or prevent growth of organisms capable of infection (Stojanović et al., 2003).

There are two methods of disinfection:

- Disinfection by physical means.
- Disinfection by chemical substances.

Disinfection by Physical Means

Physical means can be heat, gamma-radiation and UV radiation. Different forms of heat can be used such as wet heat (steam, hot water, boiling solution of acids and bases) and dry heat (hot air and UV radiation).

DISINFECTION BY WET HEAT

- Steam is used mainly for autoclaving and disinfection of finer equipment and milk pipes. It is suitable for application in the dairy but not for the farm. Usually the required disinfection is obtained if the temperature of the steam is 115°C at a pressure of 0.7 bar for 3–5 minutes.
- Hot water quickly destroys vegetative forms of microbes, but not their spores. A good disinfection for a dairy farm is a water temperature of 77°C for 10 minutes. A good effect can also be obtained with a CIP (Cleaning in Place) system with water of 90–95°C for 5–7 minutes. The disadvantage of hot water is that it can cause burns and may be

expensive due to the cost of the volumes of water needed to achieve disinfection the heating of the water. On the other hand, hot water, properly used, will kill m microorganisms and is non-corrosive.

- Boiling solution of acids and bases – usage of these types of disinfectants is simil previous, but effects are much better, especially if the solution temperature is high 77°C.

DISINFECTION BY DRY HEAT

- Hot air is less used on farms. Mainly it is used in laboratories for disinfection of laboratory glassware and equipment in dry sterilizers.
- UV radiation is used to sterilize small enclosed areas such as laboratories and cham milking machines, milking parlors and dairies and so on. It works on surfaces that a exposed to the radiation.

Disinfection by Chemical Substances

The presence of organic material, including bedding, manure, blood and pus, inter with the action of most disinfection methods. This is the reason that prior to implementa of the disinfection method by chemical substances, it is necessary to clean and wash the face that should be disinfected. After cleaning and washing it is good to allow the surfac dry, if possible. Thorough cleaning, washing and drying will remove most of the contami tion and allow disinfectants to contact the surfaces and kill the microorganisms.

Disinfectants

A disinfectant is a chemical or other substance that kills microorganisms but may not k bacterial spores, which are a dormant form of some bacteria, e.g. *Clostridia* spp. They can b applied to objects, equipment or tools. Because of their potentially toxic, irritating or co rosive properties, most disinfectants cannot be applied directly to living animals or people.

There are products that are both detergent and disinfectant. Because these substances may be toxic, farmers must strictly follow the instructions on the label before use. It is very important to pay attention to:

- Dilution rate, either as a germicidal cleaner (killing microorganisms) or as a sanitizer (reducing the number of microorganisms).
- Minimum contact time, the time required to kill microorganisms.

BOX 23.3

REQUIREMENTS FOR A GOOD DISINFECTANT

- Effectively destroys microbes
- Not toxic
- Free of smell and taste
- Not harmful to human skin and materials
- Easy to use
- Efficient
- Not expensive

This information is normally stated on the label. But the dilution rate and minimum contact time depends also on:

- Presence of organic matter.
- Temperature, pH and hardness of water.
- Concentration of disinfectant.

The main group of disinfectants and their characteristics are (Stojanović et al., 2003):

ALCOHOLS

Alcohols are commonly used for cleaning equipment on the farm but do not kill bacterial spores. Isopropyl and ethanol alcohol are commonly used, mostly for disinfection of working surfaces and smaller equipment and tools.

CHLORINES/HYPOCHLORITES

Chlorine-based disinfectants have two major advantages: excellent broad-spectrum antimicrobial activity and low cost. The major disadvantages of chlorine sanitizers are that they are very corrosive to many materials of construction and they are easily inactivated by organic materials and soils. They are commonly used but care must be taken never to mix them with acids because toxic chlorine gas will be generated. They lose some of their activity above 80°C and work best in pH < 7.

CHLORHEXIDINES

Chlorhexidines are not active against all bacteria that are found on the skin or some viruses, but they can be used for washing animals or workers' hands. They are more efficient if they are used after cleaning, washing and rinsing of surfaces.

CARBOXYLIC ACID

The carboxylic acid sanitizers are also called fatty acid sanitizers. They are a combination of acidulants, such as phosphoric acid or citric acid with a fatty acid such as octanoic acid. They have the dual function. They develop acidity for rinsing and removing mineral films and killing microorganisms. They have good broad-spectrum activity and, because of their low foaming characteristics, are very good for CIP applications.

IODOPHORS/IODINE COMPLEXES

Iodine is not very soluble in water and can be inactivated by organic matter. Therefore, cleaning and washing with a detergent and rinsing with clean water is preferable before applying iodine. To improve its efficiency, a surfactant is mixed with the iodine to form a complex known as an "iodophor." A mineral acid such as phosphoric acid is added to this combination because iodine kills best at an acidic pH (pH < 7). Iodophors have very good broad-spectrum antimicrobial properties. They cannot be used at temperatures above 80°C. Because of their natural amber color, it is easy to see if iodine is present in the sanitizing solution. Iodophor solutions, shampoo or washes can be used for washing animals (udder dipping) and workers' hands.

PEROXY COMPOUNDS

Peroxy compounds are a combination of hydrogen peroxide with organic acids suc tic acid. The resulting peracid is an excellent broad-spectrum disinfectant. An addition is that it provides an acidified rinse to remove mineral films. A big advantage is its abili microorganisms at temperatures as low as 4–5°C, which can be important on the farm in countries in the winter. Disadvantages include the fact that peroxy disinfectant loses ef ness in water that contains iron at levels of 0.2ppm and higher. Also, it will corrode soft such as brass and copper. Peroxy disinfectant is reported to be also effective against biofil

PHENOLS AND CRESOLS

Phenols and cresols work well in the presence of organic matter, e.g. foot baths. work better at higher temperatures and they are most efficient at pH < 7. A disadvanta that they are inhibited by hard water.

QUATERNARY AMMONIUM COMPOUNDS

Quaternary ammonium compounds are active against most bacteria, fungi and viru but not against bacterial spores and some viruses. They work best at pH > 7, but are inh ited by hard water.

SODIUM HYDROXIDES (LYE)

Lye can be used as a whitewash or as a dry powder for disinfecting buildings. The usu concentration in water is 2%.

SULFATES

Sulfates are a multi-purpose disinfectant. They consist of potassium peroxymonosulfate, sodium dodecylbenzenesulfonate, sulfamic acid and inorganic buffers. They are typically used for cleaning up hazardous spills, disinfecting surfaces and rinsing equipment. The solution is used in many areas where control of pathogens is required. Sulfates have a wide spectrum of activity against viruses, some fungi and bacteria. However, they are less effective against spores and fungi than some alternative disinfectants. They are sold as tablets or powders which dissolve readily in water. They should be mixed with water to form a 1–3% solution. They are colored, which is useful to gauge the concentration during preparation. Moreover, discoloration makes it obvious when they need to be replaced. The solution disinfectant does not cause skin irritation/corrosion, but can cause eye damage and should not be used as a hand-washing liquid. They work well under all circumstances and are well known for their detergent properties.

The Cleaning and Disinfection Process

Equipment and surfaces that come into contact with food, inedible by-products and waste should be of a material that allows cleaning and disinfection. Also, it is important that the surfaces are in satisfactory condition and undamaged, because otherwise cracks and scratches can trap dirt and prevent successful disinfection.

Vehicles should also be disinfected. If they are used for the transportation of animals, disinfection should be done at the latest within 24 hours after unloading,

For disinfection of facilities, equipment and tools, especially those that are in direct contact with animals, use only approved disinfectants.

To ensure efficiency, it is important to follow strictly the directions for use of disinfectants. Unless it is otherwise specified in the manufacturer's instructions, the cleaning and disinfection procedure consist of the following five steps:

1. Preliminary cleaning including brushing, scraping and deleting dirt and food residue and rinsing with clean water.
2. Next is the main cleaning, which consists of scrubbing the surface that was previously soaked with soapy water in order to remove dissolved residual dirt; scrubbing must be thorough.
3. Washing with water to remove the detergent and dissolved dirt and food residue.
4. Applying disinfectant to cleaned surfaces.
5. Thoroughly rinsing with water.

In order to avoid the contamination of food, animals or people, chemical products for cleaning and disinfection should be stored in a separate room used only for chemical storage. Particular attention should be paid to the cleaning equipment, which should also be regularly cleaned and disinfected; otherwise they will become a source of cross-contamination. Cleaning equipment should be kept in a separate room, which also needs to be maintained and cleaned. Each piece of cleaning equipment should be used only in certain areas, in order to prevent the spread of contamination (e.g. broom to clean floors of toilets must not be used to clean the areas in which food is treated). Marking equipment with colors is one of the simplest ways to ensure good control over the purpose and location of certain equipment. The system to follow is: one color – one room.

How to Handle Disinfectants

As we mentioned before, some disinfectants can be extremely toxic. Therefore it is very important to observe the same rules.

BOX 23.4

RULES FOR HANDLING DISINFECTANTS

- Always use eye protection (eyeglasses)
- Use protection (rubber) gloves and special clothes (working coat)
- It is mandatory to read and understand all warnings and instructions written on labels or declaration of product, before using the product
- Products should always be used in well-ventilated areas
- Use only approved disinfectants
- Follow all instructions on labels or declaration of product as to how to make solutions, how to apply, etc.
- Do not mix disinfectants with any other disinfectants or chemicals
- Disinfectants must be stored in a separate, locked room where only those who work with disinfectants can be allowed entry
- Keep disinfectants away from other personnel, especially children!

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

In the modern approach to food safety, application of the HACCP system has been recommended as a complement to prerequisite programs (in this context, good animal husbandry) (CAC, 2004).

For various reasons, application of the HACCP system, with the same degree of stringency as applied in food processing and manufacturing, may be difficult at the farm level. This should nevertheless not exclude the possibility of using of the concept, following its adaptation, for a proactive and risk-based approach to management of risks at the farm level. Considering that there are multiple sources of animal infection and numerous risks of food contamination, a risk-based approach to identify measures which need particular surveillance is even more warranted.

Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. It may be possible to develop HACCP-based codes of practices that include preventive controls following a hazard analysis on risks and practices at the farm.

PART 2: GOOD AGRICULTURAL PRACTICES FOR FOOD SAFETY

INTRODUCTION

Consumption of fresh vegetables and fruits is part of a healthy diet and recommended so as to prevent illnesses. Hence, an increased consumption of fresh vegetables and fruits in the world has been documented.

The number of human outbreaks of diseases and illnesses associated with the consumption of raw vegetables, however, has increased in recent years. In the United States, available foodborne illness outbreak data document 131 outbreaks associated with 20 different contaminated commodities between 1996 and 2010, causing more than 14,000 illnesses and 34 deaths (FDA, 2013a). *Salmonella*, *Shigella*, enterotoxigenic *E. coli* and *Escherichia coli* O157:H7, hepatitis A and *Cyclospora* have been linked to fresh tomatoes, lettuce, spinach, carrots, parsley, cantaloupe, berries, seed sprouts, etc. (Ackers et al., 1998; Beuchat, 2002; FDA, 2013a).

The most likely routes of contamination of produce from growing, harvesting and on-farm post-harvest activities are associated with water, soil amendments, animals, worker health and hygiene, buildings and equipment. It is very difficult to identify primary sources for contamination of fresh vegetables. The success of the detection of human pathogen bacteria on fresh fruits and vegetables depends on the methods applied and the nature of the contamination and sporadic contamination limits effectiveness testing. According to NACMCF (National Advisory Committee on Microbiological Criteria for Food, USA), for only two out of 27 human outbreaks, contaminated fresh produce has been identified as the source (National Advisory Committee on Microbiological Criteria for Foods, 1999).

It is known that *E. coli* O157:H7 could be transported from contaminated soil and irrigation water to lettuce leaves. Also, these bacteria can migrate throughout the lettuce plant (Solomon et al., 2002; Wachtel et al., 2002; Wang & Doyle, 1998). Guo et al. (2002) detected

an association of *Salmonella* spp. with stems and leaves of tomato plants that were grown hydroponically in an inoculated solution.

Knowing about microbial ecosystems on/in raw vegetables helps to understand better the nature of microbial contamination of fresh produce. Survival of human pathogen bacteria on/in fresh vegetables depends on: pH, morphology, anatomy and metabolic functions of plant organs (fruits, flowers, leaves, roots). For example, the pH of many vegetables is 4.5 or higher and this value is appropriate for growing many human pathogen bacteria. Also, differences in morphological and anatomic properties of different plant organs ensure a wide range of ecological niches, which could be colonized by different species of human pathogenic bacteria (Brandl & Mandrell, 2002; Solomon et al., 2006).

Human pathogenic bacteria as well as non-pathogenic bacteria are able to form biofilms on the surface of raw vegetables. Biofilms have been detected on leaf surfaces of lettuce, cabbage, parsley, spinach, celery, etc. (Morris et al., 1997). These biofilms represent protective environments for human pathogenic bacteria and reduce the effect of sanitizers used for washing waters. Yet, further investigation of bacterial biofilms on the surface of raw vegetables is needed.

SOURCES OF MICROBIOLOGICAL CONTAMINATIONS OF FRESH VEGETABLES

Human pathogens can contaminate fresh vegetables at any point of the production chain. They may contaminate produce in the pre-harvest and post-harvest period (see Scheme 23.1). Pre-harvest sources of contaminations implicate soil, irrigation water (Kljujev and Raicevic, 2006), water for applying pesticides, inappropriate composted manure (Fukushima et al., 1999), feces, dust, insects, wild and domestic animals, and human handling (Beuchat, 1996).

SCHEME 1 SOURCES OF MICROBIOLOGICAL CONTAMINATION (BEUCHAT, 2002)

Post-harvest sources of contamination could be: harvesting equipment, processing equipment, transport containers, transport vehicles, rinse water, ice, as well as insects, wild and domestic animals, dust, feces, and human manipulation (Burnett and Beuchat, 2001).

Non-composted and improperly composted manure can contaminate raw vegetables if it is used for fertilizing growing plants (Fukushima et al., 1999). Many human pathogens, like *Salmonella* spp., *E. coli* O157:H7 and *Listeria monocytogenes*, can be present in animal feces. Also, these pathogen bacteria may arrive on the growing vegetables through contaminated irrigation waters.

Recent data show that pathogenic bacteria, originated from irrigation water, can contaminate vegetables (Chalmers et al., 2000; FDA, 2013a). The potential risk of infecting humans by such contamination should be seen in the context of recommendations for the microbiological quality of irrigation water. Strategies to reduce the risk of causing human illness due to pathogenic bacteria in irrigation water are needed for producing safe and healthy food.

Wachtel et al. (2002) showed contamination of cabbage root by *E. coli* when plants were irrigated with contaminated wastewater, although the edible parts of the plants had not been treated with this water. Also, Islam et al. (2004) found the presence of *Salmonella Typhimurium*

on carrot and radish if water, contaminated with *S. Typhimurium*, was used. They demonstrated that *S. Typhimurium* could survive in the soil for 203 days. Lettuce plants, irrigated with *E. coli* O157:H7-contaminated water, were positive for the presence of this pathogen during the harvest period, until 30 days after the last irrigation. After 7 and 14 days, a significant increase in the number of *E. coli* O157:H7 was detected (Solomon et al., 2002).

Quantitative models of risk assessment for using wastewater for irrigation show that the risks differ between different plants. Thus, it was noted that the risk is higher with lettuce than with cucumber, broccoli and cabbage (Hamilton et al., 2006). The time interval between irrigation and harvesting has an impact on the survival of pathogenic bacteria on plants and hence on the chance that they will reach the consumer. Some investigations in the UK showed that more than 50% of producers harvest and deliver leafy vegetables within 24 hour of the last irrigation.

MICROBIOLOGICAL QUALITY OF IRRIGATION WATER

Recent investigations show high variations in total coliform counts in stream water, closed wells, public drinking fountains, underground waters and channel waters. The degree of contaminations depends on the season of the year, the location and integrity of the wells and open channel waters (Kljujev, 2012; Dulic et al., 2008).

Open channel waters or surface water pose the highest potential for contamination and the greatest variability in quality of agricultural water sources (FDA, 2013a). Three years of investigation of microbial quality of channel water through its 54 km length until it enters the Danube River show variations according to the season and the location. At the point where the city sewage wastewater enters the channel the average coliform counts were extremely high, especially close to a pig farm that drains wastewater directly into the channel; the same happens when the channel runs near settlements, industrial areas, dairy farms and meat factories (Kljujev, 2012).

PRESENCE OF PATHOGENIC BACTERIA ON FRESH VEGETABLES

It has been documented that water that is applied directly to the harvestable portion of the plant is more likely to contaminate it. The proximity to the harvestable portion and the timing of water application in produce production before consumption are important factors in determining the likelihood of contamination (FDA, 2013a).

Field experiments confirmed that pathogenic bacteria could be transported from irrigation water to edible parts of vegetables, when waste and microbiologically incorrect water was used for irrigation. Microbiological analyses of edible parts of vegetables such as carrot, parsley, celery, cabbage, spring onion, tomato, pepper and cucumber showed the presence of pathogen bacteria species. *E. coli* was found at carrot root, spring onion, tomato and pepper fruits. The bacterial strain *E. coli* O157:H7 was identified at carrot and parsley roots and tomato fruit. *Salmonella* spp. was detected at parsley root, spring onion, tomato and pepper fruits (Table 23.6) (Kljujev, 2012; Kljujev et al., 2011; Kljujev et al., 2012).

TABLE 23.6 Presence of Pathogen Bacteria Species on the Edible Parts of Vegetables

Plant Species	Pathogen Bacteria Species		
	E. coli	*E. coli* O157:H7	*Salmonella* spp.
Carrot	+	+	–
Parsley	–	+	+
Celery	–	–	–
Cabbage	–	–	–
Spring onion	+	–	+
Tomato	+	+	+
Pepper	+	–	+
Cucumber	–	–	–

TRANSMISSION OF PATHOGENIC BACTERIA FROM CONTAMINATED IRRIGATION WATER AND SOIL TO PLANTS

Commodity type, growth characteristics and surface properties (porosity) affect the probability and degree of contamination. Research has indicated a big potential risk if contaminated water is used for irrigation of lettuce plants. Results showed that treatments with contaminated water resulted in significant levels of *E. coli* inside roots and leaves, whereas uninoculated controls were free of detectable *E. coli* contamination. The highest number was found on the surface of roots (4.1×10^5 CFU) and the lowest was inside leaves (5.0×10^2 CFU). Quite high numbers of *E. coli* were found inside lettuce roots, 3.0×10^5 CFU. The highest number of *E. coli* was found in the soil, near the root (7.3×10^5 CFU). *E. coli* K-12 was not detected on the surface of lettuce leaves, or inside/outside roots and leaves in control plants (Kljujev, 2012).

Laser scanning microscopy confirmed the presence of *E. coli* inside roots and leaves of lettuce (Photo 23.1). *E. coli* was not found inside roots of control plants but nucleui of root cells were clearly seen (picture 1 on Photo 23.1). On picture 3, plant vascular tubes and bacteria and root cell nucleus inside them in the same layer can be seen. This suggests that bacteria could be transported though the vascular system of the plant, through the xylem to edible parts of plant – the leaves.

Also, by confocal laser scanning microscopy, *E. coli* was seen inside leaves, and r colonies of *E. coli* were detected below the surface of leaves. *E. coli* cells were conce near stomata (pictures 4, 5 and 6 in Photo 23.1). This suggests that pathogenic bacter enter the inside of a leaf through stomata if present in irrigation water. On the su leaves, confocal microscopic observation did not show the presence of bacteria. obtained micrographs demonstrate the presence of these bacteria inside the leave tuce and parsley plants (Photo 23.1). Observations with *Salmonella Typhimurium* LT2 s. colonization of root surface of lettuce, tomato and sweet corn plants. The same au

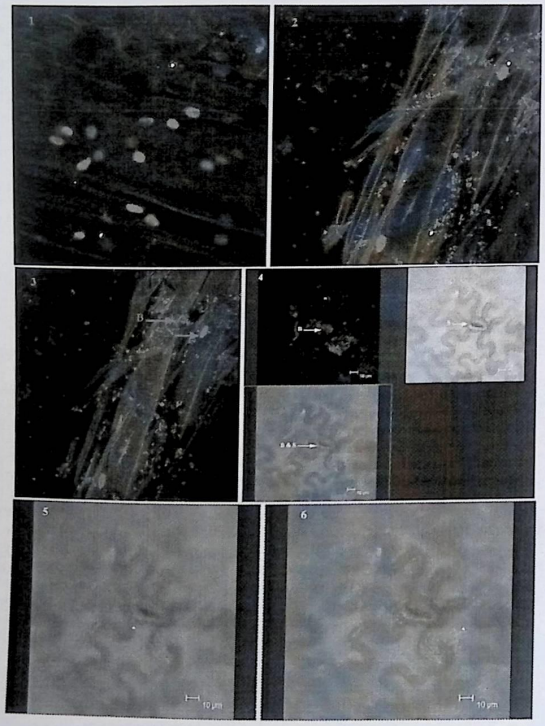

PHOTO 23.1 Microphotographs of lettuce roots and leaves, picture 1 – root of control lettuce plant irrigated with sterile water; picture 2 (the layer is 19 µm deep) and picture 3 (the layer is 20 µm deep) – root of plants irrigated with contaminated water; pictures 4, 5 and 6 (the layer is 11 µm deep) – leaves of plant irrigated with contaminated water; B – bacteria cells, N – nucleus of plant cells, S – stomata.

demonstrated that *Listeria monocytogenes* EGD-E strain has the ability for surface and endophytic colonization of carrot, parsley, celery and sweet corn root. Root colonization with *Listeria monocytogenes* SV4B strain was the most significant at herbaceous crops (lettuce and spinach). The *Listeria monocytogenes* SV4B cells were individually represented in endophytic colonization of celery and sweet corn roots (Kljujev, 2012).

GOOD AGRICULTURAL PRACTICES

The best way to control microbial, chemical and mechanical risks, but also for clear and comprehensive management strategy on farm, is to apply principles of Good Agriculture Practice (GAP). Also, practices that are directly related to monitoring and reduction or complete annulment of risks on the farm are Good Hygiene Practices, Biosecurity Principles and HACCP. These practices may be part of GAP, but also can be applied individually. Their application depends on the development of farm expertise and capabilities.

The concept of GAP is a modern agricultural management concept, which originated in the developed countries. It is an expression of the danger of ecological crisis, which seriously threatens humanity in all aspects of manufacturing activity by man. A radically different attitude to all the factors of agricultural production is required. Irrationality, inefficiency and negligence in production have resulted in increased pollution of the environment. GAP protocols were developed as a response to the increase in the number of outbreaks of foodborne diseases. Hence, GAP is both a necessity and an imperative of modern agricultural production. Key words related to GAP are knowledge, understanding, planning, measurement, control and management (Pejanović, 2008). Concept, goal and benefits of GAP are presented in Table 23.7.

Basics Principles of GAP

Basic principles of GAP include the resources, methods and practices necessary for production, which are classified into nine elements, namely: Clean Soil; Clean Landwater; Crop Production; Plant Protection; Harvesting, Processing and Storage on the Farm; Energy and Waste Management; Welfare, Health and Safety of Workers; Environment and Farm Keeping.

TABLE 23.7 Concept, Goal and Benefits of Good Agriculture Practice

Concept – involves application of certain procedures in the process of agricultural production – represents a integration of the well-established work processes and well-placed controls.
Goal – to produce safe and healthy food and other agricultural products, while achieving economic values, social stability and environmental protection.
Benefits – farmers, additional value of their products and improved market access. – consumers will have safe food products – economy will make higher profits thanks to quality products – mankind will enjoy a better environment

BOX 23.5

PRINCIPLES TO ACHIEVE MINIMUM OF LOSS OF SOIL PARTICLES AND NUTRIENTS

- Production in accordance with the potential of soil fertility
- Keeping records of inputs and outputs of each parcel
- Maintenance and improvement of soil fertility using crop rotation
- Rational mechanical tillage
- Maintaining vegetation cover to reduce the soil erosion
- Using agricultural chemicals and organic and inorganic fertilizers in adequate amounts, timelines and methods that are adequate for the requirements of human health and a healthy environment

Clean Soil

It is most important for soil to be fertile and to contain no pollutants. Physical and chemical structure and biological activity of the soil determine its fertility. Maintaining and increasing soil fertility is achieved by minimizing the loss of soil particles and nutrients by applying the principles presented in Box 23.7 (Pejanović, 2008).

To avoid or minimize microbial contamination of soil, special attention should be paid to proper management of manure, animal excrements and other farm waste. That management includes (http://www.slideshare.net/dslagoriya/good-agricultural-practices):

- Orderly collection of manure and other waste from the farm.
- Prevention of wastage of manure and other waste during transport to storage places.
- Ensuring that the content of manure and other waste cannot leak or dissipate from storage places.
- Protecting the storage place from adverse weather conditions (rain, wind, sun, snow).
- Applying manure to soil, adhering to the time and limits of fertilization.
- Keeping other domestic and wild animals away from storage places.

Clean Water

Given that agriculture is one of the major water pollutants, it is necessary to carefully manage water resources on the farm and the surrounding area.

Clean water entails that all water used for washing, cooling, irrigation and processing is potable (Pejanović, 2008).

Crop Production

Beside of needs of consumers and the market, selection of plants that will be grown on the farm primarily depends on quality of the soil, availability of inputs, possibility of crop rotation, control of pests and diseases, etc. Each harvest, in fact, presents a deprivation of nutrients from the soil, so they must be replaced with new nutrients to ensure the long-term productivity of the soil (Pejanović, 2008).

BOX 23.6

PRINCIPLES FOR GOOD MANAGEMENT OF WATER SOURCES

- Use inputs of organic, inorganic and synthetic composition, in a manner that avoids contamination of water resources.
- Protect ground and surface water sources from run-off and animal contamination.
- Use underground and surface water appropriately.
- Adjust the timing and quantity of the irrigation needs of crops.
- Prevent salinization of land.
- Improve water cycles, provide permanent cover of vegetation.
- Provide an adequate, safe and clean place where animals can drink water.

BOX 23.7

GOOD AGRICULTURAL PRACTICES IN CROP PRODUCTION

- Adequate selection of species and varieties.
- Suitability of species and varieties to planting, productivity, quality, disease resistance, adaptability to soil and climate conditions, responses to fertilizer and agrochemical and market requirements.
- Inclusion of legumes in the rotation, to ensure the required amount of nitrogen.
- Use moderate amounts of organic and inorganic fertilizers.
- Inclusion of pasture land into crop rotation.
- Use of by-products of livestock production to improve soil fertility.
- Rotation of flocks on pasture to ensure natural regeneration of pasture.

Plant Protection

Plant protection must be based on a long-term strategy. All measures for plant protection, especially those that involve the use of substances that harm human health or the environment, must be conducted professionally and with the appropriate equipment (Pejanović, 2008).

Harvesting, Processing and Storage on the Farm

Product quality largely depends on how the harvest is done, on conditions of storage and on the processing of agricultural products at the farm.

Energy and Waste Management

All operations in agricultural production should be completed on time, with minimum worker downtime and with the lowest possible energy use. During the process of

BOX 23.8

PRINCIPLES FOR GOOD MANAGEMENT OF PLANT PROTECTION

- Use of species and varieties resistant to pests and diseases.
- Use of crop rotation.
- Use of production technologies that maximize biological prevention against diseases and pests.
- Application of techniques that can predict appearance of disease or pest.
- Storage and use of agrochemicals in accordance with applicable law.
- Handling and application of agrochemicals by highly trained and professional staff.
- Keeping of accurate records on the use of agrochemicals.

BOX 23.9

GOOD AGRICULTURAL PRACTICE IN HARVESTING, PROCESSING AND STORAGE

- Harvesting of agricultural products in accordance with agro-technical terms and terms of agrochemical application.
- Clean and safe manipulation during the processing.
- Use of recommended detergent and clean water for product washing.
- Storage of agricultural products in adequate hygienic and ambient conditions.
- Packaging of agricultural products in a clean container.
- Keeping of accurate records on harvesting, storage and processing.

BOX 23.10

PRINCIPLES FOR IMPROVEMENT OF ENERGY AND WASTE MANAGEMENT

- Make plans for the nutrients, energy and agrochemical inputs and outputs.
- Design objects that save energy.
- Choose adequate machinery, equipment, tools.
- Use alternative energy sources, if possible.
- Recycle organic waste and inorganic matter.
- Reduce unusable waste and dispose of it in an environmentally friendly manner.
- Store fertilizers and agrochemicals safely.
- Keep accurate records regarding energy use, storage and disposal of waste.

BOX 23.11

WELFARE, HEALTH AND SAFETY OF FARM WORKERS

- Adequate profit of agricultural households.
- Obtaining safe working conditions, with reasonable working hours.
- Training of workers for efficient and safe use of tools and machines.
- Adequate salaries, without exploitation of workers, especially women and children.

BOX 23.12

PRINCIPLES FOR ENVIRONMENT AND BIODIVERSITY PRESERVATION

- Conservation of natural habitats on the farm.
- Cultivation of as many different crops and animals on the farm.
- Minimizing the adverse impact of working operations on nature, e.g. tillage.
- Maintaining fertile agricultural land, e.g. removal of weeds, cultivating beneficial flora and fauna.
- Managing natural resources in a way that maintains biodiversity.
- Keeping garbage containers tightly closed.
- Destruction of the waste in the specified waste disposal area located separately from the rearing area.
- Removing animal manure from housing area to avoid sources of bad odor and pathogens.
- If the effluents are discharged to public water systems, an appropriate wastewater treatment device should be provided and the quality of the discharged water should meet official standards.

agricultural products, by-products can be obtained. Some of them are potential contaminants of soil, water and air. Production of harmful by-products should be minimized, while other by-products should be recycled (Pejanović, 2008).

Welfare, Health and Safety of Workers

Welfare of both the people that work on the farm and the entire community to a large extent depends on economic well-being, i.e. farm profitability. But more important issues are the health and safety of all those who are directly or indirectly involved in agricultural production (Pejanović, 2008).

Environment

Intensive agricultural production has an influence on water, soil and air pollution, and extinction of some plant and animal species because of loss of habitat. One of the major

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BOX 23.13

INFORMATION THAT SHOULD BE RECORDED ON FARM

- Information on farm management, i.e. personnel information, training, health status.
- Information on pesticides and fertilizations applied to each production lot.
- Results of water analysis.
- Cleaning and sanitizing procedures.
- Information on production management, i.e. history of each animal, feed and water, farm management; animal health; production records and quality of animal products such as raw milk quality.

tasks of agricultural production is to preserve the environment and biodiversity, with simultaneous, economically justified, agricultural production.

Record Keeping

Farms should have a well-planned and established system of documentation. Important information should be archived for at least 3 years for the purposes of traceability.

PART 3: FISH HYGIENE

BACKGROUND

Statistics published by the FAO (Food and Agriculture Organization of the United Nations) show that inland capture fisheries production follows the general trend of most of the world's sea fishing areas, which have apparently reached their maximum potential, with the majority of stocks being fully exploited. In contrast, growth in aquaculture production has shown the opposite trend. While capture fisheries production has increased only very slightly, output from aquaculture (farmed fish, shellfish and algae) increased significantly from just over 13 million tonnes in 1990 to 33 million tonnes in 1999.

Despite its healthy growth, the aquaculture industry still faces problems with diseases which can affect its sustainability. Infectious diseases caused by viruses, bacteria and parasites are continuing threats to consistent industry growth. With increasing intensification, the incidence of diseases is also expected to increase proportionately.

DISEASE PREVENTION

Most diseases can be prevented through good husbandry practices and proper screening of incoming animals to the facility. When possible, bring in only eggs from a reputable supplier that can provide disease-free animals. Commercial blood test kits are available to

screen fish for antibodies of several important fish pathogens. These kits normally do not determine active infections but can provide evidence of previous exposure by vaccination or live-disease-causing agents. More expensive laboratory DNA tests of fish tissue using polymerase chain reaction (PCR) can provide an even higher degree of sensitivity than antibody-based tests to identify subclinical infections or previous use of vaccinations.

Isolation, rapid removal and necropsy of dead animals will reduce the spread of disease and help to provide early diagnosis and treatment of the problem. Prophylactic external (e.g. chloramine T, etc.) treatments during and after handling procedures will prevent the start of many infections. Separate nets for each tank and iodophore disinfection baths for equipment will reduce cross-contamination problems.

Vaccines are commercially available to protect against vibriosis, furunculosis, enteric red mouth and enteric septicemia bacteria. New vaccines are in development for several commercially important viral and rickettsial fish pathogens. Specialty orders of "autogenous" vaccines can also be manufactured to protect against unique or emerging bacterial pathogens. All vaccines require that the fish be held for a period of disease-free conditions (usually 3–5 weeks) after vaccination to build up immunity before any significant exposure to infectious diseases. Vaccinations against vibriosis, enteric red mouth and enteric septicemia bacteria can be delivered to the fish by immersion. For other diseases, intraperitoneal injection is the preferred route for maximum protection and duration of immunity.

Selective breeding using quantitative genetics can be used to produce strains of fish with enhanced resistance to specific diseases. The traits for selection must be based on genes with sufficient heritability for this process to be successful. Furunculosis-resistant strains of brook trout and brown trout are examples of the great potential of these efforts.

DISEASE TREATMENT

Bacterial, parasitic and fungal diseases can all be controlled with chemo-therapeutants. Viral diseases are best prevented or eliminated by isolation and quarantine procedures. The key to successful treatment is the proper identification of the primary cause of the observed losses. For example, the observation of a single external parasite is not a reason for immediately beginning treatment without further investigation of other underlying infections or water quality problems. Consultation with a fish health pathologist or experienced veterinarian is strongly recommended before starting any treatment.

All compounds can have side effects and it is essential that caution be used in handling and use of any chemical.

Fungal infections of eggs can be treated with methylene blue or formalin. However quent removal of dead eggs is critical to the success of hatching survival and may the need for such treatments. Formalin is also useful for the treatment of external par infections in juvenile or adult fish.

Damaged gills or skin can often be treated with sodium chloride to improve the osm balance between the water and the fish tissues. Dissolved salt treatments improve the effe of other surface compounds by removing debris and mucus from the gills and skin.

Judiciously applied, potassium permanganate can remove surface parasites and bacteria from fish in freshwater systems.

If a pathogenic bacterium is isolated, tests for antibiotic resistance should be done to select the best drug and treatment regime. Gram-negative organisms are commonly treated with oxytetracycline or sulfamethoxazole plus trimethoprim. Gram-positive bacteria are more responsive to erythromycin or doxycycline. Caution should be exercised if the biological filter media will be exposed to these compounds because water quality may quickly deteriorate if the nitrifying bacteria are lost.

Antibiotics added to the feed may not be appropriate if the affected population of fish is refusing to eat. Fish oil additives to enhance palatability or direct injection of antibiotics are alternatives to consider before applying oral drug treatments. Particular attention must be paid to local and federal regulations regarding restrictions on the use and withdrawal periods of antibiotics in food fish.

An indication of the magnitude of economic losses is illustrated by farm surveys conducted in 16 Asian countries, which show that annual losses due to disease in the region total more than USD 3 billion. Probably the most striking example of disease spread through international trade and consequential major economic loss in aquaculture is white spot disease in farmed shrimp. The disease first emerged in 1991 in a shrimp farm in an OIE member country and apparently has since spread to most other shrimp-farming countries of Asia and the Americas. This has been attributed by some experts to the uncontrolled international trade in live shrimp for aquaculture purposes and in dead shrimp for processing. Some countries with shrimp-farming activities continue to be free of the disease, almost certainly due to strict controls on imports of live shrimp and uncooked dead shrimp, in particular for use as fish bait.

The adverse social, economic and environmental consequences of uncontrolled movement of live aquatic animals and their products have increased global awareness of the need for improved health management standards. The serious impact of unrestricted international movement of aquatic animals has led to the development of health certification and risk reduction methodologies. The International Aquatic Animal Health Code and the Diagnostic Manual of Aquatic Animal Diseases are published by the OIE and provide recommendations and standards for reducing the spread of specific aquatic animal diseases considered to be of significance for international trade. They are recognized by the World Trade Organization as the international standards for trade.

The importance of containing the threat of diseases in fish production is a matter of global concern especially with increased trade and increased transboundary movements of goods which include live fish and other aquatic organisms. Due to this concern, the minimum EU measures for the control of the fish diseases are referred to in list I and II of Annex A to Council Directive 91/67/EEC (EC, concerning the animal health conditions governing the placing on the market of aquaculture animals and products, 1991). The diseases are categorized in three lists (Table 23.8).

An outbreak of a fish disease can quickly take on epizootic proportions, causing mortality and disturbances on a scale liable to reduce severely the profitability of aquaculture. Therefore it is important that control measures are taken when the presence of such a disease is suspected so that immediate and effective actions can be implemented as soon as its presence is confirmed. Such measures are aimed at preventing the spread of the disease, in particular by carefully controlling movements of fish and products liable to spread the infection.

TABLE 23.8 Listed Diseases/Pathogens of Fish, Mollusks and Crustacea (Annex A of Directive 91/67/EC)

Disease/Pathogen	Susceptible Species
LIST I	
Fish	
Infectious salmon anemia (ISA)	Atlantic salmon (*Salmo salar*)
LIST II	
Fish	
Viral hemorrhagic septicemia (VHS)	Salmonid species Grayling (*Thymallus thymallus*) Whitefish (*Coregonus* spp.) Pike (*Esox lucius*) Turbot (*Scophthalmus maximus*)
Infectious hematopoietic necrosis (IHN)	Salmonid species Pike fry (*Esox lucius*)
Mollusks *Bonamia ostreae* *Marteilia refringens*	Flat oyster (*Ostrea edulis*) Flat oyster (*Ostrea edulis*)
LIST III	
Fish Infectious pancreatic necrosis (IPN) Spring viremia of carp (SVC) Bacterial kidney disease (BKD) (*Renibacterium salmoninarum*) Furunculosis (*Aeromonas salmonicida*) Enteric red mouth disease (ERM) (*Yersinia ruckeri*) *Gyrodactylus salaries*	To be specified in the program referred to in Articles 12 and 13 of Directive 91/67/EC
Crustaceans Crayfish plague (*Aphanomyces astaci*)	

When fish on a farm are suspected of being infected with a list I disease, infectious salmon anemia (ISA), the official services in the member states must initiate official investigations to confirm or rule out the presence of the disease. No movement of fish, whether dead or alive, eggs and gametes are allowed without the authorization of the official service. When the presence of the disease is confirmed, fish infected with the disease are killed and destroyed as soon as possible to prevent the spread of the disease. Member states must have contingency plans for list I diseases.

List II diseases are important endemic diseases that should be contained and eradicated in the long term. Where fish are suspected of being infected with a list II disease, i.e. viral hemorrhagic septicemia (VHS) and infectious hematopoietic necrosis (IHN), an official investigation must be initiated to confirm or rule out the presence of the disease. Approved farms and zones will lose their status as free from the disease until it is proven that the disease is eradicated.

All farms rearing or keeping fish susceptible to list I or list II disease must be registered by the official service and keep records of mortality and the movement into and out of the farm.

Council Directive 2006/88/EC (EC 1991) on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, establishes:

- animal health requirements for the placing on the market, importation and transit of aquaculture animals (fish, mollusks and crustaceans) and their products;
- minimum measures to prevent diseases in aquaculture animals;
- minimum measures to be taken in response to suspected or established cases of certain diseases in aquatic animals.

MAJOR FISH DISEASES

Fish Viral Diseases

Prevention and control of viral diseases in fish are rather limited. Efficient chemotherapeuticals for viral diseases do not exist. Also, efficient vaccines are obtained only for a certain number of viruses. Unique practical measures for the control of viral diseases are: quarantine, control of trading of fish and their products, as well as strict disinfection and harmless removal of diseased fish.

In this respect, all reproductive centers for fish young have to be free of viral infections. Water-supplying systems in aquaculture have to be protected from the ingress of wild fish, as well as other water organisms, that might be carriers of viruses. If viruses enter an aquarium and infect the fish, it is very difficult to remove fish infected with that virus.

Viral diseases that affect the health of fish are: infectious pancreatic necrosis of salmonid fry (IPN), spring viremia of carp (SVC), pox disease of carp, viral hemorrhagic septicemia (VHS), infectious hematopoietic necrosis (IHN), infectious salmon anemia (ISA), and lymphocystis disease.

Infectious pancreatic necrosis (IPN) is an infectious, contagious disease, which attacks salmonid fry. It passes in acute stadium, characterized by a sudden explosive outbreak with high mortality. Affected fish become dark and rotate their bodies while swimming. They usually have exophthalmia and distended abdomens with the presence of a gelatinous material in the stomach and anterior intestine.

Spring viremia of carp (SVC) is an infectious, very contagious disease, which appears in acute form, and is manifested by symptoms of hemorrhagic diathesis, enteritis and peritonitis.

Pox disease of carp (*Epithelioma papillosum*) is an infectious, contagious disease, which attacks cyprinid fish species. It appears in chronic stadium, with hyperplasia of epidermis of skin and fins, such as hard gelatinous milky-white tumoroid proliferates, and in advanced cases with metabolic disorders of mineral matters. This disease has a benign character.

Viral hemorrhagic septicemia (VHS) is an infectious, contagious disease, which attacks mainly rainbow trout. It is the most serious viral disease of farmed rainbow trout, and is manifested by variable clinical symptoms: hemorrhagic syndrome, hydropsy characteristics and anemia, up to nervous disorders.

Infectious hematopoietic necrosis (IHN) of salmonid fry is manifested with hemorrhagiae and edema, accompanied by necrotic alterations of the wall of blood vessels. The

hematopoietic tissues of the kidney and spleen of young fish are the most severely affected and are the first tissues to show extensive necrosis. This disease is very similar to VHS.

Lymphocystis disease is an infectious disease, with chronic progression and benign character. It is manifested with the appearance of pebble or wart-like nodules most commonly seen on the fins, skin or gills, although other tissues may be affected.

Infectious salmon anemia (ISA) is an infectious disease. It is associated with high mortalities and is of great economic significance for the Norwegian fish farming industry. Infected fish are lethargic and severely anemic. Other typical signs are ascites, petechiae in internal organs and hemorrhagic liver necrosis.

More information on viral diseases can be found in FDA (2011), Hristovski and Stojanovski (2005), OIE (2012) and Woo and Bruno (1999).

Fish Bacterial Diseases

Bacteria exist in different environments in nature. Bacteria have a major role in the circulation of matter in natural ecosystems, but certain bacteria can cause serious diseases in fish.

Some fish, which show no signs of having a certain disease, may be carriers of infective agents. But if those fish are exposed to stress factors, the disease may manifest itself and begin to excrete pathogenic microorganisms into the water, leading to repeated outbreaks of disease.

Exact identification of organisms that lead to the appearance of infective disease is particularly important, as well as determination of antimicrobial substances that successfully act against them. Different species of fish need different treatments. Usage of inappropriate antimicrobial components might create resistant lineages of bacteria.

Bacterial diseases harmful to fish health are: erythrodermatitis of carp, furunculosis of salmonids, motile aeromonas septicemia (MAS), vibriosis, yersiniosis, Edwardsiellosis, Edwardsiellosis enteritic septicemia of catfish, ulcer disease of salmonids, bacterial kidney disease, columnaris disease, bacterial cold water disease, mycobacteriosis and nokardiosis.

Erythrodermatitis of carp is an infective bacterial disease, which appears in subacute or chronic form, and is manifested with characteristic alterations of skin as erosions with progressive character and possible generalized form with hard clinical picture, where general hydropsy dominate.

Furunculosis of salmonids is an infective, very contagious bacterial disease of salmonid fish species, which appears in peracute, acute, subacute and chronic form, and is manifested with local alterations on the skin, but in certain clinical cases in the form of septicemia.

Motile aeromonas septicemia (MAS) is caused by ubiquitous *Aeromonas hydrophila* complex, and is manifested by hemorrhagic septicemia.

Vibriosis (*Erysipelosis anguillarum*) is an infective, very contagious bacterial disease of salmonid fish species, which appears in peracute, acute and chronic form, and is manifested with septicemia in acute form, and formation of abscesses and ulcers in chronic form. The losses produced by this disease are so disastrous that vibriosis caused by *V. anguillarum* has been recognized as a major obstacle for salmonid marine culture.

Yersiniosis (enteric redmouth disease) is a bacterial, subacute or acute disease of salmonids, which is manifested by hyperemia and hemorrhage on the head. It is present in a carrier state in many species of fish and remains undetected until stress.

Edwardsiellosis (*Edwardsiella septicemia*) is a serious systemic bacterial, subacute or chronic disease of warm water, rarely cold water fish species, commonly known as fish gangrene, emphysematous putrefactive disease of catfish or red disease of eels. The disease is manifested by formation of erosions, abscesses and ulcers on the skin. Infective agents can cause disease at other animals (reptiles, birds, mammals). It can cause gastroenteritis, abscesses and meningitis in humans. It sometimes produces a subclinical infection in fish intended for human consumption, where it may create problems during the cleaning process, which requires processing interruption, cleaning of equipment and disposing of infected fish.

Edwardsiellosis enteritic septicemia of catfish is a bacterial, subacute or chronic disease of cultured warm water fish species from the family Ictuliridae, which is manifested by formation of petechial hemorrhage, erosions, abscesses and ulcers on the skin. A characteristic clinical symptom is a longitudinal ulcerative lesion in the area between the eyes, which can even reach skull bones. There is no indication that *E. ictaluri* poses a health threat to aquatic animals and humans, probably due to temperature limitations under which bacteria grow.

Ulcer disease of salmonids is an infective disease, which might appear as local infection of the skin or as acute septicemia.

Bacterial kidney disease is an infective, very contagious bacterial disease of cultured and wild salmonid fish species, which appears in chronic form, and is manifested with necrotic alterations of kidneys, development of anemia and high rate of mortality.

Columnaris disease is one of the most frequent infective bacterial diseases, which appears in different fish species, and is manifested with alterations of skin and gills.

Bacterial cold water disease is a serious septicemic disease of the young of salmonid fish species bred in hatcheries. It appears at $t < 12°C$. At the start the disease has a local character, with alterations of fins, musculature, gills; later even internal organs, particularly kidneys, become affected.

Nokardiosis is a chronic, granulomatous disease of fresh- and saltwater fish, which is very similar to tuberculosis, according to clinical symptoms.

Mycobacteriosis is a bacterial, contagious, subacute to chronic, systemic, progressive disease, which appears in all fish species, and is manifested by nodules and ulcerations on the skin and tuberculous nodules in internal organs. It is not of major importance in intensive fish breeding, but is particularly harmful for breeding of aquarium fish, because they are often kept for long periods of time compared with fish raised for commercial purposes. Piscine tuberculosis is caused by three species of bacteria belonging to the genus *Mycobacterium*, which is also the causative agent of tuberculosis in humans. While the bacteria that causes this disease in fish prefers cooler temperatures than most bacteria that infect humans it is still possible for the illness to be passed on to humans. Such an infection in humans usually shows in the form of an infected nodule in the skin, although there is a chance of a more serious internal infection.

Fish pathogenic bacteria are harmful to humans and others: they are pathogenic for warm-blooded animals and humans; however, fish usually are not diseased by these pathogens, but they can be germ carriers (in internal organs, skin or gills) for some time (weeks or months). Fish pathogenic bacteria are:

1. *Salmonella*;
2. *Listeria* – salmonids might be diseased;

3. *Leptospira*;
4. *Erysipelotrix rusiopathiae* – erysipeloid diseases are found in humans who work in the fish processing industry or in fish trading. The condition known as "crayfish handler's disease" is well known in the fishing industry. It can be caused by various bacteria, but particularly *Erysipelothrix rhusiopathiae* and various species of the *Vibrio* genus. The bacteria enter the skin through abrasions, lacerations or fissures and cause a painful itching or burning sensation;
5. *Vibrio parahaemolyticus* – can cause mild disease in fish. But diseases in humans who eat fresh fish, crayfish or shellfish are frequent;
6. *Clostridium botulinum* – as with other *Clostridium* species, it is ubiquitous as well. Therefore, many kinds of food might be contaminated. Type E toxin is the most poisonous of all the toxins (A–E). It is present in sediments of open waters, near coastlines.

More information on bacterial diseases can be found in FDA (2011), Hristovski and Stojanovski (2005), OIE (2012) and Woo and Bruno (1999).

Fish Fungal Disease

Fish mycoses are considered difficult to prevent and treat, particularly in intensive freshwater systems, and are reported to be second only to bacterial disease in economic importance to aquaculture.

Ichthyophoniasis, due to infection with *Ichthyophonus hoferi*, has been known in fish since the end of the 19th century. The disease is recognized to be of economic significance, in both fish cultivation and wild fisheries, and to have a wide host and geographical distribution. Included as hosts have been various marine and freshwater crustaceans, fish (35 marine fish species and 48 freshwater species), amphibians, reptiles and piscivorous birds. *Ichthyophonus* has been recorded from many temperate and some tropical waters throughout the world. Manifested external signs include skin roughening ("sandpaper effect") and occasional ulceration. Inside the body are gross white or cream-colored nodular lesions 1–5 mm in size throughout most tissues.

Fungal infections of fish by oomycetes, commonly known as water molds, are widespread in fresh water and represent the most important fungal group affecting wild and cultured fish.

Four orders are recognized in this class and the most important are the Saprolegniales. Although eight genera have been reported in infections, namely *Saprolegnia*, *Achlya*, *Aphanomyces*, *Calyptratheca*, *Thraustotheca*, *Leptolegnia*, *Pythiopsis* and *Leptomitus*, only *Saprolegnia*, *Achlya* and *Aphanomyces* are significant in aquaculture.

Some species are consistently isolated from fish and generally these are assigned to a single major cluster, which form a coherent, separate taxon, *Saprolegnia parasitica* (synonym *Saprolegnia diclina* Humphrey type 1).

The Saprolegniaceae, in particular members of the genus *Saprolegnia*, are responsible for significant infections, involving both living and dead fish and eggs, particularly in aquaculture facilities. Oomycetes are classical saprophytic opportunists, multiplying on fish that are physically injured, stressed or infected. Fungal outbreaks among farmed fish stocks are

frequently associated with poor water quality, injuries associated with handling and grading, temperature shock, infestation by parasites and spawning. However, there is evidence that some Saprolegniaceae act as primary pathogens.

The oomycetes are an economically important group of mycotic agents that affect salmonids and other teleosts. They are reported extensively in both wild and farmed fish and are considered ubiquitous in freshwater ecosystems. Oomycete infections have also been recorded in the marine fish species. In the marine environment, oomycetes are significant pathogens of lobsters and crayfish.

Saprolegniasis is frequently observed as a superficial and chronic infection. It may occur anywhere on the body of fish, but normally appears as a conspicuous, circular or crescent-shaped, white, cotton-like mycelium, on the integument and gills of host fish or eggs, particularly around the head and the caudal and anal fin, which may spread over the entire body surface. Most fish die due to osmotic or respiratory problems if the area of skin or gills is large.

Branchiomycosis (gill rot) is caused by two species *Branchiomyces sanguinis* and *B. demigrans*. It is primarily a problem in carp and eels. The disease occurs most commonly in ponds with abundant organic matter and high ammonia levels. Usually higher temperatures (20–25°C) bring about the disease. Affected fish usually show respiratory distress. There is prominent gill necrosis caused by thrombosis of blood vessels in the gills. Histologically the identification of nonseptated branching hyphae with an intrahyphal eosinophilic round body (apleospores) in and around blood vessels of the gill is diagnostic.

More information on fungal diseases can be found in FDA (2011), Hristovski and Stojanovski (2005), OIE (2012) and Woo and Bruno (1999).

Fish Parasitic Diseases

Causative agents of parasitic diseases in fish are different species of protozoa, helminths, leeches and crustaceans.

Protozoa: Mastigophora (flagellates), Rhizopoda (amoebae), Apicomplexa (sporozoa), Microsporidia, Myxozoa (myxosporidia), Ciliophora (ciliates).
Helminths: Trematoda, Cestoda, Nematoda and Acantocephala.

Fish parasites can be found on the skin, fins or gills – ectoparasites, or in their internal organs – endoparasites. Fish parasites appear either as direct causative agents of certain diseases or as factors leading to disorder or decrease of fish resistance, and therefore fish become sensitive to many infective diseases. Besides health problems, parasites are an important economic problem in intensive fish breeding, because their presence can cause excessive economic damages, e.g. impeding growth.

Development of parasites can occur in one or several hosts – mainly small water organisms. Higher numbers of helminth parasitize in fish as their final hosts in sexually matured (adult) form. But some of them parasitize only in their larval forms in fish, as their transitional hosts. In intensive fish culture there are outstanding conditions for the spread of substantial parasitic invasions. Usually parasites appear with simple life cycles. On the other hand, fish from open waters are found with a great number of different parasites with complex life cycles.

The following are some products that have been implicated in human parasite infection: ceviche (fish and spices marinated in lime juice); lomi lomi (salmon marinated in lemon juice, onion and tomato); poisson cru (fish marinated in citrus juice, onion, tomato and coconut milk); herring roe; sashimi (slices of raw fish); sushi (pieces of raw fish with rice and other ingredients); green herring (lightly brined herring); drunken crabs (crabs marinated in wine and pepper); cold-smoked fish; and undercooked grilled fish. Seafood-borne parasitic infections occur with sufficient frequency to recommend preventive controls during the processing of parasite-containing species of fish that are intended for raw consumption.

The process of heating raw fish sufficiently to kill bacterial pathogens is also sufficient to kill parasites.

The effectiveness of freezing to kill parasites depends on several factors, including the temperature of the freezing process, the length of time needed to freeze the fish tissue, the length of time the fish are frozen, the species and source of the fish, and the type of parasite present. For example, tapeworms are more susceptible to freezing than are roundworms. Flukes appear to be more resistant to freezing than roundworms.

Freezing and storing at an ambient temperature of −20°C or below for 7 days (total time), freezing at an ambient temperature of −35°C or below until solid and storing at an ambient temperature of −35°C or below for 15 hours, or freezing at an ambient temperature of −35°C or below until solid and storing at an ambient temperature of −20°C or below for 24 hours are sufficient to kill parasites. Note that these conditions may not be suitable for freezing particularly large fish.

Brining and pickling may reduce the parasite hazard in fish, but they do not eliminate it, nor do they minimize it to an acceptable level. Nematode larvae have been shown to survive 28 days in 21% salt by weight.

Trimming away the belly flaps of fish or candling and physically removing parasites are effective methods for reducing the numbers of parasites. However, they do not completely eliminate the hazard, nor do they minimize it to an acceptable level.

More information on parasitic diseases can be found in FDA (2011), Hristovski and Stojanovski (2005), OIE (2012) and Woo (2006).

Fish Helminth Zoonoses

Fish can also appear as carriers or act as transitional hosts of certain parasite species which attack humans. Numerous marine and freshwater fish serve as sources of medically important parasitic zoonoses. The majority of these zoonoses are found in coastal regions of the seas, big lakes and rivers, where fish and their products are consumed further. But with the increasing consumption of fish, as well as the new trend of so-called "natural cooking," the number of the registered zoonoses continuously increases. The potential danger of human infestation with certain helminths still exists, because in Europe, several helminth zoonoses have been recorded: metacercariae of trematodes *Opisthorchis felineus*, *Pseudamphistomum truncatum*, *Clinostomum complanatum*, *Metagonimus yokogawai*, *Heterophyes heterophyes*, *Cryptocotyle lingua*, *Echinochasmus perfoliatus*, plerocercoids of cestods of the genus *Diphyllobothrium* and larvae of nematodes: *Dioctophyme renale*, *Anisakis simplex* and *Gnathostoma hispidum*, etc. Zoonotic transmission of some bacterial diseases, such as streptococcosis or mycobacteriosis, is also possible.

In most cases fish zoonotic parasites do not lead to major health problems in fish.

Fish parasites usually cause small or moderate damages in the human body. But some of them are more frequent and are a serious threat for human health. Some show abdominal pains, diarrhea or constipation, nausea, vomiting, loss of weight, or anorexia. Hepatomegaly, eosinophilia, tetanic cramps, tremors and toxemia may also occur.

Generally, fish can be either an intermediate host of parasites involving a human as the definitive host or a carrier of larvae of animal parasites that only invade human tissues for a limited period without undergoing further development. The latter are considered incidental infections. The natural definitive hosts for parasites are usually marine mammals or birds. However, larval stages of a few fishborne parasites can mature in both animals and humans.

Fishborne trematodiasis is especially important in Southeast Asia, the Far East and regions where people are dependent on freshwater fish as the major source of protein. Infections by both large and small digenetic trematodes are common. Although the diseases are seldom fatal, they can cause morbidity and serious complications. The route of infection is by ingesting metacercariae located in muscles and subcutaneous and other tissues of fish.

There are relatively few cases of fishborne cestode infections in humans. The cestodes that mature in the small intestine of humans are not very pathogenic and the diseases are never fatal. Diphyllobothriasis is the major cestodiasis transmitted by freshwater, marine and anadromous fish.

Fishborne nematodiases are generally caused by the incidental infection of humans with nematodes whose natural definitive hosts are marine mammals, birds, pigs or other animals. Freshwater, brackish or marine fish are the second intermediate host. In most infections, the worms can only survive for a limited period after the initial invasion of the gastrointestinal tract. The method of infection is by ingesting the infective-stage larvae, which can be located in the muscles, intestine or viscera of fish. Unlike cestodiasis, some nematode infections can be fatal. In the Netherlands, since the passage of legislation against eating raw herring and requiring fish to be frozen prior to sale, anisakiasis has almost disappeared. Freezing fish for 24 hours or heating processed fish to 65°C can kill the larvae. Also, the gutting of fish soon after they are caught prevents the migration of larvae to muscles.

Theoretically, fishborne parasitic zoonoses can easily be prevented by refraining from eating raw seafood. However, in many parts of the world, such an eating habit represents an established way of life or part of the inherent culture. It cannot be easily changed, even by the implementation of a strong education program or the passage of legislation. Therefore, these diseases will remain as public health problems and there is a need to undertake regular epidemiological studies. These studies, however, cannot be carried out effectively without the development of more cost-effective, sensitive and specific diagnostic methods that can be used in large-scale screening of fish. The use of molecular biological techniques can also help to clarify species of dubious validity and to trace the source of infection. Stronger support for this neglected area of research is required.

More information on parasitic diseases can be found in FDA (2011), Hristovski and Stojanovski (2005), OIE (2012) and Woo (2006).

DISEASES OF MOLLUSCA AND CRUSTACEA

Some of the earliest records of mass mortalities of shellfish were caused by microbial disease agents, e.g. the phycomycete fungus *Ostracoblabe implexa*, responsible for "foot

disease" in the European oyster (*Ostrea edulis*) and the iridoviral agent of "gill diseases" in Portuguese oysters (*Crassostrea angulata*). Increasing development of shellfish aquaculture, and recent advances in diagnostic techniques, along with diversification of cultured species, continue to provide a seemingly inexhaustible reserve of new or emerging microbial disease problems. They have also significantly broadened the scope of microbial pathogen research and are proving useful for differentiating between primary pathogens and the ubiquitous microbial fauna that surrounds shellfish in their natural environment. Note is also made of apparently non-significant pathogens, since, given the right conditions, even the most benign infectious organism may transform into a serious disease agent. Knowledge on how to distinguish between primary and opportunistic pathogens is also important for optimizing their control or treatment.

More information on diseases of Mollusca and Crustacea can be found in Hristovski and Stojanovski (2005) and Woo and Bruno (1999).

FISH TOXICITY

The discipline of toxicology involves studying the nature and mechanisms of toxic lesions, and evaluating in a quantitative manner the spectrum of biological changes produced by exposure to chemicals. It is important to realize that every chemical can be toxic to fish under certain exposure conditions. For every chemical there should be an exposure condition (i.e. dose or concentration) that is "safe" and an exposure condition that is "toxic" to fish. The range of concentrations or doses that are toxic to fish may span several orders of magnitude. It is also important to determine toxic "thresholds," that is, concentrations or doses above which toxicity occurs and below which it does not.

Until relatively recently, toxicological studies with fish focused almost exclusively on very toxic substances which produce "acutely lethal" responses, that is, mortalities in fish exposed to chemicals for only short periods. Recently, we have become concerned with substances that may produce "sublethal" responses in fish after "chronic" exposure.

There are several chemical, physical and biological factors that influence the toxicity of chemicals to fish, including the properties of the chemical in water, the water quality conditions, the route of exposure, and the species and life stage of the fish.

Chemical toxicity to fish is often affected by external factors, such as photoperiod, temperature, salinity, reproductive status, disease and exposure to other external stressors.

Factors Affecting Toxicity

Water Quality Conditions

Since fish live in water, the extent to which fish are exposed to a chemical is dependent on aqueous solubility.

The solubility of ionic chemicals, which include most salts of toxic metals and some ionic organic compounds, is usually much higher than that of non-ionic compounds.

Ions may be dissolved in water in non-toxic forms. For instance, ions may form complexes with inorganic and organic "ligands." Inorganic ligands for cations in fresh water include carbonate (CO_3^{2-}), sulfate (SO_4^{2-}), and fluoride (F^-) ions, and Cl^- is an important

ligand in saline water. Complexes between cations and inorganic ligands tend to be fairly "labile" or reversible, depending on the concentration of the ion and the ligand, and the pH. However, complexes with organic ligands, such as humic acids, tend to be relatively non-labile. "Alkalinity," which is primarily the concentration of carbonate ions in solution, is an important measure of the cation-binding capacity of fresh water. Alkalinity and pH are important variables influencing the toxicity of metal ions to fish. Transformations of chemicals dissolved in water can occur by hydrolysis, photolysis and oxidation.

If we accept that the toxicity of ionic chemicals is usually dependent upon the concentrations of the free ion in solution, then various factors that affect speciation of ions will affect toxicity, including pH, alkalinity, hardness and concentrations of organic ligands.

The solubility of non-ionic chemicals, such as organic compounds and elemental forms of toxic metals (e.g. Hg), is influenced by the polarity of the compound.

The toxicity of non-ionizable chemicals, such as organic compounds, is affected to a lesser extent by water quality conditions such as pH, alkalinity and hardness. However, dissolved and particulate organic material in water can alter the toxicity of organic compounds by acting as ligands for hydrophobic substances.

For additional information on water quality conditions, see Di Giulio and Hinton (2008), Hristovski and Stojanovski (2005) and Ostrander (2000).

Biological Interactions

A chemical can be toxic to a fish in two possible ways. It may affect tissues on the surface of the organism (e.g. gill epithelium) or the chemical may enter the organism and cause toxicity. A toxic chemical must pass through cell membrane barriers to reach "target" organs or tissues. The epithelial and endothelial integument of fish is usually thickened and relatively impermeable to chemicals, except in the gill tissues, which are specialized for gas exchange, and in the gastrointestinal tract. Thus, branchial or gastrointestinal uptake routes are the most efficient mechanisms for uptake of toxic chemicals into fish.

The most prevalent route of exposure of fish for chemical agents is via gills. Fish gills have an enormous surface area, approximately 50% of the entire surface area of the fish. Gill secondary lamellae, flattened ridges protruding perpendicularly from the primary lamellae, provide an effective and extensive surface for gas exchange. Although designed to facilitate diffusion of respiratory gases, fish gills also provide routes for other molecules to be accumulated by fish. Small hydrophilic molecules (e.g. NH_3, CO_2 and urea) can pass through small aqueous pores or gaps between cells in the gill epithelium. Larger neutral hydrophobic molecules, including many drugs and toxic organic chemicals, readily diffuse across the gill epithelium into the vascular space. Diffusion or uptake efficiency of these chemicals by the gills depends primarily on their hydrophobicity and molecular size. In addition, free metal ions can bind to negatively charged sites on fish gills. Once bound to the gill epithelium many metals use existing ion transfer mechanisms, such as calcium channels or protein-mediated endocytosis for entry into the gill.

The next route of exposure of fish for chemical agents is with food. Systemic absorption of the ingested chemical is relatively rapid. Significant accumulation of radiolabeled methyltestosterone was detected in fish tissues 2 hours after feeding sprayed chow. Tissue levels of testosterone appeared to reach equilibrium concentrations 24 hours after feeding testosterone sprayed on food to coho salmon (*Oncorhynchus kisutch*). In a similar experiment

with carp (*Cyprinus carpio*), 4 days' feeding was required for testosterone to reach equilibrium concentrations in fish tissues. Chemical absorption from food depends on the rate of chemical dissolution from the food, its absorption efficiency in the stomach and intestine and influences of other factors, such as chemical and microbial degradation in the gut and binding to tissues. Also, physiological or metabolic differences between the two fish species may have caused differences in absorption, distribution and metabolism of the testosterone. Thus absorption efficiencies and time needed to attain equilibrium concentrations in fish will vary, depending on chemical properties and the fish species.

The most efficient method of administering a drug to fish is by injection. Ideally the chemical agent is dissolved directly in physiological saline. Chemical agents may be injected directly into veins or arteries (intravascular), into the peritoneal cavity (intraperitoneal) or into the muscle (intramuscular) of adult fish. Fish eggs or embryos may be injected into the perivitelline space or yolk sac with a micro syringe. In general, injection techniques provide a high internal dose with rapid distribution to the tissues.

Uptake of chemicals by fish can be influenced by both the lipophilicity and molecular size of the chemical.

For some chemicals, the rate of uptake is strongly influenced by the physiology of the fish. Fish species differ widely in their sensitivity to the toxic effects of chemicals.

Gill ventilation rates and dietary intake are governed by the metabolic rates of fish. There is considerable variation in the metabolism of fish; from fast-swimming pelagic predators to slow-swimming benthivores, so toxicity thresholds may vary considerably, depending on the fish species tested. In poikilothermic organisms such as fish, metabolism changes with the water temperature, so temperature may be an important factor influencing toxicity. Similarly, dissolved oxygen concentrations may influence gill ventilatory rates. Early life stages of fish tend to have higher rates of metabolism than later life stages. Therefore, the most sensitive period for chemically induced toxicity in fish is the embryolarval or early juvenile stages.

"Bioaccumulation" of chemicals represents the uptake and retention of chemical from the environment into fish via any pathway (e.g. food, water), whereas "bio-concentration" represents uptake and retention of a chemical directly from water into fish.

Fish possess metabolic pathways capable of transforming chemicals, such as oxidation and binding of chemicals to proteins or other large biomolecules (i.e. conjugation).

Although chemical contamination of our environment is often associated with human activities, plants and animals have evolved in an environment that has included continuous exposure to toxic materials. Basic mechanisms for resisting toxicity probably evolved with early life and are likely to be highly conserved in nature. Because of the large number and wide distribution of novel anthropogenic compounds introduced into the modern world, these mechanisms have become increasingly essential for survival. Organisms surviving environments heavily contaminated with anthropogenic chemicals demonstrate a diversity of mechanisms to tolerate or resist toxic effects.

Resistance or tolerance can be defined as the relative ability to function or survive during toxicant exposures that are harmful or lethal to susceptible individuals and populations. Fish and other organisms appear to develop tolerance through a variety of short-term and long-term processes. Physiological acclimation and genetic adaptation are general terms for short-term, transitory responses and long-term, heritable responses, respectively. Physiological

acclimations occur in direct response to toxic exposures and likely involve temporary alterations in the levels of expression of proteins and enzymes involved in chemical defense. Following chemical exposure, protein expression returns to normal and the state of physiological acclimation declines. Genetic adaptation or evolved tolerance occurs when the genetic basis for advantageous responses is passed on to progeny. In genetic adaptation, tolerance is retained through successive generations, even when progeny are not exposed to chemicals.

The terms physiological acclimation and genetic adaptation have been used frequently for categorizing mechanisms of chemical tolerance in fish; however, other processes and conditions may contribute to tolerance as well. For example, abundant evidence indicates that some forms of chemically induced cancer represent adaptations to harsh chemical environments, providing survival value to individuals especially during the early stages of cancer. Cancer resulting from chemically induced mutations in somatic cells and concomitant alterations in protein expression would be considered to be a genetic but nonheritable adaptation. In addition to cancer, epigenetic alterations, such as hypermethylation of promoter regions of DNA, may affect responsiveness to drug and chemical exposures. Although gene silencing due to hypermethylation has been widely studied in mammalian cancer research, it has only recently being investigated as a tolerance mechanism in fish. Finally, nongenetic but heritable factors involving maternal transfer of toxicant from an exposed parent to offspring could contribute to tolerance in offspring. In cases involving maternal transfer, tolerance may appear to have a genetic basis (i.e. tolerant field-collected parents and their progeny) but is in fact physiologically based and related to direct exposure of offspring to toxicant. Because of the possibility of maternal transfer, genetic adaptation is established only when tolerance is maintained for two or more generations.

In populations inhabiting severely contaminated sites, multiple processes likely contribute to resistance during the lives of individuals; for example, physiological acclimations could provide individuals with the ability to survive and reproduce in moderately contaminated sites. As chemical contamination at a particular site increases with time, selection of progeny that carry genetic traits with adaptive significance could become a more dominant factor. Genetically adapted individuals may rely to some extent on epigenetic mechanisms or may respond to periodic pulses of contaminants through physiological responses. Tolerant-bearing individuals may also exhibit features characteristic of genetic adaptation, physiological acclimation or epigenetic alteration.

Chemical resistance in fish has been observed in response to diverse environmental contaminants, including pesticides, dioxin-like compounds, polycyclic aromatic hydrocarbons (and other compounds associated with creosote) and metals (Table 23.9).

For more information on biological interactions, see Di Giulio and Hinton (2008), FDA (2011), Hristovski and Stojanovski (2005), Ostrander (2000) and Treves-Brown (2000).

Natural Toxins

Contamination of fish with natural toxins from the harvest area can cause consumer illness. Most of these toxins are produced by species of naturally occurring marine algae (phytoplankton). They accumulate in fish when they feed on the algae or on other fish that have fed on the algae. There are also a few natural toxins that are normal constituents of certain species of fish.

TABLE 23.9 Classes and Sources of Environmental Toxicants Addressed in Toxicity Resistance Studies

Toxicant	Source
Organochlorine pesticides	Includes DDT, the first modern highly toxic pesticide, followed by toxaphene, chlordane, aldrin, dieldrin, heptachlor, mirex, and kepone. Very persistent compounds that accumulate in fatty tissues and sediments, they are toxic to fish, wildlife and humans and are banned in the United States. Some of the earliest records of toxicity resistance involve DDT.
Dioxin-like compounds (DLCs)	Includes polychlorinated biphenyls (PCBs), polychlorinated dibenzodioxins (PCDDs) and other persistent polyhalogenated aromatic hydrocarbons (PHAHs). PCBs were valuable industrial materials used in capacitors, transformers and other products. PCDDs are produced inadvertently during a variety of processes (e.g. pesticide manufacture, chlorine bleaching of pulp). The most notorious DLC is 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), often referred to simply as dioxin.
Polycyclic aromatic hydrocarbons (PAHs)	Complex mixtures of compounds produced during combustion of organic materials, especially fossil fuels; also, natural components of petroleum. PAHs are widely studied because of their abundance in the environment and because of the mutagenic and carcinogenic properties of some members (e.g. benzo(a)pyrene).
Creosote	Abundant pesticide mixture used to protect wood pilings, telephone poles, etc., from microbial decay. Creosote is composed primarily of PAHs, nitrogen-, sulfur- and oxygen-heterocyclic compounds, and phenols.
Metals	Naturally occurring elements (e.g. mercury, lead, cadmium, chromium), including some biologically essential elements (copper, iron, zinc). Human activities alter the environmental loading, availability and toxicity of metals through a variety of activities such as strip mining, fossil fuel combustion, smelting, and industrial processes.

For fish products in the United States there are six recognized fish poisoning syndromes that can occur from the consumption of fish or fishery products contaminated with natural toxins: paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), diarrheic shellfish poisoning (DSP), amnesic shellfish poisoning (ASP), ciguatera fish poisoning (CFP) and azaspiracid shellfish poisoning (AZP).

1. Paralytic shellfish poisoning (saxitoxin) is generally associated with the consumption of molluscan shellfish from environments ranging from tropical to temperate waters. Certain gastropods (e.g. conch, snails and whelk) are also known to accumulate PSP toxins.

   The effects of PSP are primarily neurological with respiratory paralysis. PSP toxin is extremely potent toxin with a high mortality rate.
2. Neurotoxic shellfish poisoning (from brevetoxin) is generally associated with the consumption of molluscan shellfish from the Atlantic coast of the USA, New Zealand, and there are some suggestions of occurrence elsewhere. NSP is characterized by gastrointestinal and neurological symptoms. There are few, if any, after-effects and there have been no reported fatalities.
3. Diarrheic shellfish poisoning (from okadaic acid and dinophysis toxins) is generally associated with the consumption of molluscan shellfish. Outbreaks have been

documented in Japan, Southeast Asia, Scandinavia, Western Europe, Chile, New Zealand, the USA and eastern Canada. DSP is characterized by gastrointestinal symptoms, including: nausea, vomiting, diarrhea, abdominal pain, headache and fever. DSP is generally not considered life threatening but complications could occur as a result of severe dehydration in some patients.

4. Amnesic shellfish poisoning (from domoic acid) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. In these regions, domoic acid has been identified in the viscera of Dungeness, tanner and red rock crab. Domoic acid has also been identified in several fish species including anchovies, Pacific sanddab, chub mackerel, albacore tuna, jack smelt and market squid. ASP is characterized by gastrointestinal symptoms.
5. Ciguatera fish poisoning (from ciguatoxin (CTX)) is associated with consumption of toxin-contaminated subtropical and tropical predatory reef fish. The toxin is introduced to the marine food chain by microscopic algae and moves up the food chain as small plant-eating reef fish eat the toxic algae and are then eaten by larger reef fish. CFP is characterized by gastrointestinal symptoms, followed by neurological and cardiovascular symptoms.
6. Azaspiracid shellfish poisoning (AZP) is caused by the consumption of molluscan shellfish contaminated with azaspiracids (AZA). AZP was first recognized following a 1995 outbreak in the Netherlands, linked to consumption of mussels harvested in Ireland. Since then, several outbreaks of AZP have been reported in various regions in Europe. AZP is characterized by severe gastrointestinal disorders. There have been no reported fatalities.

More information on natural toxins can be found in Di Giulio and Hinton (2008), FDA (2011) and Hristovski and Stojanovski (2005).

Scombrotoxin (Histamine) Formation

Certain bacteria produce the enzyme histidine decarboxylase during growth. This enzyme reacts with histidine, a naturally occurring amino acid that is present in larger quantities in some fish than in others. The result is the formation of scombrotoxin (histamine). Scombrotoxin (histamine) formation is a result of time and temperature abuse of certain species of fish, and can cause consumer illness. Histamine is more commonly the result of high-temperature spoilage than of long-term, relatively low-temperature spoilage. Freezing may inactivate some of the enzyme-forming bacteria. Both the enzyme and the bacteria can be inactivated by cooking. However, once histamine is produced, it cannot be eliminated by heat (including retorting) or freezing. Rapid chilling of scombrotoxin-forming fish immediately after death is the most important element in any strategy for preventing the formation of scombrotoxin (histamine).

The illness is closely linked to the development of histamine in these fish. In most cases, histamine levels in illness-causing fish have been above 200 ppm, often above 500 ppm. A guidance level has been set at 50 ppm histamine in the edible portion of fish. If 50 ppm is found in one section of a fish or lot, there is the possibility that other sections may exceed 500 ppm.

However, there is some evidence that other chemicals (e.g. biogenic amines such as putrescine and cadaverine) may also play a role in the illness.

Symptoms of scombrotoxin poisoning include tingling or burning in or around the mouth or throat; rash or hives on the upper body; drop in blood pressure; headache; dizziness; itching of the skin; nausea; vomiting; diarrhea; asthmatic-like constriction of the air passage; heart palpitation; and respiratory distress. Symptoms usually occur within a few minutes to a few hours of consumption and last from 12 hours to a few days.

For more information, see Di Giulio and Hinton (2008) and FDA (2011).

Environmental Chemical Contaminants and Pesticides

Fish can be harvested from waters that are contaminated by varying amounts of industrial chemicals, including heavy metals and pesticides. These contaminants may accumulate in fish at levels that can cause human health problems (e.g. carcinogenic and mutagenic effects). The hazard is most commonly associated with exposure over a prolonged period of time (chronic exposure). Illnesses related to a single exposure (one meal) are very rare. Concern for these contaminants primarily focuses on fish harvested from aquaculture ponds, freshwater bodies, estuaries and near-shore coastal waters (e.g. areas subject to shoreside contaminant discharges), rather than from the open ocean. Environmental chemicals and pesticides may also accumulate in aquacultured fish through contaminated feed ingredients. Certain pesticides are applied directly to the water in aquaculture ponds to control weeds and algae and to eliminate fish and invertebrates.

Although some pesticides have not been produced or used for many years (e.g. dichlorodiphenyl-trichloroethane (DDT) and polychlorinated biphenyls (PCBs)), many are very persistent and tend to accumulate in soil and sediments. Once pesticides are introduced into the environment, they may travel beyond their point of application or discharge.

Many contaminants accumulate in the edible fatty tissues of fish. Concentrations of these contaminants can vary considerably in individual fish of the same species from the same location, depending on factors such as their fat content, size, age and gender.

In the case of components or extracts of whole fish (e.g. dietary supplements, dietary ingredients and flavors), the component or extract may contain higher or lower concentrations of environmental chemical contaminants and pesticides than the whole fish from which it was derived. For example, organochlorine contaminants, such as PCBs, are oil soluble. When producing fish oil and fish meal, any PCBs present will become more concentrated in the oil fraction and less concentrated in the water fraction, as compared with the levels in the whole fish.

Maximum residue levels (MRLs) are: (1) the maximum concentration of residue accepted by the European Union (EU) in a food product obtained from an animal that has received a veterinary medicine; (2) the upper legal levels of a concentration for pesticide residues in or on food or feed based on good agricultural practices and to ensure the lowest possible consumer exposure. The assessment for the safety of residues is carried out by the Committee for Medicinal Products for Veterinary Use (CVMP). In the United States, MRLs are established by the Environment Protection Agency (EPA) and the Food and Drug Administration (FDA).

Methylmercury

Mercury occurs naturally in the environment and can also be released into the air through industrial pollution. Mercury falls from the air and can accumulate in streams and oceans and is turned by bacteria into methylmercury in the water. Fish absorb the methylmercury as they feed in these waters and so it builds up in them. Nearly all fish and shellfish contain traces of methylmercury. However, larger fish (swordfish, shark, king mackerel, tuna and tilefish) that have lived longer have the highest levels of methylmercury because they have had more time to accumulate it. It is the type of mercury that can be harmful to young people. The FDA action level of methylmercury is 1.0 ppm in the edible portion of fish.

Aquaculture Drugs

A range of veterinary drugs including antimicrobial, antiparasitical and growth promoters (hormones) may be used in aquaculture to control bacterial, fungal and parasitic diseases and to control reproduction of fish. Farmers may also use a range of vitamins, immunostimulants, disinfectants and other chemotherapeutants and employ chemicals for pond soil and water treatment.

Abuse of veterinary drugs, non-respect of the withdrawal period or application of illegal drugs constitutes a potential food safety problem. The health consequences of excessive use of antimicrobial drug residues include allergies, toxic effects, changes in colonization patterns of human-gut flora and acquisition of drug resistance in pathogens. The establishment of appropriate withdrawal periods ensures that no harmful residues remain in edible tissues after use of a drug. Since fish are poikilotherms, their metabolic rate is determined by environmental temperatures. As a result, withdrawal periods are based on time and temperature, i.e. degree-days: for example, 10 days at 5°C equals 150 degree-days. Where the legislation or implementation of regulation is poor, the risk of non-compliance is greater.

Additionally, the impacts of many of these chemicals on the environment are unknown and their release into the environment is likely to have a negative effect. They can also affect microbial biodiversity and contribute to the development of antimicrobial drug resistance. Application of vaccines has been instrumental to reduce use of drugs in the farmed salmon industry.

Compliance with MRLs for products from aquaculture is beginning to be enforced. For instance, the European Union is in the course of implementing a monitoring program in which fish muscle tissue will be routinely sampled for the presence of a range of veterinary drug residues. Such monitoring programs help provide assurance that no unacceptable human health risk is posed by veterinary drug residues in products from aquaculture. Unfortunately, some countries implement monitoring programs for export products but do not offer the same assurance for domestic markets.

Reasons for the use of drugs in aquaculture include the need to (1) treat and prevent disease, (2) control parasites, (3) affect reproduction and growth, and (4) provide tranquilization (e.g. for weighing). Relatively few drugs have been approved for aquaculture. Use of unapproved drugs or misuse of approved drugs in aquacultured fish poses a potential human health hazard. These substances may be toxic, allergenic or carcinogenic, and/or may cause antibiotic resistance in pathogens that affect humans.

More details on environmental chemical contaminants and pesticides can be found in Di Giulio and Hinton (2008), FDA (2011), Hristovski and Stojanovski (2005) and Treves-Brown (2000).

PATHOGENIC BACTERIAL GROWTH AND TOXIN FORMATION

Time and Temperature Abuse

Pathogenic bacteria growth and toxin formation as a result of time and temperature abuse of fish and fishery products can cause consumer illness. This hazard is limited to bacterial pathogens since viral pathogens (viruses) are not able to grow in food. Of particular concern in seafood are the pathogenic forms of *Listeria monocytogenes, Vibrio vulnificus, Vibrio parahaemolyticus, Vibrio cholera, Escherichia coli, Salmonella* spp., *Shigella* spp., *Staphylococcus aureus, Clostridium perfringens, Bacillus cereus, Campylobacter jejuni* and *Yersinia enterocolitica.*

Pathogenic bacteria can enter the process on raw materials. They can also be introduced into foods during processing from the air, unclean hands, insanitary utensils and equipment, contaminated water or sewage and through cross-contamination between raw and cooked product. The primary method for control is to reduce levels through cooking or other treatments when feasible, and minimize the potential for recontamination and to maintain products at temperatures that do not support growth of pathogenic bacteria.

Growth rates of pathogens are highly temperature dependent. Ordinarily, pathogenic bacteria growth is relatively slow at temperatures below 20°C.

Time and temperature abuse occurs when a product is allowed to remain at temperatures favorable to pathogenic bacteria growth for sufficient time to result in unsafe levels of pathogenic bacteria or their toxins in the raw fish and fishery products (e.g. raw molluscan shellfish). Certain pathogenic bacteria grow well, and others do not. Those that grow well in time and temperature-abused raw fish include: *V. vulnificus, V. parahaemolyticus, V. cholerae* and *L. monocytogenes*. Others may grow if the natural condition of the raw fish is changed, such as through salting or reduced oxygen packaging. Those that ordinarily do not grow well, because they compete poorly with the normal spoilage bacteria, include: *C. jejuni*, pathogenic strains of *E. coli, Salmonella* spp., *Shigella* spp., *S. aureus, C. perfringens, B. cereus* and *Y. enterocolitica*.

Most pathogenic bacteria will grow well in temperature-abused cooked fish if their growth is not controlled by means such as drying, salting or acidification, because competing bacteria are destroyed by the cooking process.

Certain pathogenic bacteria are associated with specific food sources, and it may not be necessary to assume that they will be present in other foods unless introduced from a contaminated source. For example, *V. vulnificus, V. parahaemolyticus* and *V. cholerae* non-O1 and non-O139 are generally associated with marine and estuarine species of fish and not with freshwater species or non-fishery ingredients.

The infective dose or toxic dose is the total number of a pathogen, or the total amount of a toxin, that is necessary to produce human illness. The dose often varies considerably for a single pathogen based on the health of the consumer and the virulence (infective capacity) of the particular strain of the pathogen.

In humans, usually, gastrointestinal symptoms are included: nausea, vomiting, abdominal pain, abdominal cramps, diarrhea, dehydration, electrolyte imbalance, high body fluid acidity, fever, headache, muscle pain, malaise and general discomfort. Septicemia rarely appears. Symptoms usually start from 1 or few hours – 1 or few days after consumption and usually last from 1–10 days. Everyone is susceptible to pathogenic bacteria

food poisoning, but it is more common in infants, the young, the elderly, the infirm, those with underlying chronic disease, with reduced stomach acidity or malnutrition, and the immunocompromised.

Strategies for Control of Pathogenic Bacteria

Management of time and temperature of product exposure is important to produce a safe product. There are a number of strategies for the control of pathogenic bacteria in fish and fishery products. They include:

- Managing the amount of time that food is exposed to temperatures that are favorable for pathogen growth and toxin production.
- Killing pathogenic bacteria by cooking, pasteurization or by retorting.
- Killing pathogenic bacteria by processes that retain the raw product characteristics.
- Controlling the amount of moisture that is available for pathogen growth (water activity) in the product by drying or formulation.
- Controlling the amount of salt or preservatives, such as sodium nitrite, in the product.
- Controlling the level of acidity (pH) in the product.
- Controlling the introduction of pathogenic bacteria after the pasteurization process.
- Controlling the source of molluscan shellfish and the time from exposure to air (e.g. by harvest or receding tide) to refrigeration to control pathogens from the harvest area.

Inadequate Drying

Dried products are usually considered shelf stable and are, therefore, often stored and distributed unrefrigerated. Examples of shelf-stable dried fish products are salmon jerky, octopus chips, dried shrimp, stock fish and shark cartilage. The characteristic of dried foods that makes them shelf stable is their low water activity (a_w). Water activity is the measure of the amount of water in a food that is available for the growth of microorganisms, including pathogenic bacteria. Pathogenic bacteria growth and toxin formation in the finished product as a result of inadequate drying of fishery products can cause consumer illness. A water activity of 0.85 or below will prevent the growth and toxin production of all pathogenic bacteria, including primary pathogens *S. aureus* and *C. botulinum*, and is critical for the safety of a shelf-stable dried product. *S. aureus* grows at a lower water activity than other pathogenic bacteria, and should, therefore, be considered the target pathogen for drying for shelf-stable products.

Cooking or Pasteurization

The survival of pathogenic bacteria through cooking or pasteurization can cause consumer illness. The primary pathogens of concern are *Clostridium botulinum*, *Listeria monocytogenes*, *Campylobacter jejuni*, pathogenic strains of *Escherichia coli*, *Salmonella* spp., *Shigella* spp., *Yersinia enterocolitica*, *Staphylococcus aureus*, *Vibrio cholera*, *V. vulnificus* and *V. parahaemolyticus*.

In addition to eliminating bacterial pathogens, cooking and pasteurization also greatly reduce the number of spoilage bacteria present in the fishery product. These bacteria

normally restrict the growth of pathogens through competition. Elimination of spoilage bacteria allows rapid growth of newly introduced pathogenic bacteria. Pathogenic bacteria that may be introduced after cooking or pasteurization are, therefore, a concern. This is especially true for pasteurization, because that process can significantly extend the shelf-life of the fishery product, providing more time for pathogenic bacteria growth and toxin formation.

Retorting is a heat treatment that eliminates all foodborne pathogens and produces a product that is shelf stable.

There is a potential that C. *botulinum* type E or non-proteolytic types B and F will survive the pasteurization process and grow under normal storage conditions or moderate abuse conditions.

If the product is not reduced oxygen packaged, or contains a barrier that is sufficient to prevent the growth and toxin formation by C. *botulinum* type E or non-proteolytic types B and F, or is equipped with a time and temperature integrator, or is distributed frozen, then selection of another target pathogen may be appropriate. L. *monocytogenes* may be selected as the target pathogen for pasteurization of this type of product because it is the most resistant bacterial pathogen of public health concern that is reasonably likely to be present. Generally, L. *monocytogenes* is regarded as the most heat-tolerant, foodborne bacterial pathogen that does not form spores.

It is not practical to target viral pathogens in cooking or pasteurization processes because of their extreme heat resistance. Viral pathogens should be controlled through a rigorous sanitation regime as part of a prerequisite program or as part of hazard analysis critical control point (HACCP) itself.

Processes Designed to Retain Raw Product Characteristics

Some processes are designed to reduce specific pathogens to acceptable levels while retaining the sensory qualities (appearance, taste and texture) of the raw product. These processes are particularly useful in addressing the hazard associated with the target pathogen in raw products such as raw molluscan shellfish (i.e. oysters, clams, mussels and whole and roe-on scallops) that are intended for the raw ready-to-eat market. Because these processes do not eliminate all pathogens of public health concern, they are not considered cooking or pasteurization processes.

Examples of processes designed to retain raw product characteristics include:

- High hydrostatic pressure processing (HPP);
- Individual quick freezing (IQF) with extended frozen storage;
- Mild heat processing;
- Irradiation (ionizing radiation).

The survival of pathogenic bacteria through processes designed to retain raw product characteristics can cause consumer illness. The primary pathogens of concern are *Vibrio vulnificus* and *Vibrio parahaemolyticus*. *V. vulnificus* and *V. parahaemolyticus* are naturally occurring pathogens (i.e. not associated with human or animal sources) that may be present in fish and fishery products, and in particular raw molluscan shellfish.

Cross-Contamination of Fish and Fish Products

With fishery products, pasteurization is usually performed after the product is placed in the hermetically sealed finished product container. It is applied to fishery products that are distributed either refrigerated or frozen. Examples of pasteurized fishery products are: pasteurized crabmeat, pasteurized surimi-based analog products and pasteurized lobster meat. Because these products are cooked before they are packaged, they are at risk for recontamination between cooking and packaging. The risk of this recontamination may be minimized by filling directly from the cook kettle using a sanitary, automated, continuous-filling system (designed to minimize the risk of recontamination) while the product is still hot (i.e. hot filling). This control strategy may not be suitable for products such as crabmeat, lobster meat or crayfish meat.

There are three primary causes of recontamination after pasteurization and cooking performed immediately before reduced oxygen packaging:

- Defective container closures;
- Contaminated container cooling water;
- Recontamination between cooking and reduced oxygen packaging.

The introduction of pathogenic bacteria after pasteurization and certain specialized cooking processes can cause consumer illness. The primary pathogens of concern are *Clostridium botulinum*, *Listeria monocytogenes*, *Campylobacter jejuni*, pathogenic strains of *Escherichia coli*, *Salmonella* spp., *Shigella* spp., *Yersinia enterocolitica*, *Staphylococcus aureus*, *Vibrio cholerae*, *V. vulnificus* and *V. parahaemolyticus*.

For more on the growth of and toxin production by pathogenic microbes see FDA (2011) and Hristovski and Stojanovski (2005).

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CHAPTER

24

Hygiene in Food Processing and Manufacturing

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OUTLINE

Food Safety Management
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INTRODUCTION

The primary concern of food manufacturers is to produce a product that is both wholesome, i.e. it has all appropriate organoleptic qualities, and safe, i.e. it is free from pathogenic microorganisms and chemical and foreign body contamination. The schematic diagram shown in Figure 24.1 is a historical representation of the food industry and shows that the manufacture of safe, wholesome foods stemmed from the purchase of specified raw materials. Not all raw materials may be of the same quality, as the final product will be priced according to the intended market, though all raw materials should be safe and free from specified hazards. Figure 24.1 also shows that given specified raw materials, there are four major "building blocks" that govern the way the factory is operated to ensure that the safe, wholesome food goal is realized. Hygienic design dictates the design of the factory infrastructure and, until replaced by robots, the operatives! Hygienic practices maintain the integrity of the facility and include good hygienic practices (GHP) and good manufacturing practices (GMP). Process development enables the design of safe, validated products and processes, while process control subsequently ensures that each product in each batch on every day meets the product and process requirements.

More specifically, hygienic design is the food manufacturing infrastructure and consists of all the physical requirements necessary to manufacture the food product. Specifically, it includes the following:

- Factory site
- Factory building
- Segregation
- Food defense, biovigilance and bioterrorism
- Process lines

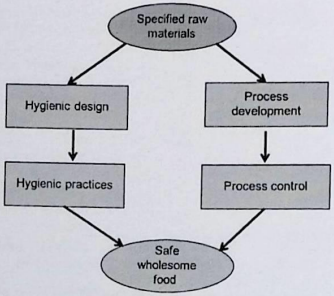

FIGURE 24.1 Schematic stages required to ensure safe, wholesome food products from a traditional basis.

- Ventilation and air flows
- Equipment
- Utensils
- Services (utilities)
- Waste disposal
- Medical screening

Hygienic practices are all the actions necessary to maintain the food manufacturing infrastructure in a hygienic manner and thus facilitate safe and wholesome food manufacture by preventing contamination to the food product, and include the following:

- Maintenance
- Housekeeping
- Cleaning and disinfection
- CIP
- Pest control
- Personal hygiene

The major change in the way that the food industry viewed food safety came with the advent of hazard analysis typified by the hazard analysis critical control point (HACCP) approach, originally developed in the late 1960s by the Pillsbury Company, the United States Army Laboratory and the National Aeronautics and Space Administration in the development of safe foods for the American Space Program. HACCP began to be practiced in the UK in the later 1980s and was published as international guidance in 1993 by Codex (Anon, 1993). Indeed, in the EU it has been a legislative requirement for food businesses since the publication of Council Regulation 852/2004 (Anon, 2004) to manage food safety with an appropriate hazard analysis-based system.

Hazard analysis via HACCP encompasses identifying the hazards that may affect the quality or safety of the food product and controlling them at all stages of the process such that product contamination is prevented. Such hazards are usually described as:

- Biological, e.g. bacteria, yeasts, molds
- Chemical, e.g. cleaning chemicals, lubricating fluids
- Physical, e.g. glass, plastic, insects or their parts, pests, metal, dust

Figure 24.2 illustrates how this affected the traditional food safety approach as identified in Figure 24.1. Hazard analysis can be viewed as an umbrella and oversees all actions related to food safety and food wholesomeness. HACCP primarily focuses on identifying hazards and controlling them via the process route, which encompasses the selection and storage of raw materials, followed by their processing and packaging and is illustrated in Figure 24.2 by the dark coloration of the "specified raw materials" box and the dark circle encircling the "product development" and "process control" boxes. HACCP recognizes, however, that the factory infrastructure, GMPs and GHPs, expressed as the "hygienic design" and "hygienic practices" boxes in Figure 24.2 are the bedrock on which the assessment and control of the hazards identified in the process are built. HACCP calls the factory infrastructure, GMPs and GHPs "HACCP prerequisites," implying that these should be in place before a hazard analysis of the process is undertaken, and these are identified by the lighter circle in Figure 24.2.

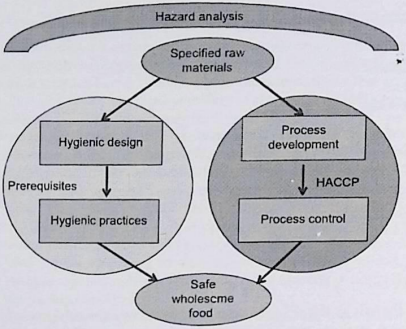

FIGURE 24.2 The advent of HACCP encouraged food manufacturers to consider the control of hazards both via the production process (specified raw materials, process development and process control) and the processing environment (hygienic design and hygienic practices) referred to as the HACCP prerequisites.

Although some principles of good hygienic practice are generic and apply to any type of business, some may be specific to a given category of food products. For instance, prerequisite programs for infant formula factories may not be the same as for coffee or fishery factories. Therefore, for the prerequisites, a hazard analysis of the product should also be undertaken at the earliest opportunity and, if possible, before the design and construction of the processing facility. This allows the design of the production facility to play a major role in reducing risks of contamination. For example, generally it is possible to identify that glass is a potential hazard and you could eliminate this hazard by designing a glass-free factory. Or more specifically in a dry foods factory, all sources of water could be eliminated from certain processing areas.

The next development in managing food safety came with the adoption of quality or business management systems. These were used as a mechanism by which food suppliers could demonstrate to their customers that they were undertaking a standardized approach to ensuring the quality of the food product. As for HACCP, the use of quality management systems began in the 1980s and was focused on BS 5750 published in 1978; this was the first published quality management system. This in turn had been developed from BS 5179 in 1969 and before that a Department of Defence standard developed to ensure the successful application of munitions. As well as providing a standard approach to managing quality, it also encouraged third party organizations to audit food companies against the standard. The adoption of BS 5750 quickly developed beyond the UK and, in 1987, this document was published as EN 29002-1987 in Europe and worldwide as ISO 9002-1987. The ISO 9000 series of standards was developed to cover the requirements of both food manufacturers and auditing bodies to ensure food manufacturers met the needs of their customers while

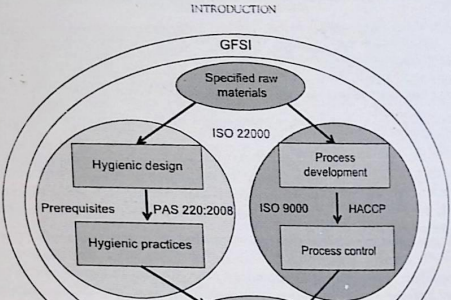

FIGURE 24.3 Current schematic food processing stages, food manufacturing standards and auditing schemes to allow food manufacturers to ensure and demonstrate safe, wholesome products.

striving to meet their expectations. Many food manufacturers still use ISO 9001:2008 (Anon, 2008a) for managing their business or quality systems, though it has little impact on prerequisites. It is noted in the dark HACCP circle in Figure 24.3.

ISO 22000 (Anon, 2005) was published in 2005 with the aim of bringing together food safety and quality management systems into one auditable standard. It supports four key elements to food safety, which it describes as interactive communication, system management, prerequisite programs and HACCP. It has also been aligned with the requirements of ISO 9001 and the HACCP principles as adopted by Codex. ISO 22000 is thus represented as a large circle in Figure 24.3 encompassing all the requirements necessary to produce safe and wholesome food products.

There was a general recognition that while there was much publically available information to support much of the four key elements in ISO 22000, particularly quality management systems and HACCP, information on prerequisite programs as a whole was lacking. A publically available specification, PAS 220:2008 (Anon, 2008b), was published by British Standards to provide additional information in this area. This document is intended to support the prerequisite program requirements of ISO 22000 (clause 7) and is noted in Figure 24.3 within the light prerequisite circle.

Finally, to complete the food safety picture, there have been complementary developments in third party auditing systems under the management of the Global Food Safety Initiative (GFSI) (www.mygfsi.org). This organization has harmonized the requirements of the major food standards organizations that produce auditable food standards such as the

British Retail Consortium (BRC, Anon, 2011a), International Food Standard (Anon, 2012) and SQF (Anon, 2008c). For example, the BRC global standard for food safety requires food manufacturers to develop and comply with the following four key elements: senior management commitment, a quality management system, prerequisite programs and an HACCP plan. Auditing standards approved by GFSI clearly then meet the requirements to audit all parts of ISO 22000 and this is represented by the circle surrounding the ISO 22000 circle in Figure 24.3.

Other than the legal requirement in some countries (e.g. in the European Union) for food manufacturers to adopt HACCP principles, the requirement for ISO 9000 or 22000 is voluntary. It may, however, be a requirement for food manufacturers to adopt these standards to comply with their customers' requirements, which may also include the need to be audited to a GFSI approved standard.

PREREQUISITE MANAGEMENT PLAN

The need to understand the role of the processing environment in how it can harbor hazards, which can be transferred on vectors to the product, has become especially important for microbial pathogen hazards in ready-to-eat (RTE) foods. While HACCP has undoubtedly improved food safety as a whole, foodborne diseases are unfortunately still highly prevalent. For instance, in both North America and Europe there have been major incidents with *Listeria* in chilled products and *Salmonella* in dry RTE products (Aavistland et al., 2001; Anon, 2008d, 2010; Centers for Disease Control and Prevention, 1998, 2008, 2009; Jackson et al., 2011). In the majority of these cases, contamination following the pathogen reduction stage (e.g. cooking or decontamination via chlorinated produce washing) is thought to be the route by which the product becomes contaminated. Post-process contamination is prevented and managed predominantly by prerequisite programs, and it can be argued that for certain products, such as RTE food products, to ensure the safety of these foodstuffs, the management of such prerequisites is as important as the management of critical control points (CCPs) where pathogens are killed, reduced to safe levels or prevented from growing.

To more effectively manage prerequisites, a prerequisite management plan (PMP) is advocated. The PMP is comprised of two elements: generic prerequisites and processing environment prerequisites. ISO 22000 and retailer audits require a number of essential hygienic practices, or prerequisites, in all food manufacturing environments. These prerequisites are generic and may be independent of the factory or the food manufacturing process it contains. Such prerequisites include those already detailed above as relating to the factory's hygienic infrastructure (e.g. factory and equipment design) and hygienic practices (e.g. maintenance, personnel hygiene and cleaning and disinfection) and should be appropriately validated, monitored and verified. Other prerequisites are recognized, e.g. in PAS 220:2008 (Anon, 2008b) management of purchased materials, rework, product recall procedures and product information/customer awareness are noted while others consider the control of foreign bodies in foods via, e.g., sieves and metal detectors as prerequisites. These prerequisites, however, relate more to quality practices or process control than to hygienic practices.

After the implementation of generic prerequisites, food manufacturers then have to consider the management of any residual hazards that may contaminate the food product

during processing. Such hazards, and the transfer vectors via which they can contaminate the product, will be unique to each food manufacturer and each food manufacturing site. The assessment of hazards in the food processing environment, their risk and how they can be controlled to prevent contamination to the food product can be described as the processing environment plan (PEP).

Generic prerequisites should be undertaken to best practice standards and the following text for each of the hygienic infrastructure and practices prerequisites gives guidance as to how that can be ensured.

Factory Site

The factory site is designed to minimize the challenge of external hazards (insects, rodents, microorganisms, dust, soil, etc.) on the factory building envelope. This may be, for example, by reducing the number of pest harborage areas, controlling pest access to waste materials, reducing soil and dust, the downwind siting of effluent plants and the control of unauthorized public access (see Chapter 25 for further details).

Factory Building

The building envelope and air intakes provide a defense against external factory hazards. These could be microorganisms, pests, unauthorized human access, airborne chemical taints and airborne particulate matter. The building envelope also segregates food production from non-food production activities such as engineering workshops, boiler rooms, chemical stores, laboratories, offices, canteens, observation areas/viewing galleries, medical rooms and rest areas, etc. (see Chapter 25).

Segregation

Factories should be constructed as a series of zones and barriers that aim to limit the challenge of contaminants. The number of barriers created will be dependent on the nature of the food product, established from the HACCP study, and each barrier should reduce the challenge of a hazard to the subsequent barrier. Figure 24.4 shows that there are up to four levels of segregation that are typical for food plants. While these barriers were primarily conceived to control microbiological contamination, they are also effective at controlling many other hazards.

Level 1 represents the siting of the factory, the outer fence and the area up to the factory wall as noted above.

Level 2 represents the factory wall and other processes which should separate the factory from the external environment (e.g. rain, prevailing wind, surface run-off, delivery and dispatch vehicles, dust, odors, pests and uninvited people). Level 2 also includes all internal barriers designed to separate production stages (raw materials, intermediate product, finished product, packaged product), incompatible materials (wet, dry, chilled, frozen, allergenic, vegetarian, organic, genetically modified (GM) materials, Kosher or Halal, packaging) and non-food production areas (engineering, boiler rooms, cleaning stores, changing areas, etc.).

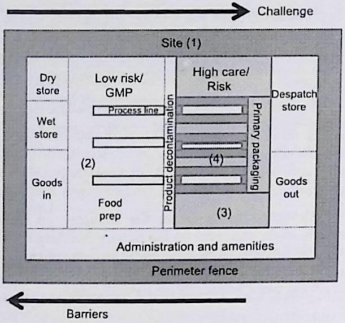

FIGURE 24.4 Schematic layout of a factory site showing 'barriers' against contamination. (1) Perimeter fence. (2) Main factory buildings. (3) Walls of high risk area. (4) Product enclosure within high risk.

Level 3 represents the internal barriers that are used to separate manufacturing processes of different microbiological risk, e.g. pre- and post-heat treatment. Product in level 3 will have a lower microbiological count than in level 2 and the microbial reduction process, incorporated as the barrier between level 2 and 3, may be a simple decontamination process (e.g. produce washing) or a pasteurization treatment (e.g. an oven, kettle or fryer). Such separation, which creates zones usually referred to as high care or risk areas, should seek to control the air, people and surfaces (e.g. the floor and drainage systems and the passage of materials and utensils across the barrier).

Level 4 represents a product enclosure zone, set within the level 3 high care/risk area. A product enclose zone could encompass true aseptic filling or "ultra clean" processing and packing areas such as glove boxes or the use of highly filtered air as a barrier around the process line (see Chapter 25).

Food Defense, Biovigilance and Bioterrorism

At all stages of production, processing and distribution, food must be protected against any contamination likely to render the food unfit for consumption and much of the protection requirements for the reduction/elimination of deliberate or accidental contamination of food products are similar, and are beneficial to both general food hygiene and bioterrorism control. The site and the production and storage areas of the factory buildings should be secured effectively by controlled access in order to prevent unauthorized entry. Site security should be reviewed and the need for fencing that fully encloses the site, close circuit television (CCTV), night lighting and/or security guards should be considered as part of a food defense program. Siting of silos, water tanks and packaging stores for raw materials,

process steps or finished products outside the protection of factory buildings is not desirable as this may increase the chance of product adulteration. Bulk unloading equipment (pumps, pipes, augers, conveyors, etc.) should be owned and operated by the factory (i.e. not from the transport vehicle) and appropriately stored inside when not in use. Additional security requirements may be appropriate for any on-site laboratory, particularly if it handles pathogens or toxic chemicals (see Chapter 35).

Process Lines

Process lines are laid out so that they facilitate efficient food manufacturing, maintain product quality, reduce environmental contamination by effectively controlling the movement of raw materials and operatives, and allow space for maintenance and cleaning. The flow of ingredients and products is such that ideally raw materials enter at one end of the factory (dirty end) and are dispatched at the opposite end (clean end). There should be no backtracking or crossovers and, where there are changes in the direction of process flow, there must be adequate physical barriers. The flow of air and drainage should be away from "clean" areas towards "dirty" zones while the flow of discarded outer packaging materials should not cross or run counter to the flow of either unwrapped ingredients or finished products. Access of personnel and visitors should be controlled and the traffic pattern of personnel (and vehicles) should prevent contamination of the product (see Chapter 25).

Ventilation and Air Flows

Food factories must have sufficient means of natural or mechanical ventilation to provide fresh air for food operatives (approximately 8 liters per person per second) while not contaminating food products. Natural ventilation should be through openings which are directly connected to the outside air and so positioned in the external walls and/or roof that effective cross-ventilation is possible. Mechanical ventilation should be provided to control humidity and ambient temperatures and to effectively remove particulates, fumes, smoke, steam and vapors and microorganisms. Where there is a risk of microbiological contamination of the product by the surrounding air, the working area should be enclosed as far as possible and be maintained at a positive pressure using filtered air drawn from a clean source. The type of filters will depend on the product and process and range from dust exclusion filters to high efficiency particulate air (HEPA) filters. Air used for the transport of product must be dust filtered as a minimum and may require additional filtration, over an above that of the room air from the hygiene zone which it is in or being moved to. This is maintain product safety and quality, as the interface between the air and the product durir transport is greatly in excess of simple sedimentation to product from still air.

Equipment

Food equipment that is designed hygienically has three key advantages: food quality, reduced costs and food safety. Good hygienic design helps to ensure sustained food product quality by preventing residues remaining in the equipment that could contaminate subsequent different product batches or, in food manufacture, ensuring that product is not "held up" within the equipment where it could deteriorate and affect product quality on rejoining

the main product flow. Good hygienic design reduces the time required for an item of equipment to be cleaned. This reduction of cleaning time, and the associated costs of staff training, etc., is significant over the lifetime of the equipment, which may be in excess of 25 years. Hygienically designed equipment, which may initially be more expensive (compared to similarly performing but poorly designed equipment), will be more cost effective in the long term. In addition, reduced downtime for cleaning may lead to the opportunity for increased food production. Finally, and perhaps most importantly, good hygienic design prevents the contamination of the product with substances that would adversely affect the health of the consumer. Such contamination could be microbiological (e.g. pathogens), chemical (e.g. lubricating fluids, cleaning chemicals) or physical (e.g. glass, metal swarf).

The hygienic design of equipment is a legal requirement in Europe under the auspices of Council Directive 98/37/EC (Anon, 1998a) on the approximation of the laws of member states relating to machinery. The hygienic design requirements in this directive were further developed as a European Standard and published as EN 1672-2 in 1997 (Anon, 1997a). The hygienic design of the requirements of EN 1672-2 and those of the 3-A standards group in the USA (www.3-a.org) was integrated into an international standard ISO/DIS 14159 (Anon, 2002). This standard described 11 hygienic design principles for food processing equipment, which are described below.

1. *Materials of construction* for food contact must have adequate strength over a temperature range to suit intended end-use exposure; have a reasonable life expectancy; be non-toxic, non-tainting, non-absorbent; be resistant to cracking, chipping, flaking corrosion and abrasion; prevent penetration of unwanted matter under intended use; and be easily cleaned. Stainless steel, because of its cleanability, corrosion resistance and wear resistance, usually meets all these requirements and there are various grades of stainless steel which are selected for their particular properties to meet operational requirements. For example, type 304 (AISI)/1.4301 (EN) for most general applications and type 316 (AISI)/1.4401 (EN) which contains molybdenum and has corrosion resistance are typically recommended. Elastomers and other polymers, used because of their high extensibility, particularly for seals, linings, flexible conveyors and moldings, etc., should conform to EU (Commission Regulation No. 1935/2004: Materials and articles intended to come into contact with food) or FDA (21 CFR 170) legislation.
2. *Surface finish* must be smooth enough to enable surfaces to be easily cleaned and disinfected. Surface roughness has been traditionally described by the roughness average (R_a) value which is calculated by measuring the average departure from an imaginary centerline running through the "peaks" and "valleys" of the surface profile (Anon, 1997b). For closed equipment (that used for liquid handling and usually cleaned-in-place – CIP) a surface finish of 0.8 μmR_a is recommended. For open surfaces, where more mechanical cleaning action can be applied and the effects of cleaning are more readily visible, higher R_a values may be acceptable, though again an R_a value of 0.8 μm is also appropriate.
3. *Joints*, such as those that are welded or bonded, should be smooth and continuous and free from recesses, gaps or crevices. Dismountable joints such as screwed pipe couplings must be crevice free and provide a smooth continuous surface on the product side. Flanged joints must be located with each other and be sealed with a gasket because, although metal-to-metal joints can be made leak-tight, they may still permit the ingress and harborage of microorganisms.

4. *Fasteners* such as exposed screw threads, nuts, bolts, screws and rivets must be avoided wherever possible in product contact areas. This is primarily because they have many metal-to-metal joints and crevices and are thus microbiologically uncleanable; however, fasteners in the product zone are also a foreign body hazard. When unavoidable for technical reasons, alternative methods of fastening can be used, for example where the washer used has a rubber compressible insert to form a bacteria-tight seal.
5. *Drainage* is a requirement for all pipelines and equipment surfaces because residual liquids can lead to microbial growth or, in the case of cleaning fluids, result in contamination of product. Care should be undertaken with the installation of equipment such that its drainability is not impaired.
6. *Internal angles and corners* should be well radiused, wherever possible, to facilitate cleaning. Ideally, materials should be joined away from the corner as, even if (in the case of welding) the joint is ground and polished, its 90° angle makes it difficult to access by cleaning equipment.
7. *Dead spaces* are areas within the equipment that cleaning systems are unable to reach during routine cleaning operations. In these areas, product is harbored which may cause product quality loss and a potential allergen issue. If dead spaces are unavoidable for technical reasons, they should be readily accessible for draining/cleaning as necessary.
8. *Bearings and shaft seals* should, wherever possible, be mounted outside the product area to avoid possible contamination of product by lubricants, unless they are edible, or possible failure of the bearings due to the ingress of the product. Shaft seals must be designed so as to be easily cleaned and, if not product lubricated, then the lubricant must be edible. Where a bearing is within the product area, such as a foot bearing for an agitator shaft in a vessel, it is important that there is a groove completely through the bore of the bush, from top to bottom, to permit the passage of cleaning fluid.
9. *Instruments* must be constructed from appropriate materials and if they contain a transmitting fluid, then the fluid must be approved for food contact. Installation should avoid dead legs and in liquid handling equipment, insertion into a shortened T-piece with cleaning fluid flowing into the upstand is a favored solution.
10. *Doors, covers, panels* and door gaskets should be designed so that they prevent the entry and/or accumulation of soil. Where appropriate they should be sloped to an outside edge and should be easily removed to facilitate cleaning.
11. *Controls*, particularly those that are repeatedly touched by food handlers in normal use, should be designed to prevent contamination and should be easily cleanable. Pathogenic microorganisms have been known to be harbored in switches and be transferred to product every time they are operated.

(See Chapter 26 for further details.)

Utensils

Utensils include all tools, containers, trays and small pieces of equipment, etc. necessary to undertake the food manufacturing process. There is no specific legislation or guidance on the hygienic design of utensils and the 11 principles outlined above for food processing equipment should be followed as best practice.

Services

Services include all processing aids necessary to manufacture the food including process water, steam, electrical supplies, compressed air and other gases. Potable (hot and cold) water should be used whenever necessary to ensure that foodstuffs are not contaminated. Where appropriate, facilities for water storage, distribution and temperature control shall be adequately designed and constructed, shall be covered and shall have air vents which are insect- and rodent-proof. Plumbing shall be of adequate size and design and adequately installed to ensure potable water is not contaminated and that all hoses, taps and other similar sources of possible contamination prevent backflow or back siphonage. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it should circulate in a separate, identified system. Non-potable water is not to connect with or allow reflux into potable systems. Steam should be generated from potable water, have approved food safe additives, be filtered, have non-return valves to prevent the drawback of product into steam lines and should have traps to ensure adequate condensate removal and elimination of foreign materials. The length of electrical cabling should be minimized and be mounted on vertical or inclined cable trays with one layer of cables per tray. Electrical connection and control boxes should be suitably protected from water and dust ingress. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be dry and filtered to remove micro-organisms, lubricants and particulates and ideally conform to *Food Grade Compressed Air: A Code of Practice*, British Compressed Air Society Limited (www.bcas.org.uk).

As many services as possible should be exterior to the food processing area and should be carried in false ceilings or service corridors. Pipework, suitably protected light fittings, ventilation points and other services in manufacturing areas should not run directly above food processing equipment or "open product" and should be sited (e.g. flush mounted or mounted at least 25 mm from the wall) to minimize dirt accumulation, to avoid creating recesses which are difficult to clean and to ensure that drips and condensation do not contaminate foods, raw materials or food contact surfaces. Cold water pipes and other service pipes which might be prone to condensation build-up should be insulated (see Chapter 26).

Waste Disposal

Waste disposal areas, for the storage and disposal of food waste, non-edible by-products and other refuse, must be designed and constructed so that the risk of contaminating food or the potable water supply is avoided, to reduce the attraction of pests and to minimize the potential for odor. Storage should be in a separate room within the main factory building, often part of the dispatch docking area, or in an external area that is constructed of impervious material and suitably sloped and drained. Waste disposal areas should be easily cleanable and, where necessary, suitably fly-proofed and free from animals and pests. Food waste, non-edible by-products and other refuse should be deposited in appropriately constructed, labeled, closable containers which are made of impervious material, are leak-proof and are easy to clean and disinfect. Waste containers should be specifically identifiable (e.g. by color) and be lidded and should not be moved through different hygiene zones.

Waste should be moved out of higher risk zones, ideally via existing hatches for bagged waste, though for waste collected in bins, it may be necessary to decant the waste through purpose-built, easily cleanable from high risk, waste chutes that deposit directly into waste skips (see Chapter 25).

Medical Screening

Until food factories are completely automated, food operatives are essential to the manufacture of the food product and are thus part of the hygienic infrastructure. Medical screening of food operatives is initially concerned with the requirement for medical certification of freedom of carriage of pathogenic microorganisms in prospective new employees. In addition, it involves an ongoing awareness by operatives of their own health and the health of those around them (e.g. at home), from whom they themselves may become infected and thus subsequently compromise food safety. Medical certification can be self-certifying or via a doctor or other health practitioner. In some countries this may be required by law; in others this may be voluntary. Once employment has started, any instance of potentially infectious diseases, including jaundice, fever, sore throat with fever, vomiting, stomach disorders, diarrhea, visibly infected skin lesions (such as boils, cuts) and discharge from the eyes nose or ears, must be reported to the operative's line management or directly to the first aider or medical department. This particularly applies to staff returning from areas of the world where there has been a risk of infection. If, through illness, operatives are identified as being at risk to the safety of the product, they should either be sent home or moved to other work areas or duties that do not include open food handling (see Chapter 28).

Maintenance

Effective hygienic maintenance is required both for food processing equipment and the processing environment. Maintenance should be preventive, i.e. planned such that parts and structures are changed/maintained so that they do not fail or become of a nature where they form a microbiological or physical hazard to the product. "Fire-fighting" or repairing equipment and structures after they have broken or become a hazard is not acceptable.

All materials used for maintenance and repair shall be fit for their intended use, and for replacement food contact parts (e.g. seals, gaskets, conveyor belts), certificates of conformity or other evidence shall be available to confirm their suitability for use. The traceability of replacement parts must be ensured to facilitate any potential recall of food products that could have been contaminated by defective parts. Essentially, the identification of the business from which the parts were supplied, where the parts are held in stores and the lines and equipment to which individual parts have been fitted, must be recorded.

Maintenance and repairs to food processing equipment should ideally be undertaken away from the line but if this is not possible, the worksite should be adequately screened. Similarly, repairs to the building fabric should be undertaken out of production periods but if this is not possible, screening should be in place, preferably from floor to ceiling and fully sealed. All tools, parts and materials brought to the job and/or removed should be accounted for and all parts and tools should be clean. This may necessitate the cleaning of

replacement parts (and also new and second-hand equipment) prior to entering the factory. Separate toolboxes should be available for low and high risk zones. Lubricants should be food safe and ideally be preserved to prevent microbial growth and conform to ISO 21469 (Anon, 2006).

For specific hazards such as broken glass or water leaks into dry processing areas, written procedures should be available as to how to control and repair these incidents. For all maintenance procedures in food processing environments, a documented handover procedure should also be in place. Engineering staff should sign off to the fact that the area is free of tools, repair materials and engineering debris. Sanitation staff should sign off to ensure that the area is cleaned to a hygienically appropriate level and, finally, production staff should sign off that they accept the area as suitable for food processing. All such procedures should apply to both own staff and external contractor working practices.

Engineering workshops should also be recognized as a potential source of food contamination and should be kept clean and have sticky mats at their exits to help remove swarf and debris from footwear (see Chapter 26).

Housekeeping

Housekeeping is undertaken to provide a safe working environment for staff (primarily reducing slips and trip hazards), to minimize any possibilities for contamination from the food processing environment to the food product and to minimize the challenge of hazard build-up on the processing line that will need to be controlled by the end-of-production clean. Cleaning and disinfection procedures can be seen as unit operations in which, for microorganisms, a given reduction, usually 2–3 log orders for the cleaning phase and 1–2 log orders for the disinfection stage, is possible. Any increase in the starting level of microorganisms prior to the end-of-production clean can thus result in an unacceptable level of microorganisms remaining after the sanitation process. To prevent excessive microbial growth on surfaces during production periods, food operatives or cleaning staff should clean the process line prior to break periods and clean up any major product spillages. Cleaning of the processing environment during food production periods must be undertaken in a way in which contamination to the food product via cleaning aerosols is minimized (see Chapter 27).

Cleaning and Disinfection

Cleaning and disinfection, referred to together as sanitation, is undertaken primarily to remove all undesirable material (food residues, microorganisms, allergens, foreign bodies and cleaning chemicals) from surfaces in an economical manner, to a level at which any residues remaining are of minimal risk to the quality or safety of the product. The principal stages involved in a typical sanitation program are:

- *Preparation.* All product and unwanted utensils/packaging/equipment should be covered or removed from the area. Machinery should be switched off, at the machine and at the power source, and electrical and other sensitive systems protected from water/chemical ingress. Equipment should be dismantled and stored on racks.

- *Gross soil removal*. All loosely adhered or gross soil should be removed by brushing, scraping, shoveling or vacuum, etc. Wherever possible, soil on floors and walls should be picked up and placed in suitable waste containers and not washed into drains using hoses.
- *Pre-rinse*. Surfaces should be rinsed with low pressure cold water to remove loosely adhered small debris. Hot water can be used for fatty soils (approximately 60°C), but too high a temperature may coagulate proteins.
- *Cleaning*. Cleaning is a combination of mechanical or kinetic energy (physical or fluid abrasion), chemical energy (cleaning chemicals), temperature or thermal energy and cleaning time. Cleaning chemicals should break down soil-to-soil and soil-to-surface bonds and prevent the re-deposition of the dispersed soil back onto the cleaned surface. No universal cleaning chemical is available and a range of cleaning agents is used for specific food soils. Water provides the cheapest, readily available transport medium for rinsing and dispersing soils, has dissolving powers to remove ionic-soluble compounds such as salts and sugars, will help solubilize proteins below their coagulation point, emulsifies fats at temperatures above their melting point, and, in high pressure cleaning, can be used as an abrasive agent. Organic surfactants are amphipolar, are composed of a long non-polar (hydrophobic) chain or tail and a polar (hydrophilic) head and aid cleaning by reducing the surface tension of water and by emulsification of fats. Alkalis break down proteins through the action of hydroxyl ions, saponify fats and, at higher concentrations, may be bactericidal. Acids are very useful in solubilizing carbonate and mineral scales, including hard water salts and proteinaceous deposits. Sequestering agents (sequestrants or chelating agents) are employed to prevent mineral ions precipitating by forming soluble complexes with them. Cleaning and disinfection can be undertaken by hand using simple tools, e.g. brushes or cloths (manual cleaning), though as the area of open surface requiring cleaning and disinfection increases, specialist equipment becomes necessary to dispense chemicals and/or provide mechanical energy. Chemicals may be applied as low pressure mists, foams or gels, while mechanical energy is provided by high and low pressure water jets or water or electrically powered scrubbing brushes. Alternatively, dismantled equipment and production utensils may be cleaned and disinfected in soak tanks or automatically in tray or tunnel washers. Cleaning should be undertaken in a sequence so that hazards are removed from the processing environment via the drains and do not contaminate cleaned surfaces. Specifically, environment surfaces, usually in the order of drains, walls then floors are cleaned prior to food processing equipment and all food processing equipment should be cleaned at the same time.
- *Inter-rinse*. Both soil detached by cleaning operations and cleaning chemical residues should be removed from surfaces by rinsing with low pressure cold water.
- *Disinfection*. Disinfection is undertaken to remove and/or reduce the viability of remaining microorganisms to a level deemed to be of no significant risk. In exceptional circumstances and only when light soiling is to be removed, it may be appropriate to combine cleaning and disinfection by using a chemical with both cleaning and antimicrobial properties (detergent-sanitizer). Elevated temperature is the best disinfectant as it penetrates into surfaces, is non-corrosive, is non-selective to microbial types, is easily measured and leaves no residue. However, for open surfaces, the

use of hot water, steam or naked flames is uneconomic, difficult to maintain target temperatures, may bake on residues, is hazardous to operatives, and reliance is, therefore, placed on chemical biocides. Quaternary ammonium compounds (quats or QACs) and peracetic acid are universally used for open and closed surfaces, respectively; hypochlorous acid is used for high-level disinfection of, e.g., floors and drains while alcohol is used for dry disinfection. The efficacy of chemical disinfectants is generally controlled by five factors: interfering substances (primarily organic matter), pH, temperature, concentration and contact time. To demonstrate their biocidal effectiveness, in Europe, chemical disinfectants should be approved for bactericidal activity against the European Standards EN 1276 (Anon, 1997c) and EN 13697 (Anon, 2001) and for fungicidal activity against EN 1650 (Anon, 1998b). In Europe it is also acceptable to leave disinfectants on surfaces without any further rinsing prior to food production. As such, disinfectants will enter foodstuffs and must be non-toxic and non-tainting. Historically, disinfectants have been regarded as safe if their minimum acute oral toxicity (with rats) is >2000 mg/kg bodyweight. Non-toxicity is now being assessed under the auspices of European Directive 98/8/EC concerning the placing of biocidal products on the market, which seeks to produce a list of active biocidal substances that have been assessed for both their toxicological properties and also their inherent antimicrobial properties. Formulated products, sold to the final user, can then only be made by incorporating an approved active ingredient and the formulated product will then itself be assessed for its toxicological and antimicrobial properties. To assess the potential for a disinfectant to taint foods, a modification of a food container transfer test is used (Anon, 1983) in which food products are sandwiched between two sheets of stainless steel and left for 24 hours. Disinfectants can be sprayed onto the stainless steel sheets and drained off, to simulate no rinse status, or can be rinsed off prior to food contact. Control sheets are rinsed in distilled water only. The results of the test involve both a statistical assessment of any flavor differences between the control and disinfectant-treated sample and a description of any flavor changes.

- *Post-rinse.* Disinfectant residues may or may not be removed by rinsing away with low pressure cold water of known potable quality.
- *Inter-production cycle conditions.* A number of procedures may be undertaken, including the removal of excess water and/or equipment drying, to prevent the growth of microorganisms on production contact surfaces in the period up until the next production process. Alternatively, the processing area may be evacuated and whole room disinfection techniques applied, e.g. ozone, hydrogen peroxide or ultraviolet light.
- *Periodic practices.* Periodic practices increase the degree of cleaning for specific equipment or areas to return them to acceptable cleanliness levels. They include weekly acidic cleans, weekend dismantling of equipment, and cleaning and disinfection of chillers and sanitation of surfaces, fixtures and fittings above 2 meters.
- *Clean the cleaning equipment.* Following their use for cleaning, cleaning equipment should itself be cleaned and disinfected. Cleaning equipment should be visually checked for damage and any areas where microorganisms could reside, or loose parts which might become a foreign body hazard, should be replaced. Cleaning equipment should be stored in racks to dry or kept in disinfectant solution until their use is required.

Sanitation is managed via a series of plans or schedules. The cleaning plan should list all the cleaning and disinfection tasks that need to be undertaken across the food manufacturing site and their frequency (daily, weekly, monthly, etc.). Cleaning schedules are the written work instructions that detail precisely how the cleaning and disinfection procedures for each task should be undertaken and can also be used as the work instruction against which cleaning operatives can be formally trained. The "whole room" plan details all the requirements for the practical management of the cleaning and disinfection operation and includes manpower, any specialist engineering support, equipment, chemicals and their dosing, health and safety, room preparation, protection of any food production operations, how cleaned surfaces are protected from recontamination, how the room is prepared for subsequent production and how the cleaning equipment itself is cleaned and maintained. End-of-production cleaning plans detail the specific requirements of single or groups of equipment and include any specific dismantling or health and safety instructions. Periodic cleaning schedules detailing, e.g. weekend or monthly cleaning and site decontamination plans, detailing a planned decontamination of the processing areas following a potential pathogen contamination incident, may be required, particularly for ready-to-eat food (see Chapter 27).

Cleaning-In-Place (CIP)

CIP is the cleaning of complete items of equipment or pipeline circuits, *in situ*, without dismantling and with little or no manual involvement. The prime consideration of CIP cleaning is that the process and CIP equipment must be designed hygienically; otherwise cleaning will not be acceptable. Separate CIP sets for raw and post-heat-treated product lines are also required. Much of the science of CIP cleaning is the same as for open surfaces, though the relative inputs for each of the four cleaning factors can be very different. Mechanical or kinetic energy is generally limited and is provided in pipelines by turbulent flow of cleaning solutions and in vessels by either falling films or spray impingement of cleaning solutions. As the system to be cleaned is enclosed, the concentration of cleaning solutions and their circulation temperatures can thus exceed those as used for open plant cleaning. Typically, caustic detergents (e.g. sodium hydroxide) have an in-use concentration of 0.3 to 2.0% and are circulated in excess of 70°C whereas acidic detergents (e.g. phosphoric or nitric acid) are used at 0.2 to 1.0% acidity and circulated at 50 to 60°C. Methods of thermal disinfection include hot water at temperatures between 70 and 80°C and maintained for 15 minutes.

The actual cleaning mechanism within the CIP circuit is divided into the cleaning of pipelines (and other items with total submersion in the cleaning fluids) and the cleaning of vessels. The cleaning of pipelines is undertaken by circulating the cleaning fluids at a velocity of approximately 1.5 m/s throughout the whole of the pipeline system. The cleaning of vessels is undertaken via spraying devices that produce a "falling film" of cleaning fluid or an impingement jet of cleaning fluid over the whole of the vessel surface. Fixed (static) spray balls, via the use of holes drilled in specific patterns, direct cleaning fluids to cover the vessel surface. Approximately 30 to 50 liters of cleaning fluid per minute per meter of the vessel circumference, at 1.5 to 3 bar, are generated to maintain a continuous liquid film on the tank

wall which falls due to gravity to provide some mechanical action. Low pressure rotating (dynamic) sprayheads can also be used which have lower water consumptions. High pressure rotating (dynamic) impingement sprayheads can be water or mechanically driven to provide a (geared) rotation around the vertical and horizontal axis such that all points on the vessel surface are impacted over a defined time period. Once this time period has been established, cleaning must always meet or exceed this time to ensure full surface coverage. The vessel must be designed to ensure adequate drainage of solution and prevent pooling of chemicals and soil in the bottom of the vessel, which is controlled by ensuring that the (scavenge) pump used to remove fluids from the vessels is operating at a flow rate in excess of the supply pump.

It is absolutely critical to prevent the cleaning and disinfection chemicals from contaminating the food product, and as such the CIP circuit must always be separated from the food product. Traditionally, the potential for contamination was minimized by bringing product and CIP lines to a flow selector plate at which specific short lengths of pipe were manually removed and reconnected to ensure that product and cleaning fluids were separated. The use of single valves between the chemicals and the product is never sufficient to separate the systems and modern circuits use, e.g., block and bleed valves to assure adequate separation (see Chapter 27).

Pest Control

Pests are attracted to food processing environments primarily for water, food and shelter. Their presence, however, can lead to consumption and/or damage of the food product and packaging, physical contamination of foodstuffs by, e.g., rodent droppings, insect parts or other foreign bodies, contamination with disease-causing agents, e.g. microbial pathogens and intestinal worms are carried in the guts and/or on the external surfaces of pests and direct damage to the building and its services. Pests can therefore be described as any animal at any stage of its life cycle that may reasonably cause biological/physical contamination to food or its presence will be detrimental to its wholesomeness, and include small mammals (e.g. black and brown rats and mice), crawling insects (e.g. cockroaches, ants, beetles), flying insects (e.g. houseflies, blowflies, fermentation flies, moths, bees, wasps) and birds (e.g. seagulls and pigeons).

Pests can be environmental, i.e. can enter the factory from the external environment, or can be associated with raw materials, often termed stored product pests. The pests relevant to a particular food processing environment can be determined by history and previous findings, inspections by pest control technicians and sightings by company staff. As company staff are regularly on the premises, and if trained in the detection of the signs of pest infestation, they are the best source of information on the presence of pest hazards and a Pest Sightings Register should be maintained at all sites which details the date, pest, location, reported by and subsequent actions taken by the food manufacturer and pest contractor.

Pest control has to be undertaken by both the food manufacture (and its raw material suppliers) and the pest control contractor (which may be an in-house function). As such, it is commonly referred to as integrated pest management (IPM) and comprises four key elements; neighboring activities; the factory environment; raw material quality control; and

pest management. The activities of neighboring properties, the movement of materials on and off the factory site and any environmental features such as water courses should be considered as to their ability to attract pests. The factory site and building envelope should then be designed and maintained to minimize pest harborage, visualize pests and restrict pest entry. At the same time, however, the factory must practice good GMPs such as good housekeeping, waste handling and cleaning and disinfectant practices to limit the presence of water, food sources or harborage sites. All raw materials entering the factory which could be susceptible to stored product pests should be inspected, sampled and positively released to the food manufacturing operation. Strict stock rotation should be implemented and, as infestation can potentially remain undetected, it is important to establish batch-to-batch freedom from pest contamination.

While some food manufacturers employ their own pest control teams, most contract this service out to a pest control company. Contracts usually consist of two parts, a practical part consisting of a scope of works and an administrative part consisting of a logbook or service report. The scope of works may include the pests covered, the frequency of the services offered (technician/field biologist visits), agreed methods of pest capture or treatment (e.g. small mammal and insect traps, electric fly killers, pesticides, bird scarers, stored product fumigation and heat or freezing treatments), reporting structures, reviews and trend analysis and contractual warranties and insurances. The logbook may contain general information (pest company details, qualification certificates or licenses for pest control technician, name of daily contact person); materials and resources applied (applied pesticides overview, material safety data sheets, applied pesticide labels); monitoring devices (registration lists, maps with location indicator, capture statistics and trend analysis); and notification of pest activity, reports, advice and corrective actions (see Chapter 29).

Personal Hygiene

All food manufacturers should have in place, for all employees, visitors and contractors entering food processing areas, a personnel hygiene policy. This should cover:

- Medical screening (referred to above)
- Induction training
- Personal hygiene measures
- Company requirements – hand washing/clothing
- Monitoring and verification auditing

Induction training, provided in as many different languages as necessary for the whole work force, is essential to ensure that food operatives recognize that they may act as potential routes of food product contamination and that they should undertake personal hygiene procedures in a way that minimizes such risks. Of particular importance is the demonstration of an appropriate, validated hand hygiene procedure as operatives do not inherently know how to wash hands to maximize microbial cleanliness. This is best undertaken using a kit combining a UV-sensitive dye and a small, portable UV lamp, e.g. GloGerm System, Deb Ltd (www.debgroup.com). The dye is applied to the hands prior to hand washing and, following hand washing, the hands are placed under the UV lamp to indicate areas that have been "missed." Individuals' training records should be kept and reviewed as appropriate.

Food operatives should be encouraged to follow basic hygiene procedures at home and in the workplace to minimize their risk to foodstuffs. Such procedures cover the control of personal habits (e.g. nose picking, spitting, nail biting) and activities (e.g. eating, smoking and drinking), the wearing of make-up and jewelry and the coverage of any wounds with, e.g., blue, metal detectable plasters.

Protective clothing is provided by the food manufacturer primarily to protect the food from microorganisms released from the body and includes hair nets, hats, masks, beard snoods, overalls, coats, gloves, wrist and forearm sleeves, trousers and footwear. Personal protective equipment (PPE), which includes hard hats, gloves, safety spectacles, ear defenders, aprons, overalls and footwear with non-slip soles and metal toe caps, is provided to protect the operator from the food processing environment (cold, water, food products, etc.) and specific safety hazards as appropriate (e.g. detergents and disinfectants, falling objects, knives). Consequently the type of material used and the design of protective clothing will depend upon its prime function. Factory clothing should be hygienically designed so that it does not shed foreign bodies directly (e.g. buttons or lint) or indirectly (e.g. having outside pockets from which objects can fall out) and is often of different colors to delineate either operatives working in different risk areas or specific categories of people, e.g. engineers, cleaning staff, first aiders and management. A laundry policy should also be in place to clean and maintain such protective clothing.

Hands need to be washed before embarking upon food handling procedures and after any operation that may lead to the hands becoming contaminated, which could include: visiting the toilet; handling raw food; handling waste and chemicals; blowing noses; sneezing into hands; touching body parts; carrying out cleaning duties; removing and changing gloves; picking items off the floor and touching non-food contact surfaces, e.g. machine adjustment, power switches, buttons, etc.

Hand washing on entry to food processing areas can be combined with the donning of factory clothing in a manner that limits the transfer of hazards into food handling areas. A suggested procedure is as follows:

1. Remove outer clothing and place in personal locker.
2. Remove jewelry and watches in line with personal hygiene policy and place in personal locker.
3. Put on hair net/snood.
4. Remove shoes and place in locker.
5. Step over a barrier into the food handling area.
6. Wash and dry hands.
7. Put on clean, dry food handling area footwear.
8. Put on clean food handling area clothing.
9. Use a hand disinfectant immediately before handling food.

Good personnel hygiene and hand wash compliance can be monitored by visual assessment by line supervisors and auditing staff, or via the use of CCT cameras. It is also possible to install, e.g., turnstiles at the entrance to food processing areas such that the turnstile will only open when a recognized hand washing trigger has been activated, e.g. the application of an alcohol handrub (see Chapter 28).

RECOMMENDED PROCEDURE FOR DEVELOPING A PROCESSING ENVIRONMENT PLAN

It is recognized that as a new, additional, component of food safety, the Processing Environment Plan (PEP) is likely to be approached with a degree of suspicion by the food factory staff that have to practically implement it, on top of the requirement for the HACCP plan. To make this task easier to undertake, and from practical experience in the factory, two things have been recognized that should facilitate implementation. First, and wherever possible, the same terminology has been used in the PEP as in the HACCP plan. Second, the PEP should generally only be undertaken once, to encompass the majority of food products manufactured. Only if the products to be manufactured in the processing area of concern use different processing equipment or different ingredient transfer systems are sources and vectors of contamination likely to change.

The undertaking of the PEP follows the 14 principles of the HACCP plan as defined by Gaze (2009) and is a recently proposed food safety initiative (Holah et al., 2011, 2012).

Pathogenic microorganisms can enter food processing areas from four main routes: the external environment, raw materials, infected food operatives and visitors and laboratories undertaking pathogen testing. Microorganisms from the external environment are controlled by the design of the factory building and its segregation. Microorganisms in raw materials are controlled by the HACCP plan, while infected food handlers are managed by best practice personnel hygiene prerequisites. Finally, pathogenic microorganisms in food laboratories, typically used as media positive controls, are controlled by the complete isolation of the laboratory from the factory, including air systems, drainage systems, waste removal and the movement of laboratory staff.

The environmental plan usually starts, therefore, within the food processing environment and especially where product is most susceptible to contamination. In effect, it works in the reverse to the HACCP plan (which starts at the raw materials and moves to the finished product) as it starts from the finished product and works backwards until any contamination routes are effectively controlled. The nomenclature of the Gaze (2009) 14 HACCP principles is used as follows to define the plan, and readers should access the original document for a full description of these widely established principles.

1. Obtain Management Commitment

Senior management must be committed to providing the necessary resource for the study to be planned, undertaken, implemented and periodically reviewed. In many cases this may be implicit as the PEP and PMP can be seen as part of the HACCP plan which, for some countries, may be a legal requirement. For RTE manufacturers, management must also be committed as the outputs of the environmental plan will be critical in controlling contamination and may be significant controls for the business and the protection of its brands. Senior management should also appoint a manager and/or team leader to take responsibility for the plan's development and implementation.

2. Define the Scope or the Terms of Reference

The processing area(s) for the study should first be determined. Will the study investigate the contamination of hazards into the food manufacturing building envelope, consider the processing environment from raw materials storage up to any hazard decontamination step, or just the post-decontamination step processing environment, after which any microbiological hazards entering the product may not be controlled prior to the foods consumption?

Second, what hazards will be considered? Will all biological, chemical or physical hazards be considered and, in addition to product safety, will any effects on product quality be considered. If the study is to focus on microbiological pathogens, the specific pathogen must be noted. This is because different pathogens may require different environmental niches to survive, grow or become established; for example, in chilled environments, *Listeria* spp. may dominate in low temperatures and moisture (e.g. evaporative condenser trays), whereas *Escherichia coli* requires higher temperatures (e.g. surrounding motor drive shafts where friction creates higher local temperatures).

Lastly, the types of potential sources and routes (vectors) of environmental contamination transfer may need defining, particularly if these have already been considered at the generic prerequisite stage. For example, and for most countries' climates, if the compressed air supply is dried to a dew point of −40°C, it may not be necessary to consider the use of compressed air in a processing area as a source or vector of microbiological contamination.

3. Select the Processing Environmental Plan Assessment (PEP) Team

As the study will assess hazard sources and vectors within a given process area, many activities and events may occur in this area at different times of the day, week, year, etc. and the selection of team members should reflect all of these activities. Engineers will be required who understand the building's construction, ceiling, wall and floor finishes, food production equipment, service provisions and all maintenance activities. Production staff representing all products produced in the area, together with sanitation managers who have to clean and disinfect the area following such production, will be essential. Hazard specialists such as microbiologists, chemists, pest controllers, etc. will be required dependent on the hazards assessed in the study. Finally, HACCP, technical and quality staff, who can advise on the planning and undertaking of the study, and then will need to implement the study's findings, will also be required.

As with all projects, good teamwork is essential and the team members and details of their specific skills, qualifications and responsibilities should be recorded. A scribe may be useful in helping the team leader manage meetings and to record findings. Particularly for small companies, consultants can be used for their technical knowledge, but they should not write the plan. The PEP should be owned, written, implanted and managed by the food manufacturer.

4. Describe the Environment

All physical and operational parameters of the processing environment under study should be recorded and/or measured with due regard to activities in adjacent processing

areas, beside, below or above the area of study. The physical properties will include the size and layout of the processing area; any zones of segregation; entrance barriers into the area; services flowing through or above the area; air flows, temperatures and humidity; personnel flows; transport flows for product and packaging; and solid and liquid waste streams. Operational activities will include products processed, production lengths and seasonality; housekeeping, end-of-production and periodic cleaning and disinfection practices; maintenance activities; and shutdown periods.

With respect to the hazards of concern, any historical data from previous routine sampling or observational studies (e.g. routine environmental microbiological sampling, pest control records, glass and hard plastic records) should be recovered and reviewed.

5. Identify Intended Product Use

The intended use of the product should be established with respect to the fate of any hazards entering the product in the processing area of study. First, will there be any further treatment of the product or controls of the process line that might affect the removal, reduction or growth of any hazards entering the product directly or from the food production equipment? Second, as for a classic HACCP study and particularly for RTE foods, if there is no removal or reduction of the hazard, how will these hazards affect the target consumer group?

6. Construct Flow Diagram

All information collected during principle 4 should be recorded in the form of physical maps or diagrams of the processing area. Ideally this should start with a map of the processing area with the layout of food processing equipment and services. Overlaying this map can be specific diagrams of, e.g., alternative production equipment set-ups, air flows, personnel flows, transport flows and waste flows. The diagrams present both a record of the plant construction and activities taking place in the processing area at the time of the study, together with a vehicle that can be used for entering the position of any subsequently identified hazard sources and contamination vectors.

7. On-site Confirmation of Flow Diagram

The PEP team should audit the processing area at all processing, sanitation, maintenance and down times to ensure that the flow diagrams produced are accurate and representative. The flow diagrams can then be signed off as a true record of the processing area.

8. List all Potential Hazards, Conduct a Hazard Analysis and Consider any Measures to Control the Identified Hazards

Within this step the PEP team conducts a thorough investigation of the processing environment to identify any hazard sources and any mechanisms or vectors via which these hazards could enter the food product directly or via food processing equipment. Step 8

according to Gaze (2009) equates to step 1 of the seven HACCP principles as defined by the Codex Alimentarius Commission (Anon, 1993) and subsequently, steps 9–14 relate to Codex steps 2–7. The investigation of sources and vectors in the following text is illustrated for microbial pathogens as the hazard, but is equally applicable to the analysis and control of other hazards. The identifications of hazard sources and contamination vectors can be undertaken at each food processing step within the processing environment (as for a traditional HACCP study) or can be undertaken at an environmental level, as illustrated in Figure 24.5.

Once within the processing environment, pathogens can be sporadic visitors, being present until they lose viability or are removed via cleaning and disinfection procedures or more persistent, surviving in harborage sites or growth niches to form sources of contamination. Harborage sites are physical areas in which pathogens can lodge and be protected from external forces such as cleaning and disinfection actions, e.g. poor hygienic design features of processing equipment or damaged areas of the plant's building structure. Growth niches are also harborage sites, but which also provide an environment for growth, e.g. nutrients, temperature, oxygen, water or humidity and lack of competition from other microbial flora.

Pathogens from harborage sites and growth niches and, perhaps less frequently, from the general environment as sporadic contaminants, can be transported to food products via three prime vectors. These are physical contact with a solid surface, physical contact with a liquid or settlement and/or impingement from the air (or other gases). The difference between solid contact and liquid contact is that the liquid may be absorbed into the food product which may increase the transfer of microorganisms to the food (towards 100%). For contact between solid surfaces, microorganisms will partition to and from the two surfaces, dependent on the physical properties of the microorganisms and surfaces. Smith and Holah (2007) demonstrated that the transfer of microorganisms from one contact surface to another can be approximated to 50% for practical purposes. For stationary air, transfer of microorganisms from the air is via sedimentation, which has defined rates for particles of given size (Stokes law, cited in Lamb, 1994), and the number of microorganisms transferred is dependent on the microbiological loading of the air and the exposure time. When product is transported via air, or when air is forced into the product for cooling or drying purposes, microorganisms can enter the product via impingement in addition to sedimentation, and the number of microorganisms transferred may be related to the microbial loading and volume of air that the product is exposed to.

Contamination usually occurs as a contamination event, in which a number of vectors may be involved. For example, entering a food product stream to help clear an obstructing product may have vectors of the operator's hand (or glove), the operator's sleeve, the tool to be used for cleaning away product debris and the air. In some instances the contamination event could have only a single vector, e.g. contaminated water droplets from a compressed air line.

The determination of potential pathogen sources and contamination vectors in a processing plant is a combination of physical examinations and microbiological sampling. Sources can be determined by dismantling process equipment to identify potential harborage sites and niches, together with physical inspection of the building structures and finishes. The potential presence of pathogens in such harborage sites and niches can be determined by

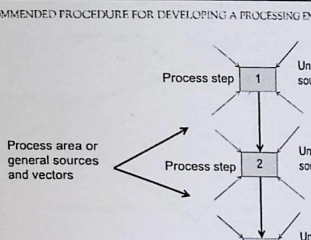

FIGURE 24.5 Hazard sources and vectors can be identified at each process step or within the general processing environment, which may affect many steps.

microbiological sampling and over prolonged periods (e.g. via environmental microbiological sampling records) an indication can be gained as to the likelihood of pathogens being present in these sites. The observation of all potential sources should be recorded as a record of the environmental survey, for example in a tabulated form as shown in Table 24.1. In these examples from the author's experience in a factory that is no longer in existence, meat residues were seen inside a meat slicer on/off switch in a high risk area of a cooked meats factory and fluid was seen oozing from underneath the meat slicer foot support plate

Pathogens may transfer from sources directly to the food product, on product vectors, or indirectly to other parts of the processing environment via environmental vectors (Figure 24.6). If observational and microbiological data identify likely pathogen sources, all potential environmental contamination routes from this source should be determined to identify the potential for secondary or temporary sources. Using the equipment foot support plate example in Table 24.1, liquid oozing from under the plate was transferred throughout the process area on operatives' shoes and on equipment wheels and was re-deposited at random sites on the floor to act as potential temporary or short-term sources.

Contamination vectors can be identified by inspection of all of the activities associated with the production line and processing environment. Inspections should reflect all operating conditions including process type, product type, time of day or batch process, cleaning and disinfection, maintenance procedures, QC procedures, production downtimes and any seasonal events. Observations of contamination vectors should be made independently of known or likely pathogen sources, because contamination could arise from temporary sites, and is best observed from the process itself – i.e. the identification of potential transfer vectors to the process line, observed from the process line.

It is unlikely that microbiological sampling of vectors would be helpful, as the likelihood of observing a pathogen on a potential vector would be very small. Observational data for

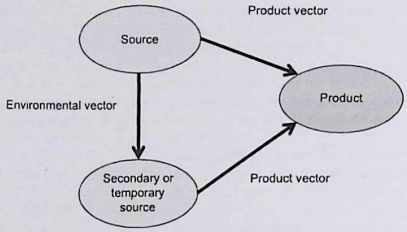

FIGURE 24.6 Transfer of pathogens from likely sources directly to food products via product vectors or indirectly to secondary or temporary sources.

vectors should also be recorded as indicated in Table 24.2, again from the author's experience in a factory that has been subsequently refurbished, showing the personnel hygiene of operatives and spray dryer interventions in a milk spray drying operation.

When observing and identifying potential contamination sources and vectors with the PEP team, any current direct controls of observed sources and vectors should be recorded as illustrated in Tables 24.1 and 24.2. For vectors, subsequent controls within the food process may have an effect on the hazard that could be transferred by the contamination event, and these should also be recorded.

When undertaking a process environment study, many potential sources and contamination vectors could be observed, though the degree of control necessary for each source and vector will depend on their potential risk to food product contamination. Hazard analysis is a fundamental aspect of HACCP studies, and a familiar approach to risk analysis is to consider the likelihood and severity of a hazard in a food as a three-point scale, or low, medium and high risk. A risk analysis for a contamination source is similar and can be described as the risk of a pathogen being present at the potential source and the ability of the pathogen to be transferred from this source via an environmental and/or product vector.

A risk assessment for a contamination transfer vector is a little more complex as it involves three factors: the potential for a pathogen being present on the product vector, the frequency of the vector and the severity of the impact of the hazard to the consumer of the product.

If a risk ranking of 1, 2 and 3 were used as a substitute for low, medium and high risk, respectively, a multiplication range can then be used to determine a risk score, which can help describe the significance of the contamination source or vector. For a source, the risk score would be in the range of 1 (low potential presence multiplied by low potential spread) to 9 (high times high). For a vector the risk score would be in the range of 1 (low potential presence multiplied by low frequency multiplied by low severity) to 27 (high times high times high).

TABLE 24.1 Potential Sources of *Listeria* Contamination Detected around a Meat Slicer in a High Risk Food Production Area that is no Longer in Existence

Process Step or Environment	Observation	Likely Hazard	Source Hazard Analysis without Controls: Microbial Source Presence LMH	Source Hazard Analysis without Controls: Potential to Spread Via Environmental Vectors LMH	Source Hazard Analysis without Controls: Risk Score	Current or Intended Control	Source Hazard Analysis with Controls: Microbial Source Presence LMH	Source Hazard Analysis with Controls: Potential to Spread Via Environmental Vectors LMH	Source Hazard Analysis with Controls: Risk Score
Meat slicer	Meat residues were seen on the inside of a switch that operated the meat slicer. When the switch was pressed in to start the machine slicing, the movement of the switch into its housing extruded meat residues onto the food operative's finger. If *Listeria* were present in the switch (which has occurred in previous installations) it could be transferred to the meat by contact with the operative's finger. Routine microbiological sampling of the switch for *Listeria* was always negative	*Listeria*	Medium 2	Low 1	2	Switches routinely cleaned as part of the end-of-production sanitation program	Low 1	Low 1	1
Meat slicer	Fluids were seen oozing out from below the foot plates supporting the legs of the meat slicer. The immediate area surrounding the foot plates is a heavy traffic area for both operatives and wheeled containers. Environmental microbiological sampling occasionally detects *Listeria* spp. from around the support plate	*Listeria*	High 3	High 3	9	Following cleaning during the end-of-production sanitation program, the foot plates are sprayed with 1% sodium hypochlorite	Medium 2	High 3	6

TABLE 24.2 Potential Vectors of *Salmonella* in a Milk Spray Drying Operation that has been Subsequently Refurbished

Process Step or Environment	Observation	Likely Hazard	Contamination Event Vector	Product Vector Analysis without Controls: Potential Presence on Vector LMH	Frequency of Vector LMH	Severity of Hazard LMH	Risk Score	Subsequent Control Step	Current or Intended Controls	Product Vector Analysis with Controls: Potential Presence on Vector LMH	Frequency of Vector LMH	Severity of Hazard LMH	Risk Score
Personnel hygiene	Food operatives are able to enter toilets without first removing their protective cleaning	*Salmonella*	Clothing touching food or food contact surfaces during food handling	M 2	H 3	H 3	18	None	Staff are responsible for the laundering of their own protective clothing	M 2	H 3	H 3	18
Personnel hygiene	Food operatives are able to enter toilets without first removing their protective cleaning	*Salmonella*	Clothing touching food or food contact surfaces during food handling	M 2	H 3	H 3	18	None	Staff are provided with professionally laundered clothing every day which is worn only within food production areas	L 1	H 3	H 3	9
Milk spray drying	Guillotines are inserted into the dryer to separate, e.g., the dryer from the baghouse during CIP cleaning of the dryer	*Salmonella*	Contamination on the reverse side of the guillotine entering the dryer on insertion and/or removal	M 2	H 3	H 3	18	Prior to start-up, the dryer surfaces are subjected to 200°C for 2 hours	General GMPs are practiced				
Milk spray drying	Approximately once per shift, milk injectors are removed from the dryer, cleaned, disinfected and reinserted	*Salmonella*	Dryer nozzles touch hands (gloves) clothing, tools and the dryer prior to entry	H 3	H 3	H 3	27	None	Gloves are worn and nozzles, tools and dryer contact surfaces are decontaminated with alcohol prior to dryer entry	L 1	H 3	H 3	9
Milk spray drying		*Salmonella*	Air can enter the dryer during the nozzle removal and reinsertion process	L 1	H 3	H 3	9	None	None				

Risk ranking of sources and vectors should be recorded as illustrated in Tables 24.1 and 24.2, both before and after controls are applied. Undertaking a risk analysis before and after the application of any controls can help identify whether controls are necessary and/or whether current or intended controls are sufficient to reduce the risk of the source or contamination event. As a minimum, this allows consideration of the adoption of controls for the uncontrolled sources and vectors that the environmental study has identified, which may have an immediate impact on improved food safety. In the case of current controls not being sufficient to adequately control the hazard risk, additional controls are required. To illustrate this and using the clothing vector as described in Table 24.2, a better control would be to implement a policy where protective clothing was only worn inside the food processing area and had to be removed before staff could leave this area (Table 24.2). In comparing the two controls in Table 24.2, it can be seen that the severity of the potential contamination to the food product with *Salmonella* remains the same, as does the frequency of the wearing of the uniform and its potential contact with a food product. However, as the uniform now no longer leaves the processing area, the potential presence of *Salmonella* on the uniform is significantly reduced, lowering the overall risk.

Subsequent controls should also be considered when assessing the risk of a contamination event. In the example in Table 24.2, operatives had to insert a stainless steel guillotine into the powder line to prevent CIP fluids entering sensitive areas during the dryer CIP program, e.g. the bag house or the gas burners to heat the incoming air. Any microbial contamination entering the dryer, particularly during the removal of the guillotines, would then be subjected to the dryer start-up procedure which could include the circulation of heated air for several hours (e.g. 204°C/400°F for 2 hours).

In the second dryer intervention example in Table 24.2, the removal, cleaning and insertion of the milk spray nozzles occurred every day, while CIP cleaning was undertaken every 3 weeks. Any microorganisms entering the dryer during these potential contamination events would not be subjected to a process control step. In this example, it is possible to do a risk assessment on the contamination event or, and particularly if the contamination event results in a high risk score, individual vectors related to the event to determine which of the vectors are important to control. In this case the entry of air has been chosen as an example of one of the vectors and the risk assessment for the air indicates that other vectors associated with the contamination event may be more important.

A high risk score if controls are not implemented can also be used to justify capital expenditure. For example, in Table 24.1, the capital required to stop production, remove the poorly designed foot plate, decontaminate the floor and fit and seal an improved hygienically designed foot plate could have been justified as the existing controls were inadequate and the risk of the potential for any contamination to be spread from this point remained high as the slicing machine was in a high personnel and vehicular traffic area.

9. Determine Operational Prerequisites

Control of food product contamination is a combination of reducing the number of possible hazard harborage sites and niches, controlling those that microbiological sampling has previously identified that may be a known risk, removing all unnecessary contamination vectors and controlling those that remain or are intrinsic to the food production process.

However, the control of some sources or vectors (prerequisites) may be more critical to the safety of the food product than others. The concept of a ranking system for prerequisites has been addressed by ISO 22000 (Anon, 2005), which differentiates operational prerequisites from prerequisites and defines them as being *identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or processing environment*. ISO 22000 thus suggests that a hazard analysis may identify that there may be some sources or routes of contamination that are so important to the safety of the food product that their control is essential and are thus elevated as a higher classification of prerequisite, i.e. operational prerequisites. Other definitions of operational prerequisites exist, however, for example Gaze (2009) defines operational prerequisites as control *measures associated with a particular process step and which manage specific significant hazards identified during hazard analysis but are not otherwise managed by CCPs* and *with a frequency of monitoring/checking of the control measure that is not sufficient to enable immediate corrective action*.

There is no agreed definition, therefore, of operational prerequisites and neither ISO 22000 nor Gaze (2009) give guidance as to the hazard analysis steps to be undertaken to identify an operational prerequisite. Similarly, there may be some confusion in terminology between individual operational prerequisites (OPs), which are single, and operational prerequisite programs (OPRPs), which are a collection of operational prerequisites.

The hazard analysis as described in Tables 24.1 and 24.2 for sources and contamination event vectors, respectively, can further be developed by considering the risk scores for the sources and vectors without controls. For the maximum risk scores associated with the meat slicer equipment floor plates (Table 24.1) or the removal, cleaning and reinstallation of the spray nozzles (Table 24.2), theses scores indicate that if these sources or contamination events were uncontrolled, or more practically, if the required controls failed, there would be a significant risk of pathogens being present in the processing environment (meat slicer foot plate) or product (spray nozzles). The control of these sources and vectors is thus critical to the safety of the product and, based on this risk assessment approach, such controls could be described as operational prerequisites.

10. Establish Control or Operating Limits

Wherever possible, control or operating limits should be identified for each OP. These may be defined in legislation, codes of practice and other guidance documents, though the majority are likely to be determined from collection of experimental data during trials, e.g. cleaning validation data, or from the advice of experts. In some cases there may be lower and upper control limits, together with a target limit. In rare cases the control limits may be critical limits as defined in HACCP (Gaze, 2009), though this would be unusual. For example, in water treatment systems to allow water reuse, disinfectant levels such as a minimal chlorine level of 0.5 ppm may be deemed critical to the safe disinfection of the water.

The specific control limits for each OP must be a measurable (e.g. ATP or protein levels after cleaning, disinfectant levels, flow rates, pHs, temperatures, pressures, contact times) or an observable parameter related to the control option. Measurements are preferred but where control limits are based on subjective data (e.g. visual observations) the food processor needs to provide clear guidance on requirements for compliance with practices or

procedures or pictorial examples of what is acceptable (e.g. photographs to define clean surfaces or appropriate wearing of protective clothing). For the example in Table 24.3 an operating limit could be applied to a rapid assessment of the cleanliness of the wands, nozzles and tools by ATP or protein testing prior to entry. The PEP team should record details of how the control limit was determined, including relevant sources of information or experimental/validation trial data.

11. Establish a Monitoring System

Monitoring systems describe the methods by which the food processor ensures that the OPs are operating within their defined control or operating limits and are thus "in control" and, as a corollary of this, produces an accurate performance record which can be used for process verification (Stage 13). The monitoring system must be able to detect loss of control at the OP in a timeframe to provide corrective action to regain control of the OP.

Monitoring systems should ideally be on-line and could include air and gas pressure, humidity, temperature, chemical concentration, redox, conductivity or pH probes; UV intensity, flow rate; and rapid hygiene checks such as ATP, allergen and protein tests. Some on-line monitoring systems have a direct feedback system with the ability to directly control (and record) any drift in the control limit, and these are preferred. For these analytical methods, the PEP team should establish whether there are any required national reference methods for the parameters to be monitored. Microbiological sampling of source and vector controls would not be considered as a monitoring option as it may take 24–48 hours to enumerate samples; too long a time to maintain effective control.

Other monitoring checks may be visible and could include an assessment of cleanliness, an assessment of a personnel clothing changing procedure or whether a procedure is correctly being followed. For the example in Table 24.3, during the nozzle removal procedure, observations could be made to ensure that the procedure was being undertaken correctly and that there were no extrinsic factors which could act as additional contamination vectors.

The PEP team should record the job title or name of the individual(s) responsible for monitoring and ensure that they have the knowledge, competence and authority to take appropriate and stated corrective actions (Stage 12). Records of the necessary training and competence of these individuals must be signed and retained. The PEP team should also ensure that detailed specifications, procedures or work instructions to enable the monitoring to be effectively undertaken are added to the company's quality system.

12. Establish a Corrective Action Plan

Practical and achievable corrective actions to be undertaken when the results of monitoring at an OP detect a situation where a control limit has not been met (deviation) or when a treatment system is drifting out of control should be specified by the PEP team. Responsibilities for corrective actions should be clearly defined and all relevant personnel should be trained and competent. The relevant person(s) should have the authority to undertake the stated corrective actions. For the example in Table 24.3, corrective actions would review the training of the staff against removal and reinstallation procedures and the effectiveness and validation of the tools and cleaning equipment decontamination programs.

TABLE 24.3 Operational Prerequisite Management Table as Adapted from Classical HACCP CCP Management

Process Step or Area	Likely Hazard	Source or Contamination Event Vector	Control Measure(s)	Operating Limit(s)	Verification(s)	Corrective Action(s)	Records
Milk spray drying	*Salmonella*	Removal, cleaning and reinsertion of milk spraying nozzles	(1) Spray dryer processing is air filtered to 95% removal of 1.0 μm particles (2) Gloves are worn by operatives to remove and replace nozzles (3) Nozzles and support wands are removed and replaced by an alcohol-decontaminated blanking plate (4) Nozzles cleaned and covered with plastic bag until reinsertion (5) Gloves and plastic sleeve change by operatives prior to reinsertion (6) ATP assessment of cleaned nozzles. If RLU value <150, nozzles inserted (otherwise re-cleaned) (7) Use of dedicated tools (8) Alcohol decontamination of gloves, sleeves, nozzles, wands, tools and spray dryer contact surfaces (9) Blanking plate removal and nozzle reinsertion (10) Tamperproof tag installed	ATP <150RLU	(1) ATP assessment of the cleaned wand and nozzle (2) Visual assessment of the removal and reinsertion procedure (3) Occasional microbiological verification of wand, nozzle, tool and spray dryer contact surface cleaning	(1) Staff retraining (2) Revue of wand, nozzle, tool and spray dryer contact surface cleaning	(1) Dryer intervention record including correct observation of removal and reinsertion procedure (2) Post-decontamination RLU values (3) Post-decontamination microbiological values (4) Tamperproof identity tag number

Any product that could have been contaminated through any loss of control should be placed on hold following company quarantine procedures to allow authorized personnel to determine its fate. It is unlikely that a product recall would be instigated as the frequency of monitoring of the OP should be sufficient to prevent unsafe foodstuffs reaching the consumer. The cause of the deviation should then be investigated and appropriate remedial action taken, such that the OP will be returned to control. Further steps must then be taken to ensure that the same issue cannot occur in the future and the company should confirm that remedial actions have been undertaken and that they will be effective.

13. Verification

The verification stage is concerned with three activities: validation, verification and review. The objective of the validation stage is to ensure that all sources and contamination vectors for hazards that could be present in the processing environment have been considered and that the controls put in place to reduce or eliminate them are technically sound and effective. The first stage of the validation is a desktop activity to review the identification, selection and/or exclusion of hazards, the risk analysis of identified hazards, the appropriateness of the selected controls, the designation of controls as OPs, the suitability of their control limits and monitoring/verification methods and the adequateness of the corrective actions. This can be undertaken by the PEP team, but may be improved by the input of additional, independent experts, and the environmental plan must be signed off by the person ultimately responsible for product safety management in the food operation.

The second stage of the validation process is the validation of the identified control actions, as appropriate. In the example in Table 24.3, the efficacy of the tool and nozzl cleaning and disinfection process can be validated by undertaking the cleaning exercise number of times and recording the level of cleanliness achieved as an ATP relative light uni (RLU) count. On each cleaning occasion everything should be undertaken to the best possible standards with defined chemicals at the correct concentration and temperature, the appropriate cleaning staff and techniques and for the scheduled times. The average ATP value after these cleans is thus the minimum level that could be obtained for these nozzles and tools, following their particular use and using the cleaning and disinfection method adopted. The target ATP level to be reached on each occasion may thus be this value plus a small margin for error.

Verification of the PEP gathers information from routine analytical tests that are used to demonstrate the effectiveness of the hazard controls and OPs in a timeframe beyond that of monitoring (Stage 11). For example, while microbiological sampling of the tools and nozzles in Table 24.3 is not acceptable for monitoring of a control measure, it could be undertaken for verification purposes. As with monitoring, the PEP team should record the job title or name of the individual(s) responsible for verification and ensure that they have the knowledge, competency and authority to take appropriate and stated corrective actions (Stage 12). There should also be detailed verification specifications, procedures or work instructions added to the company's quality system. Signed records of all verification activities must be retained to provide evidence that the PEP has been correctly implemented and the controls are working effectively.

Verification is also a desktop and audit exercise to examine the entire PEP and examples of such activities include: internal auditing of OPs to establish, e.g., that personnel are following the stated procedures/work instructions; external auditing programs (supplier audits, third party audits); analysis of customer complaints; trending of monitoring and verification results and a review of any deviations, corrective actions and any resulting foodstuff disposal.

In accordance with the general principles of food safety management, the safety of the Environmental Plan has to be reviewed on a regular basis and at least annually. The review should demonstrate that the plan is still relevant and that controls are working effectively. A review of the plan should also be initiated following any significant change to the food production process or the processing environment, for example (see Chapters 1 and 31):

- Change in the production process which affects its management from the processing environment, e.g. transport flows, service routes.
- Change in factory environment, e.g. building work.
- Changes in cleaning and disinfection practices.
- Changes to production equipment and maintenance schedules.
- Changes in legislation or codes of practice relating to, e.g., control limits or methods of analysis.

14. Establish Documentation and Record Keeping

Accurate and efficient record keeping is essential to the successful application of the PEP. Records should be accurate, timed and dated, include the actual as well as any calculated results, and be signed by the individual responsible for the assessment and by a delegated supervisor/manager who reviews the results. All records should be retained for at least the shelf-life of any foodstuffs and be sufficient to enable records to be available to support a defense of due diligence. In the example in Table 24.3, records would be kept of all interventions into the spray dryer, whether nozzle removal and reinstallation procedures had been correctly followed, ATP and microbiological counts following nozzle and tool cleaning and the use of any tamperproof tag numbers.

FUTURE STUDIES

The concept of the PMP and the PEP, which contain the identification of sources and vectors of contamination, their risk assessment to determine their necessary controls and the management of operational prerequisites in a similar fashion as critical control points, is a developing study. Together with the process of assessing all hazards of concern to the food product and implementing appropriate prerequisites as required by the HACCP plan, this overall concept can be represented by the prerequisite management plan pyramid as illustrated in Figure 24.7. By elevating the control of some contamination sources and vectors to the level of operational prerequisites and giving them the same management status as CCPs, this concept has aided a number of pioneering food manufacturers to focus their attention on the control of what are thought to be the highest risked contamination events to

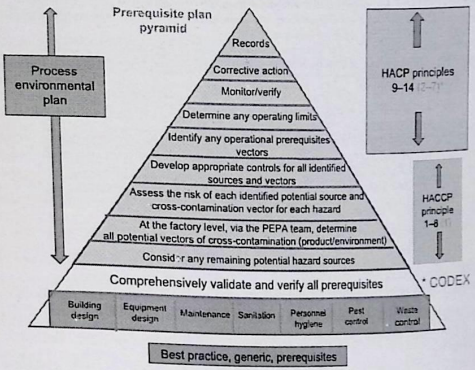

FIGURE 24.7 Prerequisite Management Plan pyramid.

the RTE product in their manufacturing process and as such has enhanced their food safety management plans.

The PMP may be constructed as a separate document with any procedures and work instructions integrated into the company business management system (BMS) or as part of the prerequisite section of the HACCP plan. What is clear, however, is that appropriate attention has to be applied to the control and management of the manufacturing process and the processing environment, via the HACCP plan, PMP and BMS to ensure that a combined food safety plan is truly effective. Additional studies are required to establish how this concept can be further improved.

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CHAPTER

25

Site Selection, Site Layout, Building Design

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OUTLINE

Food Safety Management
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INTRODUCTION

The integrity of the building influences the access of pests (rodents and other small crawling animals, birds, insects), microorganisms, dust and polluted air to the products that are produced. The chances of such contaminations depend on the environment of the factory and therefore it is important to pay attention to the site. The higher the concentration of any type of contamination in the environment, the more difficult it will be to ensure that the production area will be suitable for the production of safe food products, and consequently the more expensive it will be to meet the food safety requirements.

Reconstruction and maintenance works often are done while production is continued in other areas of the same building. At such times, the safety of the food processing operation may be severely challenged. Adequate measures to prevent loss of integrity of the operation must be taken before such works start, otherwise the food operations must be interrupted until these works are finished and inspection shows that the plant is clean and ready for resuming production.

REGULATORY REQUIREMENTS

To protect the consumer, many countries currently have strict requirements with respect to food safety. Enforcement, however, may be insufficient, because in many countries legislation is weak or there is insufficient inspection capacity to ensure that regulatory requirements are met. Traditionally, this has to do with governmental budgets and priorities. Subsequent to well-publicized food scares the budget will temporarily be higher. Although the food safety requirements may be fairly, but certainly not completely (Boisrobert et al., 2010), similar between countries, it may be obvious that there are differences in requirements with respect to the environment and buildings. This is because the burden of hazards varies between regions. Factors like local climate (particularly temperature and humidity), domestic pests, husbandry (use of manure), degree of air and soil pollution and geological conditions may lead to differences in the concentration of undesirable chemicals and microorganisms in the factory environment. Some countries are prone to earthquakes, others to flooding and some to both. Consequently, risks of food safety incidents may differ too. Although in many countries food safety regulations are in place, the situation is rather different for environmental regulations. In some countries such regulations are non-existent. The consequence is that the environment of a factory may unexpectedly change and cause tremendous problems. Authorities may decide that a certain location is the best one to dump municipal wastes, because if it is disposed of closer to the population it will affect the opinion of the electorate. Nevertheless, in many countries the law requires that the premises (buildings) for food handling and processing are hygienic. These laws, however, do not specify how this must be done and hold the company fully responsible for ensuring that the premises are hygienic. An organization that does provide guidance on meeting hygiene requirement is EHEDG (see www.ehedg.org).

RETAILER'S REQUIREMENTS

Retailers are the first to deal with complaints of consumers; their reputation may be at stake, in particular where they have their own labeled goods. Therefore, retailers have good reasons to have their own requirements with respect to the hygienic condition of the factories from which they obtain their products. Even in countries where food safety regulations are adequate, retailers increasingly inspect and certify their suppliers for the simple reason that the regulators usually fail to do so or do so effectively.

SITE SELECTION

The site influences the design of the building, in order to cope with local conditions that may influence food safety. Examples are the quality of water and air, local pests (insects, birds), farms, water treatment plants, etc.

If the site is in an area with a more than average concentration of airborne microorganisms, insects and birds, there is also an above average chance of contamination of unprotected raw materials (such is often the case with fresh produce and meat) during off-loading. Sites near waste treatment plants and farms, in particular if downwind from them, may have to cope with severe problems, because untreated waste water and manure are likely to contain high concentrations of pathogenic bacteria, including *Vibrio*, *Salmonella*, *Escherichia coli*, *Campylobacter* and *Yersinia* species, and *Shigella* in addition to protozoa and viruses. These microbes may become airborne, depending on the design of the wastewater treatment system and at times when farmers spread manure to fertilize the land. The microbes will challenge the factory's air system. In addition, every time an entrance is open, anything airborne may successfully attempt to get into the factory. The building must therefore be provided with loading and off-loading bays that reduce this risk to an acceptable minimum. For the same reasons, any entrance for people, materials and air will need additional measures to keep the contamination risks sufficiently low. This is an important aspect in the selection of a suitable site. It is better not to have the factory near a sewage treatment plant, and also to make certain that such a plant will not be situated near the factory in the future. The same applies to legal waste disposal facilities and landfills. Local zoning plans will need checking and written confirmation will be needed to ensure such plants will not be built a certain distance from the factory. Nearby chemical industries may produce potentially toxic substances, which may contaminate not only the air but also the soil (with, e.g., heavy metals or chlorinated hydrocarbons), which is particularly important if well water is used, as discussed below. Be aware that the site under consideration may have been polluted, e.g. as a result of mining activities, chemical industries or (legal or illegal) waste disposal. The presence of pollution in the soil should be carefully checked.

Another requirement is the quality of water available at the site. There are large areas in the world where safe water is readily available, but there are also large areas where it is not. If available, but of unacceptable quality, an in-house water treatment facility must be

installed and maintained. If the availability of water cannot be guaranteed, a well may have to be drilled. Such measures will add to the final product costs.

To operate a factory, energy is required. The energy supply may be unreliable, in particular with respect to electricity. This may severely undermine food safety management and cause incidents, because to maintain conditions to prevent the ingress of contaminated air, such as maintaining pressure differences between the various zones in the factory, electricity is essential. The same holds for cooling and freezing and for the operation of measuring, controlling and registration equipment. If the electricity fails, so will the control of processing temperatures and flow rates through pipelines. Hence, if interruptions are likely to take place, adequate back-up systems (e.g. oil-powered electricity generators) must be installed, the capacity depending on how long interruptions may last. It is important to obtain a guarantee from the local electricity supplier and to be certain also to ask for advice from a reliable local consultant.

SITE LAYOUT

For the same reasons as discussed above, the layout of the site must prevent access of pests to the factory. To keep animals at bay, there must be fences that are high enough to prevent dogs and cats from entering the area, but at the same time deep enough to prevent burrowing animals (rats, rabbits) to gain access. The fences must be such that they do not allow animals (including monkeys) to climb over them. Any unpaved surface must be covered by grass that is kept short to avoid breeding of small animals. For similar reasons, there should be no shrubs or trees or they should be remote from the factory wall and particularly its entrances and air inlets. Because they provide places for microbes and insects to breed, there should be no ponds or any other possibilities for stagnant water or mud. For these reasons, pavements should be horizontal or slightly sloping towards drain pits.

External lighting should always be away from the factory walls and entrances, luring insects away from the building instead of attracting them to it.

Every effort must be made to prevent insects, small animals and microbes from multiplying and worsening the environment of the factory: waste disposal areas too must be such that they do not allow ingress of insects and animals. Moreover, to limit undue growth of molds and bacteria, solid waste should be kept dry. This means that, although the disposal area must be outside the factory, it should nevertheless be covered to cope with precipitation. Doors to the area must be rodent resistant and be insect-proof. The doors should preferably be self-closing, otherwise an alarm should sound if the door has been open for any length of time (minutes, rather than hours).

Access to Production Areas

The entrance of the production area must be equipped with hand-washing facilities such that everybody entering the area must pass these facilities. Restrooms (toilets, washrooms, lavatories) must not be directly connected to the production area and must be easy to clean. Depending on the type of products handled in a certain area, it may be necessary to minimize the risk of transfer of contamination from the outside into that area by using a change room, where garments can be exchanged for special production room garments. The room

should have a step-over barrier to leave shoes and boots that are worn outside on one side, and on the other side to put on footwear to be used exclusively in the production area. The step-over must be sealed to prevent contamination on the floor from moving to the production area. There must be a means for cleaning, disinfection and drying of hands.

Processing and packaging areas should not be used as a passageway to canteens or other amenities. Therefore, the layout of the building should take into account that cafeterias, kitchens, offices, laboratories, workshops, chemical stores, etc. are not connected to the production and packaging areas. Anybody, including laboratory staff, directors and important visitors, who needs to be in the production area should pass the change room or handwashing facilities, as applicable, and use them as per the personal hygiene instructions. Similarly, any vehicle that is needed to transport raw materials, ingredients or finished products should have designated routes and should not be used for anything else.

BUILDING DESIGN

Supporting Structure, Foundation, External Walls and Roofs

The supporting structure for the factory should ensure that the floor is at an elevated level, so that there is no risk of rain, mud or other precipitation entering the factory. In regions with potentially heavy rainfall, the floor level should be higher than any area in the environment, to avoid the factory being flooded.

Apart from their function to protect the factory from bad weather conditions and sometimes the sun, external walls, roofs and the foundations are the first and most important barriers to the ingress of pests, in particular rodents, geckos, birds and insects. Hence, the design must be such that there are no openings that allow animals and insects to enter the building. In addition, it must be ensured that the structure is such that rodents and, in some areas of the world, termites, cannot gain access. Any areas between the ceiling and the roof must be entirely closed off to avoid them being used for nesting by birds, mice or rats. Bird droppings contain high concentrations of microorganisms, including pathogens such as *Salmonella*. Special attention should be paid to effectively seal the connections between roof and walls. Similarly, the connection between the foundation and the wall must be rodent-proof.

To avoid attracting vermin on the roof, it should be kept dry and also be sloped. External walls and roofs should be easy to clean and maintain. The outer walls should not have ridges or other protrusions that allow birds to settle and breed. Adequate measures should discourage birds from settling.

Entry and Exit Points

Entry points should be designed such that they allow passage of personnel and goods but prevent entry of pests as effectively as possible. This requires automatically closing doors that are rodent resistant and in some locations also termite resistant. The doors should close such that even small insects like ants cannot gain access.

It is important to build the factory in such a way that the openings are downwind, at least as much as possible, so that wind is not blowing any undesirable matter into the

factory. Doors and windows that normally are not used are places where insects may breed in the narrow space between the frames and the doors and windows. Hence, care must be taken that such crevices be sealed with a good quality tape that is resistant to cleaning chemicals. Also, windows and doors must still be able to be used in case of emergencies.

Internal Walls, Floors and Ceilings

Walls must be non-absorbent and well cleanable, and should not have recesses or cracks that can harbor insects. The wall must be able to withstand damage that may result in product contamination. For the same reason, any paint used should be of a quality that does not flake off. The use of strong, slightly elastic wall coatings is recommended. Corners may have to be protected by metal reinforcements. The same applies to the lower part of the walls, where bumper constructions should prevent damage when fork trucks may accidentally hit the wall.

The floor often plays an important role in product contamination incidents. Improperly designed floors may accumulate moisture and nutrients for insects and bacteria. Movement (e.g. of people, vehicles) over such floors then causes aerosols that carry microorganisms. Insects full of microbes may crawl out and enter the product, visibly or not. Hence, floors, unless in areas that will never be wet, must be watertight and slope towards drains, so that any liquid spilled can be easily removed. The floor must also withstand cleaning chemicals and the temperature of hot water that may be needed for cleaning. Floors must be able to withstand damage by personnel and moving of equipment. Since the 1970s, composite floor materials (epoxy, meta-acrylate, polyester, polyurethane) have become popular, in particular in new or refurbished factories, but often with disappointing results. The materials are not as strong mechanically as good quality tiles. Forklift trucks, containers with raw materials or intermediate products and waste containers can easily damage such floors. The floors must also withstand the installation of machinery. If machines are installed on an intact epoxy floor, the integrity of that floor may be affected and moisture may penetrate to the supporting structure. The lively matter developing under these floors cannot be removed without removing the affected area of the floor. If the floor is to be subjected to heavy loads and to the movement of forklift trucks or equivalent, tiles are to be recommended. Care must be taken, however, that the tiles are grouted such that no moisture is absorbed, creating undesirable circumstances. Hence, the grouting must be resilient and water repellent. It is also easier to repair a damaged tiled floor than a damaged composite floor. Although floors should be easy to clean and hence be smooth, they should not be so smooth that they will be too slippery to walk on. Despite the drawbacks, there may be applications where composite floors provide the best solution, taking into account the prevailing operation conditions.

To allow effective cleaning, the transition between floor and walls must be rounded. For tiled floors, special tiles are available.

To avoid dust falling down on exposed product or product contact surfaces, ceilings must be tight and hence false ceilings should not be used in food processing plants. Suspended service ceilings, however, are fully acceptable and provide the advantage of mounting cables, service ducts, etc. above the process area from where they can be extended downwards to where they are needed. This way, the risk of contamination of product by dust that accumulates on these provisions is drastically reduced. The construction of these service floors must self-evidently be such that it does not allow any dust to pass from the area

above the ceiling to the production area, which means that the passages of the ducts, etc. must be effectively sealed.

Lighting

There must be enough light in the factory firstly for the personnel to do their job properly and efficiently and secondly so that dust, dirt and vermin or their traces can be detected. To avoid the risk of contamination of product with glass, glass windows are generally avoided, but modern types of glass are very strong and are available in shatterproof quality. If well mounted they will not easily break and if they do, they will not splinter into small pieces, even if accidentally struck with any great force.

Lamps for artificial illumination must be covered by shatterproof covers that are tight, so that an exploding lamp cannot contaminate product. To avoid accumulation of insects and dust, lighting should preferably be mounted in the suspended service ceiling, with the underside flush with the ceiling. Besides preventing the collection of dust and insects, it also enables the replacement of the lamps from the top, without interfering with the products. In the absence of a suspended ceiling or if the ceiling is too high above the surfaces to be illuminated, the topside of the housing of the lamps must slope at an angle of approximately $45° (\pi/4)$ to prevent anything from settling.

Temperature Control

For the comfort of the personnel in the factory, air conditioning may be needed. Where food is processed under chilled conditions, cooling units are used. These units have trays underneath to prevent condensate from dripping onto personnel and product. What is not realized but is very important from a food safety point of view is that these trays are perfect places for the selective cultivation of psychrotrophic bacteria, specifically *Listeria monocytogenes*, a pathogen that may cause listeriosis. It is a fairly selective process because at low temperatures, *Listeria monocytogenes* grows faster than most other microorganisms. The fans of the cooling unit complete the food safety risk because the circulation of air helps to spread the contaminated condensate over the product. Therefore, collectors of condensate should always slope to one side, from where the condensate is led to a hygienic drain pit. Moreover, collectors need to be easily accessible for regular inspection, cleaning and disinfection.

To make the control of the temperature efficient and affordable, as well as to prevent condensation on walls, ceilings and windows, thermal insulation of walls and roof (and/or service ceiling) and double-glass windows are needed. Care must be taken that the installation of insulation panels does not create a space for the breeding of insects between the wall and the panel. The panels should be smooth for ease of cleaning and their surface should be strong enough to prevent damage under the applicable conditions.

Noise Control

Machinery may produce more noise than is desirable or legally acceptable. Noise-absorbing panels may and have been used on a large scale. Nevertheless, because they must be cleanable and hence their surface must be smooth, these hygienically acceptable panels

are not very effective. Increasingly, food processing machinery is designed to produce significantly less noise than a few decades ago and the best solution for noise reduction may be encasing the noisy parts using panels with the sound-absorbing surface at the inside and having a smooth outer surface. There may also be situations where it is more attractive and efficient to use noise-canceling earphones for personnel working near noisy machinery.

Sewers, Gutters and Drains

Sewers can be a serious means of contamination of the interior of a building. The design may be such that even large animals like rats gain access, unless appropriate measures are taken to prevent this. The design must also be such that there cannot be pressure differences large enough to cause gases to enter the interior of the factory in any way. It is highly recommendable to keep the sewer system physically separated from other waste water systems, which are connected to floor drains throughout the factory. Gutters tend to be covered by perforated covers and cleaning the gutters and covers is usually troublesome. Moreover, water, often contaminated with spilled product, tends to be stagnant in most parts of the gutters, allowing microbial growth and nesting of cockroaches and other insects. Gutters therefore should be avoided and hygienic floor drains should be used instead, while the floors should slope towards these drains. The drains, however, can also become breeding places for insects and bacteria. They therefore should be of a design that can be disinfected and in high-care areas should preferably be of a kind that can hold disinfecting substances.

Internal Zoning, Ventilation and Air Conditioning

An adequate air supply is needed to ensure a sufficient supply of oxygen and to control the temperature in the production environment. Depending on the temperature required and the amount of heat produced by the machinery or the processing of the product, the amount of air needed may vary greatly between factories and hence also the dimensions and design of air ducts and exhausts. To make the risk of airborne contamination of exposed product or food contact surfaces as small as possible, the air should flow from the exposed final product area, through areas where such contamination is less important, to the area where materials arrive. This requirement influences the differences in pressure needed between the various zones in the building. The air supplied to the cleanest areas should self-evidently be adequately filtered, to the degree needed to meet the product safety requirements. HEPA (high-efficiency particulate air) filters will be required where microbiologically vulnerable products are exposed to the air. Between pre-filters, intended to remove course particles and insects, and the fine (HEPA) filters, intended to remove microorganisms, dehumidifiers must be installed to ensure that the fine filters remain dry and to prevent condensation in the production area. The combination of differences in temperature and humidity may result in condensation and hence wet spots in the process area, resulting in the growth of bacteria and fungi, which may become airborne and contaminate the product. Hence, care must be taken that either such condensation cannot take place or takes place under control, at easily accessible locations, enabling inspection, cleaning and disinfection. Air inlets should be positioned at a distance from the air outlets of the factory to prevent

contaminated air to unnecessarily burden the air inlet filters and dehumidifiers. Both inlets and outlets must be provided with screens to prevent entry of flying animals and insects.

If in the factory materials are processed that contain allergens, special attention should be paid to air flows to avoid the air from the area where allergenic products are processed passing to areas where products are processed or packed which must be or are supposed to be free from these allergens.

Zoning of food production premises is important to prevent (re)contamination of exposed food and also proportionate use of protective measures and verifications (e.g. environmental monitoring). Details on zoning can be found in Holah and Lelieveld (2011). It may be difficult to realize appropriate zoning in very small premises (Todd et al., 2010). Nevertheless, if vulnerable products are made in such premises, the zoning rules should be met or such products should not be produced.

Walkways and Stairways

Footwear, also the special footwear that has been put on before entering the production hall of the factory, collects dust and dirt and hence may shed dirt again when the wearer moves around. It would be safest if levels of contamination on footwear of any person who needs to be in the factory during production would stay below those of any exposed food product and any food contact surface. There are circumstances, however, that necessitate staff to cross over such areas and hence stairways and bridges are needed. It may be required that during production, parts of machinery that are positioned high on a machine must be adjusted or replaced. In such a case, an elevated walkway is needed. Stairs, bridges and walkways must be designed and constructed such that no dirt from footwear can contaminate the food and food contact surfaces. Consequently, open structures are not acceptable and there must be sides that are high enough to prevent any dust or dirt from falling down.

Process Support and Utility Systems

To operate the food processing and packaging equipment, product, ingredients, cooling or heating media (steam, water), air, electricity, signal cables and packing material all have to be brought to where they are needed. This requires pipes, cables, conveyor systems and support structures. Together this can become a nightmare from a hygiene point of view. When combined, which is unavoidable, because they all need to reach the same machine, these items form ideal places for insects and other pests to hide and breed. They collect dust and dirt and are a source of dead insects that may fall down to contaminate product underneath. Moreover, they are very difficult if not impossible to clean.

Cables (electric power supply, signal transfer) and small pipes (compressed air, nitrogen, lubricants) should best be grouped together in ducts, which can be larger pipes or special designs. To prevent ingress of insects, these ducts must be effectively sealed at any entry or exit point of a cable or pipe, at least at the processing side. When building a new factory, probably the best way would be to have a service area below the production floor, provided that the space will be high enough for access of service personnel. From that area, service ducts may rise to the machine and the cables and pipes stay largely below the exposed

product level. If a service floor is not possible, a suspended service ceiling can be a good solution. The passage of the ducts through the floor or ceiling must be such that nothing else, not even air, can pass through.

Pipes for transport of product or product ingredients may have to pass through walls or ceilings between various processing departments. Care must be taken that such passages are either tight, not allowing anything passing around them, or large enough to allow cleaning and inspection of the passage. If tight, the construction must be such that they remain tight with time and hence the passage can absorb vibrations caused by machinery to which the pipes are connected and the changes in length and diameter of the pipes as a result of thermal expansion.

Where product or packaging material must pass through walls or ceilings using conveyor belts, chains or slides, care must be taken that the passage itself is cleanable and accessible for cleaning and inspection.

Food Storage Rooms

Food storage must be designed to make certain that insects and other pests cannot reach the food, even if the food is packed. It must be possible to control the humidity to ensure that the area is always dry. Temperature control and monitoring is essential for storage of perishable products. Entrance of insects and small animals can be prevented by building the storage room on an elevated level, but such that also the entrance is higher than the outside pavement. Further, the storage room should meet the general requirements that also hold for the processing area to ensure that the space can be cleaned: smooth walls and ceilings, no ridges, no surface cracks and other crevices where insects may hide. Walls must be watertight to avoid wet surfaces on the inside. It is important that the lighting is sufficient for inspection to spot any traces of vermin. There must be enough space between the wall and the stored products for inspection.

Storage of Grain

Large qualities of grains (rice, wheat, corn, etc.) are usually stored in silos. Self-evidently, the silos must be sealed to avoid the entrance of vermin. Chances are, however, that there are insects already in the grain. Measures should be effective in ensuring that there will not be any larger animals in the silos. The insects should be prevented from multiplying by keeping the product dry. Insects, like other animals and people, need water to survive and the absence of water may perhaps not kill all insects, but at least the survivors would be dormant. Another, equally important reason to make certain that the grain remains dry is to prevent mold from growing. Molds produce metabolites that are toxic (mycotoxins) for humans in very low concentrations. For instance, *Aspergillus* species produce a variety of aflatoxins. The EU regulations require that the concentration in grains for human consumption of all aflatoxins together is below 4 μg/kg. Ochratoxins are produced by some *Aspergillus* as well as *Penicillium* species. The maximum concentration in grain for human consumption of Ochratoxin A, the most important one, is 3 μg/kg (these are parts per billion, $1{:}10^9$). Mycotoxins are also harmful to animals (e.g. horses) and hence the above also applies to feed.

The problem with large silos is that it is difficult to ensure that the temperature is the same everywhere in the product. Temperature differences, however, will cause transport of

moisture to the colder spots, which subsequently may become moldy and thereby toxic. It is therefore recommended to use thermally insulated silos.

Storage of Oils

The solubility of water in oil is strongly temperature dependent. At 20°C the solubility in sunflower oil is approximately 75 mg/kg; at 40°C it is about 50% higher. The consequence is that in oil that contains more water than is soluble at the lowest temperature in the storage tanks, water will separate. In addition, if the tank is not well insulated, water may condense at the inner wall of the tank. Because of its higher density, all water will sink to the bottom of the tank and where there is water and nutrients, microbes will grow and therefore the oil becomes contaminated with microorganisms that in turn may produce potentially toxic substances. The message is that it is important to control the temperature of the room for storage of oils and to prevent oil from cooling down. In other words, letting the temperature drop in wintertime to save energy is not a good idea from a microbiological safety point of view.

Storage of Chilled Food

Self-evidently, chilled food storage rooms need adequate temperature control. It is important to take into account that lighting and ventilators produce heat and that as a consequence, despite the temperature control, there are temperature differences in the cold room. Similar to chilled rooms for food processing, condensate trays underneath cooling units should slope towards a drain, from where it is led to a hygienic drain pit. The trays need regular inspection, cleaning and disinfection.

Storage of Packing Material

Some packing material, in particular carton and paper and the increasingly popular biodegradable materials, are substrates for microorganisms and should therefore be kept dry to prevent microbial growth. Other materials, like glass, metals and non-biodegradable polymers, can be stored in areas without temperature and humidity control, unless the humidity at the location can be extreme. Switching from non-biodegradable to biodegradable materials will probably need measures to prevent microbiological problems.

Storage of Chemicals and Lubricants

The design and location of the store for chemicals for cleaning and sanitation must be such that any risk of contamination of product and packing material with chemicals is avoided. The store must be provided with a lock and there should be no direct connection between product areas and the chemicals store. The same holds in principle for lubricants, glues and inks needed in the process and packaging areas, unless the lubricants, glues and ink comply with the requirements for food contact material or they are used only in areas where the product is packed in well-sealed containers.

Storage of Refuse and Waste Materials

Waste materials, such as used cartons and boxes, must have adequate space for storage, enabling "good housekeeping" in the entire factory. Without such spaces, pests (including rodents, cockroaches) will find places to harbor and breed.

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Further Reading

This chapter provides limited information on the issues that need consideration when deciding to build a new or improve an existing food factory. When it has been decided to build or refurbish a factory, much more detailed information will be needed to be able to develop a plan that covers all aspects. Such information can be found in a recently published book by Holah and Lelieveld (2011).

CHAPTER

26

Hygienic Design and Maintenance of Equipment

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INTRODUCTION

There is a global trend in the food industry towards minimal food processing and preservation. Consumer demand for "fresh-like" additive-free foods, which maintain their nutritional and sensorial properties during preparation, conservation, packaging, storage and finally consumption, is increasing. But the general tendency to apply mild processing and conservation techniques to achieve that purpose often shortens the shelf life of food, may put foods at risk and may compromise consumer health. Therefore, more than ever, good hygienic engineering and design practice is one of the tools to reduce or exclude microbial (e.g. pathogens), chemical (e.g. lubricating fluids, cleaning chemicals) or physical (e.g. glass, wood) contamination of food. Good hygienic design also may eliminate product "held-up" within the process equipment where it could deteriorate and affect product quality on rejoining the main product flow. As such, good hygienic design may prevent one batch cross-contaminating a subsequent batch. Good hygienic design also reduces the downtime required for an item of process equipment to be cleaned, while at the same time allowing an increase in the time to produce. Therefore, although initially more expensive than poorly designed equipment, hygienically designed equipment will be more cost effective in the long term.

To reduce and eliminate food product recalls, lost production and site closure, due to contamination arising from poorly designed equipment, this chapter intends to inform food

safety professionals and inspectors/auditors about the risks associated with poor hygienic design. With typical examples of poor hygienic design, the necessary technical and practical guidance will be given to identify and control equipment-related food safety hazards. As such, this chapter may help the food manufacturer to select the most suitable food processing equipment, to construct a food production line that meets all current and future hygienic requirements, and to set up an appropriate food safety management plan (e.g. HACCP) to eliminate or control all food safety hazards along the food chain.

In the first section, an overview is given on the current legislation and standards dealing with the hygienic design of food processing equipment. A second section lists the basic hygienic requirements that food processing equipment must meet to produce microbiologically safe food products. The third section describes the hygienic and food grade materials that can be used in the manufacturing of food processing equipment; followed by a section that outlines the requirements to the food contact surface finish. The next two sections make recommendations with respect to the hygienic design of respectively open and closed equipment for processing of food. The seventh section considers the hygienic installation of food processing equipment in the food factory. The last section deals with hygienic practices during process equipment maintenance operations in the food industry.

LEGISLATION

Many countries around the globe have developed legislation on the production of food, requiring that microbiologically safe food shall be produced by means of process equipment that minimizes the risk of contamination and that is easily cleanable. Hence, food producers are encouraged to purchase hygienically designed food processing equipment that aims to meet these criteria. In response to this demand and because they are also forced by national and/or international legislation, manufacturers of food processing equipment have developed process equipment that is hygienically designed and easily cleanable. An overview on existing legislation and standards describing the hygienic requirements applicable to food machinery is given in Hauser (2008a), van der Meulen (2010) and Moerman (2011a).

BASIC HYGIENIC REQUIREMENTS

Processing equipment intended to produce safe food should at least meet the following basic hygienic requirements (Holah, 2000; Lelieveld et al., 2003):

- Materials of construction used for equipment must be completely compatible with the food product, environment, cleaning chemicals and disinfectants, and the methods of cleaning and disinfection.
- Product contact surfaces (including the welds in the product contact area) should have a smooth surface finish to enable them to be cleaned easily.
- Food equipment should be designed to prevent bacterial ingress, survival, growth and reproduction on both product and non-product contact surfaces of the equipment. The food processing equipment must be constructed to ensure effective and efficient cleaning over the lifetime of the equipment.

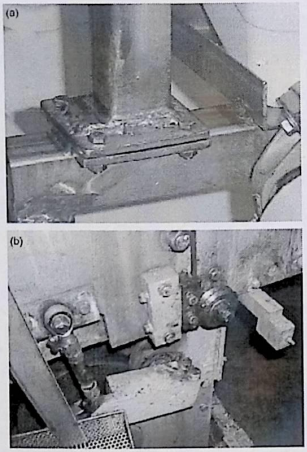

FIGURE 26.1 The pits, cracks, crevices, recesses, open seams, gaps, lap seams, bolts and threads will accumulate dirt and will make this equipment not cleanable. Moreover, galvanic corrosion can be observed. *Courtesy of John Butts, Land O'Frost.*

- Welding or continuous bonding are preferred over fastenings. Exposed screw threads, nuts, bolts, screws and rivets must be avoided whenever possible in product contact areas. Alternative methods of fastening can be used where the washer used has a rubber compressible insert to form a bacteria-tight seal.
- To make permanent pipe joints, welding is the preferred method of joining. These welds must be continuous and smooth. Screwed pipe couplings must be crevice free and provide a smooth continuous surface on the product side. Flanged joints must be sealed with a gasket to avoid ingress of microorganisms.
- In design, construction, installation and maintenance, hollow areas of equipment such as frames and rollers must be eliminated or they shall be hermetically sealed. As such, bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps, sleeves and other such items must be continuously welded to the surface, and shall not be attached via drilled and tapped holes.
- Niches such as pits, cracks, crevices, open seams, gaps, lap seams, inside threads that accumulate dirt and hamper the cleanability of the process equipment are not allowed (Figure 26.1).

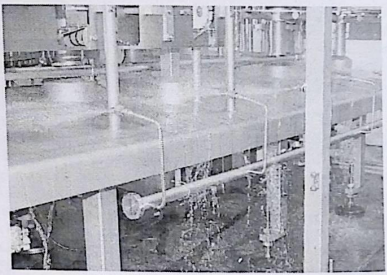

FIGURE 26.2 All surfaces in the product zone are designed to be self-draining for liquid food, cleaning and disinfection solutions, and rinsing water. *Courtesy of Krones AG.*

- Dead areas, dead ends, pockets or other conditions which may trap food, harbor contamination, prevent effective cleaning and disinfection, and allow cross-contamination shall be avoided.
- All inaccessible horizontal flat areas, ledges, projections, protrusions, recesses, edges, etc. where product rests can accumulate should be eliminated.
- For the same reason and to facilitate cleaning, internal angles and corners should be well radiused.
- The exterior of non-product contact surfaces should be so arranged that harboring of contamination in and on the equipment itself, as well as in its contact with other equipment, floors, walls or hanging supports, is prevented.
- All pipelines and equipment surfaces in the product zone must be so arranged that they are self-draining (Figure 26.2) to minimize contamination and corrosion risks when liquid food, cleaning and disinfection solutions, and rinsing water are retained during idle periods. Microbes can flourish in stagnant pools of water, when supported by nutrients which are trapped in the internal pockets. Moreover accumulated and pooling cleaning and disinfection solutions may contaminate food products.
- Certain equipment surfaces operate at or below the natural dew point of water vapor. Equipment design, therefore, should not permit the formation of condensate that may enter the food zone and contaminate product or product-contact surfaces.
- All parts of the equipment shall be readily accessible for inspection. Because potential contaminants on representative surfaces throughout the product contact zone must be readily detectable, all surfaces in the product zone must be immediately visible for inspection, or the design of the equipment shall allow readily dismantling without the use of tools for such inspection. Equipment surfaces must be readily accessible for manual cleaning and disinfection (Figure 26.3), unless it can be demonstrated that the

FIGURE 26.3 Product contact surfaces of this equipment are not readily accessible for manual cleaning and disinfection. Moreover, the dome screw with drive slot and washer creates gaps and crevices where debris collects. *Courtesy of Joe Stout, American Meat Institute.*

result of in-place cleaning and disinfection procedures without dismantling is equivalent to the result of dismantled and manual cleaning procedures. All potential obstructions to cleaning, disinfection and maintenance should be avoided or minimized.

- Instruments not only must be hygienically designed, but also hygienically installed.
- Equipment design also must ensure hygienic compatibility with other equipment and systems, such as electrical, hydraulics, steam, air and water.
- Maintenance equipment enclosures and human machine interfaces such as push buttons, valve handles, switches and touchscreens must be designed to ensure food product, water or product liquid does not penetrate or accumulate in and on the enclosure or interface. Also, physical design of the enclosures should be sloped or pitched to an outside edge to avoid use as storage area. Doors, covers and panels should be designed so that they prevent entry and/or accumulation of soil. To facilitate cleaning, they should be easy to remove.
- Bearings should be mounted outside the product area to avoid contamination of food products by lubricants and to exclude the ingress of bacteria. When the bearing is within the product area, its design should allow the passage of cleaning fluid.
- Food grade oil should be used, and leaking of oil onto food product has to be excluded. A drip pan which protects the product zone should be used, or motors driving equipment components such as agitators, belt drives, etc. should be placed outside the product area. If they are within the splash area, they should be protected by a removable cover.

MATERIALS OF CONSTRUCTION

General Recommendations

Materials of construction for food processing equipment, process piping and utilities should be homogeneous, hygienic (smooth, non-porous, non-absorbent, non-toxic, easily

cleanable, impervious and non-mold supporting), inert (non-reactive to oil, fat, salt, etc.; may not adulterate the food by imparting deleterious substances to it, nor affect its organoleptic characteristics), chemical resistant (corrosion-proof; non-degrading and maintaining its original surface finish after sustained contact with product, process chemicals, cleaning agents and disinfectants), physically durable and mechanically stable (resistant to steam, moisture, cold, heat, the actions of cleaning and sanitizing agents; resistant to impact, stress and fatigue; resistant to wear, abrasion, erosion and chipping; not prone to cracks, crevices, scratches and pits, unbreakable) and easy to maintain, in agreement with the guidance described in EHEDG guidelines No. 8 and No. 32. Additional requirements could be availability, welding ability, machinability and capability of being shaped. Notice that materials which are worked (for instance, bent, cut, sheared, extruded or drawn) during manufacture may require additional treatment (such as surface finishing) following fabrication in order to render them corrosion resistant. Hence, materials should be selected that are suitable for surface treatment (Hauser et al., 2004a).

Product contact surfaces – all the surfaces exposed to direct contact with the product as well as indirectly impacted surfaces from which splashed product, condensate, liquid or solid particles may run off, drop off or may fall into the product – should be constructed of materials that meet the highest hygienic requirements, while materials used in the construction of components located in the non-food contact area may be of a lower grade.

Use of Metals and Alloys

Carbon steel cannot be used in the food contact area due to its corrosion sensitivity, especially by salt and chlorine-containing bleach. To retard its corrosion, it is often galvanized (zinc plated) but, with time, galvanized steel becomes damaged when the zinc coating peels off. The only permitted application of galvanized steel is in contact with dry and non-acidic foodstuffs. Painted steel never shall be used in the neighborhood of food because paints often contain zinc, lead, cadmium and phenolics. Moreover, paint can crack or flake, and some cleaning agents rupture the physical integrity of paints. Paint that peels off can fall onto the product, creating a health risk. Paint surfaces used in non-product contact areas may crack or flake and should be repainted immediately.

The austenitic chrome–nickel or chrome–nickel–molybdenum steels are mainly used for the construction of equipment and machining in the food industry. Stainless steel AISI SS 304(L) can be used for the construction of food processing equipment and food processing support systems in applications with low chloride levels (up to 50 mg/l [ppm]), near neutral pH (between 6.5 and 8) and at low temperatures (up to 25°C). However, stainless steel AISI SS 304 is sensitive to sodium hypochlorite and to salt that is usually present in food in high content. In these less appropriate circumstances, stainless steel can still be used for exterior equipment surfaces, motor and electrical cabinets, etc. Because cheaper grade AISI SS 304/304(L) will suffer some corrosion over a long time period, the small additional cost of using AISI SS 316/316L rather than AISI SS 304/304L almost certainly will be worthwhile in terms of trouble-free operation. Stainless steel AISI SS 316(L) is commonly used as construction material for food processing equipment. However, as temperatures approach 150°C, even AISI SS 316 stainless steels may suffer from stress-corrosion cracking in regions of high stress and exposure to high levels of chloride. Therefore, other stainless steel types

were developed to overcome that problem (e.g. duplex steel and nickel alloys) (Hauser et al., 2004a).

The best known application of copper is vessels, traditionally used in many breweries and distilleries. Copper does not really constitute a food safety problem but it is recommended to avoid direct food contact with copper utensils, as they can cause unacceptable organoleptic effects. Moreover, copper can be quickly and severely affected by strong alkaline detergents, sodium hypochlorite, acidic and salty food, making it unsuitable in the food contact zone. The copper alloys brass (60–70% copper, 30–40% zinc) and bronze (80–95% copper, 5–20% tin) are more prone to corrosion by alkaline and acidic detergents, salty and acidic food than the ferrous steels. They become quickly porous, especially brass that undergoes de-zincification by acid and steam.

Because aluminum is attacked by alkaline detergents, sodium hypochlorite and acidic food, the use of uncoated aluminum utensils should be limited. Anodized aluminum is acceptable in the food contact area. Exposure to aluminum is usually not harmful, but its intake should be limited.

Lead, cadmium and mercury in food contact materials must be avoided. Notice, however, that these components are largely present in electrical and electronic components. In 2003, the EU adopted the *Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment* (RoHS) Directive (2002/95/EC). Alloys for food contact may only contain aluminum, chromium, copper, gold, iron, magnesium, manganese, molybdenum, nickel, platinum, silicon, silver, tin, titanium, zinc, cobalt, vanadium and carbon.

Use of Plastics

Plastic materials may be used to preclude metal-to-metal contact (e.g. for bearing surfaces), as guides and covers, or for hoses because of their plasticity and corrosion resistance. These plastics should be odorless, non-porous, smooth and free from cracks, crevices, scratches and pits which can harbor and retain soil and/or microorganisms after cleaning. They must not absorb product constituents and microorganisms, must have high mechanical strength (resistant to ageing, creep, brittleness, fatigue, etc.) and good wear/abrasion resistance, and must be resistant to heat, cold flow, hydrolysis, electrostatic charging, etc. Further, no migration of plasticizers, monomers or additives into the food product must occur.

When using a plastic material (belts, gaskets, electric cables, etc.), it is of utmost importance to ensure that the material is able to withstand all temperatures from −50°C to temperatures as high as 121°C (steam sterilization) without cracking or breaking. Moreover, the plastic material must be chemically resistant to solvents, acid, alkaline, reducing and oxidizing agents, cleaning and disinfection agents and corrosive food gases at these temperatures. The equipment manufacturer should test the chemical and temperature resistance of the plastic material (Partington et al., 2005; Moerman, 2011a).

Use of Rubbers

Elastomers must be chemically resistant to fat, cleaning agents and disinfectants; they must not show expansion and shrinking under the influence of temperature changes or chemical fluids; they must be abrasion resistant (e.g. rotary shaft seals, or seals in static

TABLE 26.1 Resistance Characteristics of Different Rubber Materials (Plett and Graßhoff, 2006)

Contact Medium	Natural Rubber	Acrylonitrile Butadiene Rubber	Silicone Rubber	Ethylene Propylene Diene Monomer	Chloroprene	Fluor Elastomer
Temperature range	−60 to 80°C	−35 to 120°C	−70 to 200°C	−60 to 135°C	−40 to 230°C	−30 to 180°C
Hot water (120°C)	–	+++	+++	+++	+++	+++
Hot water (145°C)	–	–	+++	+++	–	+++
NaOH (5%; 90°C)	++	+++	+++	+++	++	+++
NaOH (5%; 140°C)	–	–	–	++	+	+++
H_3PO_4 (2%; 90°C)	–	+++	+++	+++	+++	+++
H_3PO_4 (2%; 140°C)	–	–	–	++	–	+++
HNO_3 (1%; 70°C)	– –	–	++	++	++	++

+++ = unlimited resistance; ++ = limited resistance; + = only short contact; – = non-resistant; – – = absolutely non-resistant.

applications that are subjected to abrasion from dry material product), and they must retain their surface and conformational characteristics (no loss of elasticity, no embrittlement, no rubbed-off parts, no crevices, etc.). However, elastomers can be degraded by product, by cleaning agents, by disinfectants and by thermal and mechanical stress much quicker than metal components, with the following results: leakage of lubricants, loss of bacteria tightness, increased adherence and retention of dirt and bacteria in crevices leading to permanent product and process contamination, insufficient cleaning and problematic disinfection. Partly destroyed sealings allow ingress of liquids containing chlorides under gaskets and seals, so that a high chloride concentration may subsist between damaged sealings and adjacent metal, which favors crevice corrosion even in stainless steel. Therefore, gaskets and seals preferably should be of a removable type. Appropriate rubber materials are fluoro elastomers, natural rubber, silicone, neoprene, EPDM, nitrile and nitrile/butyl rubber. Their resistant characteristics can be found in Table 26.1 (Partington et al., 2005; Plett and Graßhoff, 2006).

Other Materials

Wood and certain types of insulation are not allowed within the product contact area (exceptions are butcher's blocks; wooden barrels, etc.). To avoid their exposure to the outside, they must be permanently and tightly sealed off from the product zone.

Glass may be used as a food contact surface, but its application is not recommended due to the potential for breakage. Specially formulated glass materials such as Pyrex® have proven successful. When glass is used, it must be durable, robust and heat resistant. Some applications where glass is used are light and sight openings into vessels, and to a very limited extent glass piping. Replacement by transparent alternatives like Perspex® or polycarbonate is recommended (Hauser et al., 2004b).

Ceramics are very resistant to acids and sufficiently resistant against lye. They are very hard and can withstand pressures of 100–400 MPa. They are used in the coating of other stable materials, in the production of ceramic membranes, and in the construction of pipes or processing equipment for very sensitive products. The main drawbacks of ceramics are their brittleness and porosity. To be food safe, all ceramic surfaces in direct contact with food must have smooth, unbroken and lead-free glassy surfaces, entirely free of crazing (small hairline cracks) and blemishes. Although not many bacteria may hide in a crack, in contact with food those few may be become a large culture.

The use of nanomaterials in the food industry may present potential risks, requiring the need for risk assessments to identify and quantify these risks. Some nanoparticles have been found to exhibit negative effects on tissues such as inflammation, oxidative stress and signs of early tumor formation (Stone et al., 2009; FAO/WHO, 2010; Becker et al., 2011). Because nanoparticles may become wasted in surface waters along with cleaning solutions, experimental evidence is needed to demonstrate that these nanoparticles can be removed from this surface water if it is used as a source of drinking water.

The European Hygienic Engineering & Design Group clearly states that materials which have been modified with antimicrobial chemicals may not be considered as a substitute for hygienic design. Microorganisms may build up resistance against such chemicals over a period of time, and antimicrobial chemicals are only effective if the microorganisms are in intimate contact with them.

SURFACE FINISH

Product contact surfaces must be finished to a degree of surface roughness that is smooth enough to enable them to be easily cleaned and disinfected. The surface finish must be such that there are no cracks, pits or cavities where water or soil might remain. In the pharmaceutical industry, a surface finish of roughness $R_a \leq 0.4\,\mu m$ is often used, while a surface finish of roughness $R_a \leq 0.8\,\mu m$ is considered acceptable for the food industry. Surface roughness, R_a, of enclosures in hygienic production areas should not exceed 2.5 μm. Surfaces will deteriorate making cleaning more difficult (Hauser et al., 2004a).

The technique used for achieving the appropriate surface finish is of great importance. Although with different surface finish techniques (glass blasting, ceramic beats blasting, electro polishing, pickling) a surface roughness of R_a 0.8 μm can be achieved, the topography/structure of the surface can differ immensely, which gives different cleaning results.

HYGIENIC DESIGN OF OPEN EQUIPMENT FOR PROCESSING OF FOOD

Permanent and Dismountable Joints

Permanent Joints

It is better to use permanent joints rather than dismountable joints, because the latter type of joints may give rise to projections, protrusions, edges, recesses, metal-to-metal

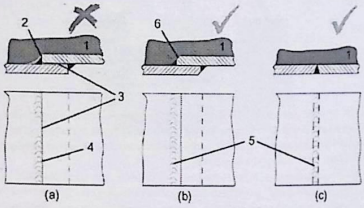

FIGURE 26.4 (a, b) In the product contact area (1), product debris may become trapped at step (2) and in the crevices and metal-to-metal contact areas between the seams (3), if overlapped sheets of metal are intermittently welded (4) instead of continuously welded. (b) Overlapped sheets of metal must have continuous welds (5) and sloped edges (6) for easy cleaning. (c) However, it is still better to avoid overlapping sheets of metal, and to give preference to smooth continuously welded sheets (Lelieveld et al., 2003; Hauser et al., 2004b).

contact, etc. In this way, welded joints are preferred over mechanical fixings, such as bolted or screwed joints.

Permanent joints of equipment should preferably be welded, but notice that several types of common defects may arise in welded joints (e.g. misalignment, cracking, porosity, inclusions), which can act as a source of microbiological problems. All welds in the product contact area are recommended to be continuously welded and with sufficient weld seam protection (inert shield-gas protection at both sides) in agreement with EHEDG guidelines No. 9 and No. 35. Higher alloyed filler metal in comparison to the welded material may reduce the risk for corrosion. When necessary welds must be polished to have the same surface finish ($R_a \leq 0.8\,\mu m$), appearance, etc. as the surrounding materials. They should be inspected for any discoloration and defects (Hauser et al., 1993; Kopitzke et al., 2006).

To avoid crevices at metal-to-metal interfaces where product debris may become trapped, intermittent or spot welds are not acceptable (all welds should be continuous or filled) and overlapping must not be used (Figure 26.4a). If overlapping is unavoidable due to the need for added strength at the weld location, reliable draining and cleaning conditions of shadow areas must also be taken into consideration. In the case of thick sheets, the edge of the upper plate must be sloped to avoid areas at the overlap edge which can retain soil and be difficult to clean (Figure 26.4b). However, it is still better to avoid overlapping sheets of metal, and to give preference to smooth continuously welded sheets (Figure 26.4c) (Hauser et al., 2004b).

Sharp corners ($\leq 90°$) and welding in sharp corners of equipment (Figure 26.5a and b) must be avoided. Radiused corners (sloped sides) and welding seams away from corners and preferably made at the non-product contact side are recommended (Figure 26.5c). Weld fillets in the food area should have a minimum radius of 6 mm. If the material is less than 4 mm thick, the minimum radius should be 3 mm. Where a corner cannot have a radius of greater than 3 mm, its cleanability should be demonstrated by testing.

Use of adhesives on metal-to-metal joints should be avoided. If adhesives are used for permanent joints they must be compatible with materials, products and cleaning/disinfecting agents with which they are in contact. All bonds should be continuous and mechanically

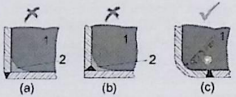

FIGURE 26.5 (a, b) Welded seams in ≤90° corners of receptacles containing food product (1) will create uncleanable areas where residual soil (2) will accumulate. (c) Well-rounded corners (radius $R \geq 3$ mm) and correctly welded seams in the plain area away from corners and preferably made at the non-product contact side avoid any hygiene risk (Lelieveld et al., 2003; Hauser et al., 2004b).

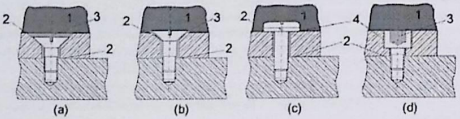

FIGURE 26.6 Screws may not be exposed to food product (1) because debris collects in the screw drive, because they give rise to metal-to-metal contact corrosion (2), and because they create gaps, dead areas (3) and crevices (4). Countersunk screws with slots or other drive configurations are not recommended for the reasons mentioned, and incorrect machining of the countersunk hole may cause the screw to either (a) form a pocket in which debris collects or (b) to protrude into the product flow giving rise to circumferential crevices where debris may become trapped. (c) Pan, dome, round and truss screws are not suitable because they protrude in the product flow. (d) Socket head cap screws are not allowed in the food area because debris accumulates in the recess or socket to fit an Allen wrench for turning. In addition, the use of counterbores is not recommended for all the reasons mentioned earlier (CFPRA, 1983; Lelieveld et al., 2003; Hauser et al., 2004b).

sound so that the adhesives do not separate from the base materials to which they are bonded.

Dismountable Joints

Dismountable joints (e.g. of plates or appendages) fixed by fasteners (e.g. screws or bolts) must only be used if dismantling is unavoidable. Joining components with hexagon nut-and-bolt pairs which protrude in the product zone or with screws exposed to product is not allowed. Besides, crevices, screws, bolts and nuts also give rise to metal-to-metal contact corrosion, and create gaps, dead areas and/or exposed threads (Figures 26.6 and 26.7).

Wing nuts and pop rivets are also not allowed on the product side. It is recommended to have a plain or domed bolt head sited on the product side, to cover exposed threads with domed nuts, and to use solid rivets instead of pop rivets (Figure 26.8). But overall, the use of welded butt joints that are ground and polished instead of fastenings is preferred (CFPRA, 1983).

Correct design of bolt heads and their effective sealing with metal-backed elastomer gaskets (Figure 26.9) can render them hygienic. The head of the hexagon headed bolts will be plain or domed. Domed nuts can be used to cover exposed threads. Sealing the

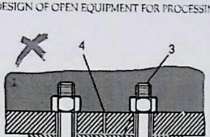

FIGURE 26.7 Exposed bolt ends and nuts in the product zone (1) are not allowed because they give rise to metal-to-metal contact corrosion (2), exposed threads (3) and crevices (4). Debris also tends to adhere to and around fixings and provides nutrients for microbial slime growth. Exposed threads should be cut to the correct length or preferably domed nuts should be used (Lelieveld et al., 2003; Hauser et al., 2004b).

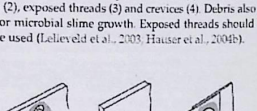

FIGURE 26.8 (a) Wing nuts are often used where adjustment is required but debris collects around and in the exposed portion of the slot behind the nut. (b) It is recommended to cover exposed threads with domed nuts. (c) Pop rivets (1) are not recommended where construction necessitates this type of fabrication. Solid rivets (2) should be used instead of open rivets (CEFRA, 1983).

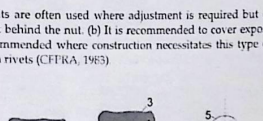

FIGURE 26.9 (a) To prevent crevices at the product side (1), screws, pins or a stud welded on the non-product side (2) should be used. (b) A bold head (3) that is hexagonal (4), domed (5) and provided with a sloped circular collar (6, 7) is easily cleanable, and the metal-backed (8) elastomer gasket (9) is used to seal the thread (Lelieveld et al., 2003; Hauser et al., 2004b).

crevice between the bolt head and the food contact surface will protect the annular clearance between the shaft of the bolt and the hole through which it passes.

Dismountable joints must be crevice free and provide a smooth continuous surface on the product side. Further, metal-to-metal contact should be avoided. Therefore, where components butt against one another in the product area, the crevice between them should also be sealed by means of an elastomer. Compression of the seal can be controlled by means of screws and interference-fit location pins on the reverse side to the product (Figure 26.10a).

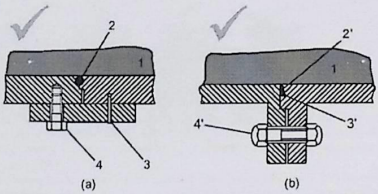

FIGURE 26.10 Where components butt against one another in the product area (1), the crevice between them should also be sealed by means of an elastomer (2). (a) Compression of the seal can be controlled by means of interference-fit location pins (3) and screws (4) on the reverse side to the product. (b) A flange (4')-like connection can control compression (2') and the design of the groove should allow space for expansion (3') of the seal (Lelieveld et al., 2005; Hauser et al., 2004b).

A flange-like connection can control compression (Figure 26.10b). The design of the groove for the seal must allow space for expansion in order to avoid extension of seal material into the product area during heating.

Split pins, self-tapping screws, staples, spring tension pins, bushings, etc. which may be loose and cause damage to other equipment and physical danger to the consumer are unsuitable fastenings. Tape, rubber bands and wire should not be used to permanently modify equipment. A designer also must avoid very small fastenings, and fixings in plastics which cannot be identified by metal detectors. Stainless steel or dull-nickel-plated fixings should be used as specified in the fixings and fastenings handbook. Finally, one must allow for sufficient space around fixings for cleaning (min 25 mm).

Hygienic Design of Process Vessels, Containers, Bins, etc.

Interior and Exterior Design of Process Vessels, Containers, Bins, etc.

Appropriately designed and installed process vessels shall meet the following recommendations:

- Equipment without bottom outlets must be pivoted (Figure 26.11) for fully discharging of product and cleaning solution. Materials or contaminants from the exterior of the vessel must not gain access to the food product being discharged. Besides full drainability, the vessel tipped for discharge also should be designed for improved cleanability (e.g. vessel corners should be well rounded; hinges must allow for maximum cleanability).
- For good drainability and cleanability, food containing equipment (tanks, vessels, troughs, reservoirs, bins, etc.) shall have their discharge outlet at the lowest level; their bottom shall be sloped (more than 3° towards the outlet); and their corners shall be well rounded. These corners should preferably have a radius equal to or larger than 3 mm. Sharp corners ($\leq 90°$) must be avoided (Figure 26.12).

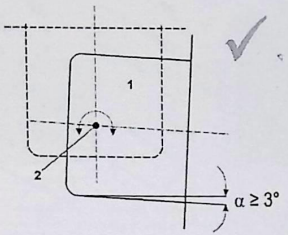

FIGURE 26.11 To fully empty containers without bottom outlet, they must tip over an angle of at least 93°. The interior and exterior of the container must be designed to exclude any contamination of the food product when it is drained. Vessel should have well-rounded bottom corners, with hinges designed for maximum cleanability (Lelieveld et al., 2003; Hauser et al., 2004b).

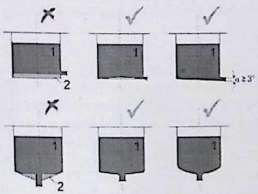

FIGURE 26.12 For good drainability and cleanability, equipment (tanks, vessels, troughs, reservoirs, bins, etc. used in the processing of food (1) shall have their discharge outlet at the lowest level; their bottom shall be slopec (more than 3° towards the outlet), and their corners shall be well rounded. Where food product and cleaning solu tions are not allowed to drain, residual soil (2) will be left (Lelieveld et al., 2003; Hauser et al., 2004b).

- The design of the top rims of product containing equipment (e.g. open tanks, chutes, boxes) must avoid ledges where product can lodge and which are difficult to clean (Figure 26.13a). Open top rim designs must be rounded and sloped for drainage (Figure 26.13b). If the top rim is welded to the wall, the weld must be flush and polished to provide a smooth surface and the rim must be totally closed. Any holes, therefore, must be sealed by welding or by fitting sealed caps (Figure 26.13b).
- Lids are used (e.g. for process vessels, tanks, bins,) to avoid contamination of product from the environment during processing or storage. They can be completely detachable for cleaning, but if they are non-removable they must be sloped for drainage. If hinged covers are used the hinge must be designed in such a way that it can be cleaned easily

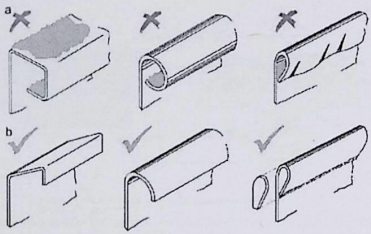

FIGURE 26.13 Top rims may impart rigidity to the construction. (a) However, a rim with an upper horizontal part provides a surface where debris may collect. When the rolled-over part of the rim is badly designed, it may provide a ledge where product debris can lodge. This soil can indirectly affect the product. (b) Open top rims must be rounded in a way that at one side the product drains back in the bulk of the product, while the more exterior part of the rim must allow drainage to the outside. Where preference is given to closed top rims, the top rim should be welded correctly to the wall over its full length. The weld must be flush and polished to provide a smooth surface and the rim must be totally closed. Any holes, therefore, must be sealed by welding or by fitting sealed caps (CFPRA, 1983).

and that accumulation of product, dust and foreign bodies (including insects, etc.) is avoided. When the vessel is covered, no sharp corner at the top should be created when the lid is placed on the vessel. Flat lids provide a horizontal surface where dirt may accumulate. Moreover a sharp corner is created at the top near the seal. Preference should be given to domed lids with a sloped top that collects less dirt and allows for proper drainage of liquids (Figure 26.14).

- Elastomers can be deformed, but the volume cannot be reduced! This means that when a flat gasket is compressed so that the thickness is reduced by say 20%, the width of the gasket is increased by 25%, assuming that the length can be kept constant. As a consequence, a considerable amount of movement takes place at the edges of the gasket. In view of the inconsistency of the friction between stainless steel and elastomers it is most uncertain how the deformation of the gasket will take place. Overcompression of the flat gasket (Figure 26.15a) may affect the hygienic characteristics of equipment in two ways. First, overcompression may lead to destruction of the gasket, particularly if it is heated (such as during hot cleaning and/or sterilization). The gasket may exceed the maximum of compression caused by thermal expansion and become brittle and fail to perform, while particles of it may break off and contaminate the product. Second, overcompression may lead to protrusion of the gasket into the product flow, thereby impeding cleaning and draining. Undercompression (Figure 26.15b) is also highly undesirable as it may lead to both indentations and crevices and failure to provide a reliable seal. Even when it is not visibly leaking, the seal may permit the ingress of microorganisms. It is good practice to slope the groove that receives the gasket (Figure 26.15c) in a way that space for expansion is provided at the non-product side while controlled compression of the gasket is possible

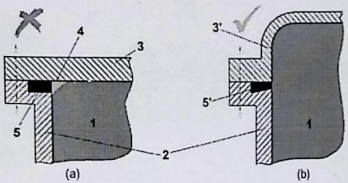

FIGURE 26.14 (a) Covers are used (e.g. for process vessels, tanks, bins, etc.) to avoid contamination of food product (1) from the environment during processing or storage. When the vessel (2) is covered with a flat lid (3), a horizontal surface is provided where dirt may accumulate. Moreover a sharp corner (4) is created at the top near the seal. This seal (5) is not very appropriate because overcompression may lead to protrusion of the seal in the product area, thereby impeding cleaning; while undercompression may lead to both indentations and crevices and failure to provide a reliable seal. Even when it is not visibly leaking, the seal may permit the ingress of microorganisms. (b) Preference should be given to domed lids (3') with a sloped top that collect less dirt and allow for proper drainage of liquids. The present gasket groove allows for controlled compression of the gasket (5') at the product side (Lelieveld et al., 2003; Hauser et al., 2007).

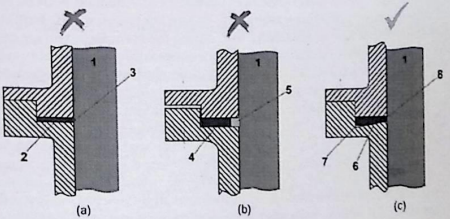

FIGURE 26.15 (a) Overcompression of the gasket (2) may lead to protrusion of the gasket (3) into the product area (1), thereby impeding cleaning and draining. Moreover, because the gasket may exceed the maximum allowable limit of compression during thermal expansion, it may become brittle and fail. (b) Insufficient compression of the gasket (4) may give rise to a crevice (5) between the two flanges and the possibility of leakage. (c) It is good practice to slope (6) the groove that receives the gasket in a way that space for expansion (7) is provided at the non-product side while controlled compression of the gasket is possible at the product side (8). A further possibility to reduce the effects of friction is to avoid even compression of the gasket by using gaskets with a profiled section which "involutes" along the sealing faces rather than sliding under compression (Lelieveld et al., 2003; Hauser et al., 2007).

at the product side. Such a design also allows reduction of the area of the gasket in direct contact with the food product. A further possibility to reduce the effects of friction is to avoid even compression of the gasket by using gaskets with a profiled section which "involutes" along the sealing faces rather than sliding under compression.

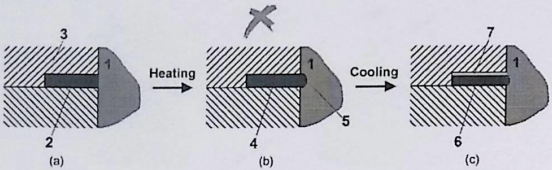

FIGURE 26.16 (a) A non-resilient flat PTFE gasket (2) is installed in a rectangular groove and compressed between the sealing faces of two stainless steel surfaces (3) to separate the product area (1) from the outside. (b) Because of the large difference in thermal expansion coefficient of both PTFE gasket and stainless steel, a heat treatment changes the shape of the PTFE gasket (4). Protrusion of the gasket (5) takes place. (c) Because of the lack of resilience, the PTFE gasket may become irreversibly deformed (6). Hence, after cooling down, the gasket will not return to its original form and proportions, and as such a crevice (7) will be generated (Lelieveld et al., 2003; Hauser et al., 2007).

- As with metals, not all polymeric materials and elastomers exhibit the same coefficients of thermal expansion (Figure 26.16). Therefore, not only the dimensions of the metal components but also those of the seal must be correct, ensuring adequate compression at the product side, under all conditions of intended use. Attention must be given to thermal expansion at high temperatures (e.g. during hot cleaning and sterilization) and to loss of resilience at low temperatures (e.g. during the manufacture of ice cream). To ensure a smooth durable surface with sufficient temperature and corrosion resistance, equipment manufacturers tend to use polytetrafluorethylene (PTFE) as gasket material in food processing equipment. However, PTFE has insufficient resilience and expands significantly more than stainless steel (expansion coefficient for PTFE is approximately $100 \times 10^{-6}/°C$, compared to approx. $16 \times 10^{-6}/°C$ for stainless steel). Due to this large difference in thermal expansion coefficient, a heat treatment changes the shape of the PTFE gasket (gasket protrusion occurs) and after cooling down a crevice occurs. For a gasket of 5 mm thickness and a temperature change from 20 to 120°C and back, the crevice may be 36 μm wide if there is no resilience at all (in practice the gap will be slightly smaller). Therefore, seals made from non-resilient materials should not be used.
- Conventionally designed right-angled grooves containing O-rings invariably create gaps and crevices that are impossible to clean in-place and/or to sterilize in-line (Figure 26.17). One cause is that the elastomer material of the O-ring has a significantly higher thermal expansion coefficient than steel. During heating the seal will expand to cover an increasingly larger surface of steel, protecting microorganisms trapped between the O-ring and the steel surface against contact with hot water, chemical solution or steam. Although the seal contact surface will usually reach the correct temperature during treatment with hot water or steam, the water activity in the grooves will be too low for the destruction of most microorganisms at the temperature and time applied. After cooling down and shrinkage of the seal, the surviving microorganisms may be released and will multiply and contaminate the product. Additionally, repeated thermal expansion of the seal into the product flow may result in it suffering damage which will

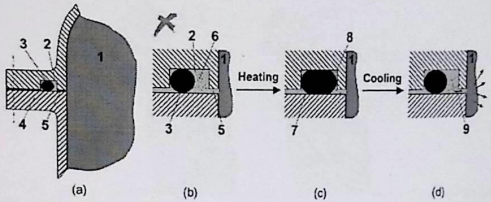

FIGURE 26.17 (a) A conventionally designed right-angled groove (2) contains an O-ring (3) that is compressed between the sealing faces of two stainless steel surfaces (4) to separate the product area (1) from the outside. (b) Such a rectangular groove-O-ring design invariably creates gaps and crevices (5) that are impossible to clean in-place and/or to sterilize in-place. The groove provides sufficient space for microorganisms (6) to enter via the crevice. (c) During heating, due to the difference in thermal expansion between metals and elastomers, the O-ring will expand (7) to cover an increasingly larger surface of steel, protecting microorganisms (8) trapped between the O-ring and the steel surface against contact with hot water, chemical solution or steam. (d) After cooling down and shrinkage of the seal, the surviving microorganisms may be released (9) and will multiply and contaminate the product (Lelieveld et al., 2003; Hauser et al., 2007).

not only contaminate the product but may also progressively reduce its ability to seal again upon re-cooling.

Installation of Agitators in Open Vessels (e.g. Kettles)

Equipment like stirrers, homogenizers or mixers should preferably be arranged in such a way that the need to seal shafts into the product is avoided. Where mounting of the equipment outside the product zone is possible, the mixer used to mix open product should be fixed beside the equipment, not only to prevent the contamination of the product with dripping oil, but also to avoid the introduction of soil, and concomitantly spoiling microorganisms and pathogens into the product along with overhanging electrical cabling (Figure 26.18).

Permanently Mounted Agitators in Closed Vessels

Top entering agitators with shaft seals are typically mounted to a vessel using a flanged or hygienic clamp connection, with hygienic O-rings or gaskets to seal between the mating surfaces. The selected mounting arrangement must support the agitator mounting design loads while achieving an appropriate seal. The upstand for the top mounting of the agitator should have limited length L because of the difficulty of cleaning of the annular space in-place. The annular space between the agitator shaft and agitator nozzle shall, for cleaning purposes, have the target maximum L/A ratio of 2:1. At least a 25 mm gap is required to facilitate CIP spray coverage (Figure 26.19) (CFCRA, 1997; BISSC, 2003; ASME, 2009).

Agitator motors should be equipped with permanently lubricated bearings. Where lubrication is required, the design and construction shall be such that lubrication cannot leak, drip or be forced into the product zone. Self-lubricating agitator shaft (packing) seals shall be provided with convenient means for adjustment to prevent leakage and to allow

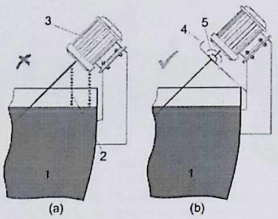

FIGURE 26.18 (a) A motor and cabling mounted over any exposed product (1) can contaminate it by soil, condensate or lubricants (2). (b) The motor drive (3) and power line should be placed beside the equipment. A self-draining protection sheet with "upstand" (4) in combination with a cowl (5) on the shaft must exclude any food safety risk. The bottom side of the thrower ring (cowl) should be made inspectable (Lelieveld et al., 2003; Hauser et al., 2004b).

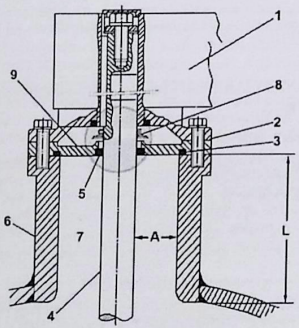

FIGURE 26.19 The top entering agitator with motor (1) is mounted to a vessel using a flanged or hygienic clamp connection (2), with hygienic O-rings or gaskets (3) to seal between the mating surfaces. A retained gasket having limited compression is more hygienic than an O-ring in the face for sealing the joint. The agitator shaft (4) passes through the mounting flange via a seal (5). The upstand (6) for the top mounting of the agitator should have limited length L because of the difficulty of cleaning the annular space (7) in-place. The annular space between the agitator shaft (4) and agitator nozzle (6) shall, for cleaning purposes, have the target maximum L/A ratio of 2:1. Agitator motors (1) should be equipped with permanently lubricated bearings. Where lubrication is required, the design and construction shall be such that lubrication cannot leak, drip, or be forced into the product zone. Self-lubricating agitator shaft (packing) seals (8) shall be provided with convenient means for adjustment to prevent leakage and to allow for complete drainage to the exterior. In that way, accumulations of foreign material in the event that leakage does occur can be avoided. Further, a drip protection plate (9) can be provided to prevent lubricant from entering the product zone (CFCRA, 1997; BISSC, 2003; ASME, 2009).

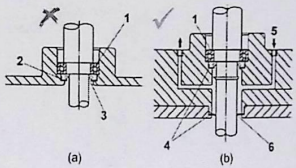

FIGURE 26.20 Rotary shafts running at a high number of revolutions are held in place in an adapter sleeve with a radial roller bearing (1). (a) Single dynamic seals (2) are lubricated by a lubricant (top mounted agitator) or the product (bottom mounted agitator) which may be transported past the seal and back again, further contaminating the product. They may be easy to clean if properly designed but they will not prevent the passage of microorganisms, and hence they are not suitable in aseptic process equipment. There is also a narrow annular space (3) at the product side in the proximity of the seal, which makes cleaning very difficult. (b) A double seal arrangement (4) allows the use of a barrier medium (5) such as steam, hot water, condensate or a disinfectant solution which makes it well suited from a microbiological standpoint. The volume of the annular gap around the shaft is increased (6), improving the cleanability of the seal and its proximity (Holah, 2000).

for complete drainage to the exterior (Figure 26.19). In that way, accumulations of foreign material in the event that leakage does occur can be avoided. Further, drip protection is commonly provided to prevent lubrication from entering the product zone. All surfaces of shaft seal ring assemblies passing through a bowl or cover shall be accessible, removable or retractable to permit cleaning of all product zone surfaces.

Rotary shafts running at a high number of revolutions are held in place in an adapter sleeve with a radial roller bearing. Single dynamic seals (Figure 26.20a) will not prevent the passage of microorganisms. If properly designed, they may be easy to clean but not bacteria tight because rotating shafts may exhibit some axial mobility. This makes single dynamic seals unsuitable for aseptic equipment. A narrow annular space at the product side in the proximity of the seal such as shown in Figure 26.20a must be avoided because it is difficult to clean. The space around the seal should be as wide as possible. Rotary shafts with a double seal arrangement allow the use of a barrier medium, and have been shown to be well suited from a microbiological standpoint. In Figure 26.20b, one seal is seated rigidly in the housing (longitudinal shading), while the other moves with the shaft. The sealing surface between the two seals must be lubricated. If the shaft opening has product flowing through it, which could be the case with agitators having a shaft entry from the bottom of vessels, the product itself can be directly used as lubricant. The product flowing through can be carried away by the barrier medium, which could be steam, hot water, condensate or a disinfectant solution (e.g. alcohol). The sterile fluid may scavenge the microorganisms that enter the space between the seals, maintaining absolutely sterile conditions. Which flushing fluid should be used will depend on the product and the process but both the barrier medium and lubricant chosen must be product compatible. To avoid transfer of microorganisms from the outside of the equipment to the inside, without an adequately long exposure to antimicrobial fluid the distance between the two seals must always be sufficiently large (Lelieveld et al., 2003; Hauser et al., 2007).

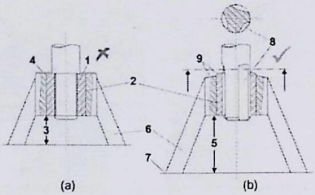

FIGURE 26.21 (a) Cleaning may be impeded due to too tight clearance (1) in the foot bearing itself (2), and due to too little clearance between it and the base (3). Horizontal ledges (4) where product may accumulate or where liquids are not allowed to drain must be avoided. (b) The foot bearing is now mounted clear of the bottom of the vessel (5), allowing free flow of product and cleaning solution around it. Bearing pedestal support members (6) should preferably be made of solid construction. Hollow constructions are not recommended, but if used, they shall be of sealed (welded) construction, inspected for integrity. Round legs are preferred over flat members, even if the latter are radiused. The legs should be flush welded in place to the tank bottom (7). All welds must be ground and polished to blend smoothly with the adjacent surfaces. The agitator shaft is provided with grooves (8) in the bearing area to facilitate both lubrication by fluid products and cleaning. Sloped and radiused surfaces (9) reduce the probability of debris getting lodged on the top of the foot bearing and allow for proper drainage of liquids (e.g. cleaning solution) (CFCRA, 1997; Lelieveld et al., 2003; Hauser et al., 2004b; ASME, 2009).

Bearings in the product area should be avoided but an application may mandate the use of foot bearings. As an example, if the shaft of a top entry agitator is very long, a foot bearing may be required at the bottom of the vessel to steady it. It shall be of a packless bearing type. The foot bearing must be mounted well clear of the base so as not to impede free draining of product and also to allow easy cleaning of their supports. Design features and/or procedures required to ensure cleanability are: drain holes, spray ball and/or wand additions, increased CIP flow, and operating the steady bearing immersed in CIP fluid. The arrangement of wear surfaces (bushing, shaft or shaft sleeve) shall facilitate drainage. A longitudinal or helical groove may be cut in either the bush or the shaft. It should be deep enough to allow access into the bearing of either the product as a lubricant or the detergent for cleaning (Figure 26.21). Sealed bearings should not be used in the product area because they can cause hygiene risks at their seals. If, however, their use is unavoidable, their lubricants should be specified as being allowed with the food contact.

Hygienic Design of Agitators

Agitators and agitator shaft assemblies passing through the seals shall be designed and constructed to be smooth, with all surfaces meeting all the hygienic design criteria applicable to a product contact area. Agitator shaft assemblies shall be readily accessible to allow all surfaces to be effectively cleaned via spray, directed flow, immersion or cleaning-in-place. Agitator ends shall have surfaces of minimum area immediately adjacent to the recipient ends and no longer than necessary to ensure proper incorporation of ingredients into a mix.

The design of agitator product contact parts should minimize the occurrence of crevices, void spaces and dead spaces in grooves. All voids should be closed by either fabrication

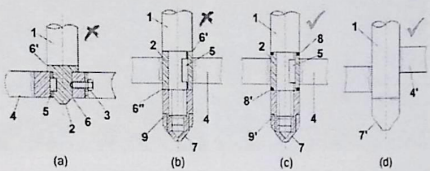

FIGURE 26.22 (a) The hub (2) is secured to the shaft (1) by means of a screw (3), which is exposed to product that may collect in and around the screw head. The hub-to-shaft connection gives rise to a metal-to-metal joint (6') that may permit the ingress of product and bacteria. Agitator blades (4) should be welded to the hub, although screw connections are sometimes observed. These exposed screw heads (even bolts with dome head nuts and washers of suitable food grade material) again will create a food safety hazard, and the blade-to-hub connection gives rise to a new metal-to-metal joint (6). To avoid the latter problem, the joint between the blade and the lug on the hub can be sealed by a thin gasket. Keyways (5) exposed to product are not recommended, because product and microorganisms may be retained in the keyway. Keyways may require additional design and/or cleaning practice to ensure drainage and cleanability, e.g. spray ball and wand additions, increased CIP flow and adjusted spray coverage. (b) Once the hub (2) is secured to the shaft (1), an end cap (impeller nut, 7) is screwed on the interior male thread end of the shaft. The non-welded impeller hub-to-shaft and hub-to-end cap connections give rise to crevices and metal-to-metal joints (respectively 6' and 6") that may allow the ingress of product and bacteria. In that way, the keyway (5) also may retain product and microorganisms. The sharp corners of the spanner flats (9) on the end cap may be difficult to clean. (c) Food quality gaskets under controlled compression respectively may seal the propeller hub to the shaft (8) and to the end cap (8'). Keyways (5), where employed due to mechanical design considerations, shall have edge radii not less than 3 mm. The corners of the spanner flats on the end cap have been radiused (9'). (d) An all-welded impeller assembly (e.g. hubs, blades, end cap) is still preferred. Impeller hubs welded to the shaft are preferred over removable hubs. The designer may omit the hub and immediately attach the blades to the shaft by welding (4'). Finally, the end cap can be welded to the shaft (7') (CFCRA, 1997; Lelieveld et al., 2003; Hauser et al., 2004b; ASME, 2009).

(welding) or approved sealing techniques (O-rings, seals, etc.) to give surfaces ground flush and free of crevices at points of metal-to-metal contact. Metal-to-metal joints (e.g. keyways, hub-to-shaft joint, hub-to-end cap joint, etc.) may allow ingress and accumulation of product and/or microorganisms (Figures 26.22a and b and 26.23).

Food quality gaskets under controlled compression may seal the propeller hub to the shaft and to the impeller nut (end cap) that secures the end of the agitator shaft (Figure 26.22c). Alternatively, the hub should be welded to the shaft and the end cap (Figure 26.22d). Because debris may collect on exposed screw threads, the hub shall not be fastened to the shaft by means of a screw. To avoid any screwed joints (even bolts with dome head nuts and washers of suitable food grade material), the blades of appendages (stirrers, homogenizers, mixers, etc.) should be welded to the hub. As an alternative to hub-to-shaft and subsequent impeller blade-to-hub attachment, blades can be attached to shafts by welding. All welds used in the assembly of agitator parts should be grounded and polished.

Permanently joined metal surfaces with a total included internal angle less than 135° on agitators (e.g. at hubs and nuts) shall have a radius of not less than 3 mm tangential to both adjacent surfaces. Corners (e.g. at hubs, nuts, spanner flats, etc.) must be radiused to facilitate cleaning, and horizontal areas must be sloped to prevent debris from becoming lodged on the surfaces and to allow for maximum drainabilty. Machined transitions such as shaft

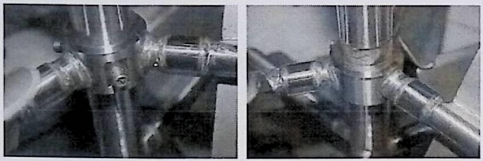

FIGURE 26.23 The hub is secured to the shaft by means of bolts with dome head nuts, which are exposed to product that may collect in and around the screw head. This non-welded hub-to-shaft joint also lacks a food grade gasket that could seal the dead spaces in the groove and avoid crevices at points of metal-to-metal contact. Ingress and accumulation of product and/or microorganisms at the inside are observed. Welds also have a high degree of roughness. *Courtesy of Burggraaf & Partners B.V., www.burggraaf.eu.*

steps, coupling surfaces, spanner flats, etc. should have 15 to 45° sloped surfaces. Impellers with flat, horizontal surfaces (e.g. flat-blade disc turbines, concave-blade disc turbines) may require additional design and/or cleaning practice to ensure drainage and cleanability, e.g. drain holes, spray ball and/or wand additions, increased CIP flow, adjusted spray coverage, and faster impeller rotation.

Agitators permanently mounted are not required to be removable if they are readily accessible and do not interfere with drainage from the tank. Where permanently installed agitators are equipped with an outer frame to which rubber, plastic or other similar scraping edges are attached, these scrapers shall be readily removable from the agitator. In kettles, however, it is recommended that the entire unit shall be constructed so that it can be tilted or lifted out of the kettle.

Welded in-tank shaft connections are preferred, although in-tank threaded shaft connections (Figure 26.24f) and in-tank shaft couplings (Figure 26.24a–e) are allowed if they are of acceptable hygienic design. Threaded shaft connections are preferred over in-tank shaft couplings, although shaft rotation of the first is limited to a single direction to avoid the shaft sections separating. The designer must ensure that the use of a threaded shaft connection is appropriate for the selected shaft diameter and design loads. To avoided exposure of the threads to the product, O-rings or flat gaskets (preference for the first mentioned) should be used to seal mating surfaces (Figure 26.24f). Hygienic bolted coupling construction may be used where appropriate for the particular application. The preferred location for fastening hardware is on the underside of couplings, and the fasteners typically used should be hex-head cap screws, acorn-head cap screws and threaded studs with acorn nuts (Figure 26.24d). These fastener heads shall be free of raised or engraved markings that might inhibit cleanability. Again O-rings or flat gaskets (preference for the first mentioned) should be used to seal coupling mating surfaces. Elastomer seal washers (Figure 26.24b–d) must avoid metal-to-metal contact.

Good Insulation Practices

Non-chloride-releasing insulation material should be used. For thermal insulation of vessels, appropriate qualities of rock wool are acceptable. However, for piping, Styrofoam,

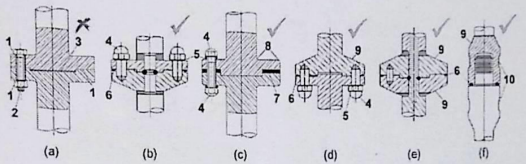

FIGURE 26.24 (a) Bolted agitator couplings with flat hexagon head screws without elastomer gasket under the bolt head and the nut give rise to metal-to-metal crevices (1) that may allow the ingress of food product and bacteria. Moreover, debris may lodge in and around the bolt thread (2). The absence of a circumferential O-ring or flat gasket gives rise to another metal-to-metal crevice, and product and microorganisms may be retained in the cavity (3). (b, c) Agitator couplings made by means of domed hexagon bolt heads and nuts (4) provided with an elastomer gasket (5) under the bolt head and the nut allow for a crevice-free joint without metal-to-metal contact. Due to the presence of a circumferential O-ring (6) or flat gasket (7), no product or microorganisms can enter inside the agitator coupling. Corners are radiused (8). However, there is still a horizontal flat surface at the upper side of the agitator coupling where debris may lodge. (d, e) Aseptic applications require for fastening hardware at the bottom side of the agitator coupling, and the upper parts of the coupling should be sloped to a minimum of 15–45° (9) to prevent debris from collecting at these places and to allow for maximum drainability. (f) The most optimal agitator coupling in an aseptic environment is a threaded shaft connection with a O-rings or flat gasket (preference for the first mentioned) (6) to seal the mating surfaces to avoid exposure of the interior thread. The corners of the spanner flats on the end cap have been radiused (10) (CFCRA, 1997; Hauser et al., 2004b; ASME, 2009).

foam glass or another rigid foam are better choices over fibrous materials. The problem with fiberglass batting is that this material has already proven to be an excellent harborage of dust, insects and rodents, and a clean-up and maintenance nightmare if not properly installed and maintained. Therefore, it is highly recommended to install fully welded, vapor-tight, aluminum or stainless steel cladding of appropriate thickness that resists tear and abrasion. The exterior of the insulation protection should be smooth, properly sealed to avoid ingress of dust, liquor, air and moisture, and should be installed in a correct way with joints facing downwards. Such ingress could promote corrosion between the walls, assisted by possible microbial growth. Damaged or wet insulation should be repaired or immediately replaced (Figure 26.25). Insulated lines should be kept high overhead where there is less chance for food products to contact the insulation. Pipes that are frequently soiled by food products or require periodic disassembly may be left uninsulated. Insulation is also often omitted around steam pipes inside cleanrooms, to preserve a clean exterior surface.

Equipment Framework

The number of support legs and cross bracings should be reduced but shall be of sufficient number and strength and so spaced that the process equipment will be adequately supported. Cross bracers should be fitted in a diamond configuration. Solid cross members as structural members are preferred over hollow section members. Although for use in the horizontal plane and to minimize horizontal ledges and crevices, completely sealed hollow section members are still preferable over open profile angle or channel sections (Figure 26.25a).

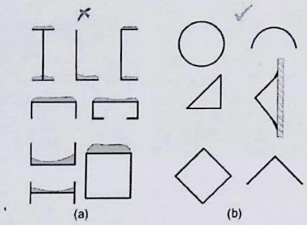

FIGURE 26.25 (a) Prevent unnecessary flat open and closed horizontal support members on which debris can lodge. (b) Round section, square section members turned through 45° and open profile members provide sloping surfaces (Lelieveld et al., 2003; Hauser et al., 2004b).

Round section members or square section members turned through 45° that provide sloping surfaces are recommended (Figure 26.25b).

For the design of framework that will be exposed to continuous vibrations (e.g. drying towers, etc.) the use of open profile construction should be considered. Small fatigue cracks can arise from vibration, allowing penetration of moisture, soil and microorganisms in closed profiles. For vertical parts of frames all the cross-sections shown in Figure 26.25 can be used when legs and supports are designed with open profiles; the folding should be turned outward for easy cleaning, or alternatively as completely closed pipes.

Rolled hollow sections must be sealed by welding, should be filled and made drainable away from the product zone. Plastic plugs are less recommended. Tubular sections shall not be penetrated, e.g. with fasteners, and hence drilled and tapped holes are not allowed. Preference should be given to welded plugs when fastening to hollow sections. Welded studs and tapping plates are not recommended.

Feet

Feet begin at the point where they attach to the leg of the body of the equipment and end at the support point on the floor. These feet are non-product contact surfaces but have a hygienic significance because they may become a harborage of soil and create a source of secondary contamination to the products (e.g. during pressure cleaning, dirt present on the feet may splash on the food contact surfaces).

Use a minimum number of support legs/floor mountings, because they are important obstacles for cleaning and service personnel. However, feet must be sufficient in number and strength and so spaced that the equipment will be adequately supported. The general rule is to minimize the floor contact area, but the contact face of the foot must be sufficient to absorb the pressure. If the equipment is heavy and requires leg pads to distribute the load, such pads or bases shall be fastened to the floor. The manner in which feet are fastened

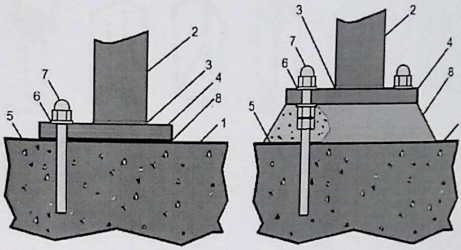

FIGURE 26.26 If the equipment is heavy, the contact face of the foot (2) with the floor (1) must be sufficient to absorb the pressure. To distribute the load, feet should be provided with leg pads or bases (4) welded to the foot leg (3). The foot may be fastened to the floor (5) by means of stainless steel anchor bolts which must have seal washer(s) (6) and dome nut(s) (7) fitted. When the equipment is bolted to the floor, pads or bases shall be sealed (figure left, 8) or grouted (figure right, 8) to the floor.

to the floor depends on the type of floor and the presence of equipment (e.g. machinery producing heat, etc.) or services (e.g. electricity, etc.) immediately below the surface. Fastening to the floor may occur by bolting, but chemical anchors without bolting (fixing to floors by means of a polymer seal) are recommended. If the equipment must be bolted to the floor, pads or bases shall be sealed or grouted to the floor (Figure 26.26). Care must be taken during installation to assure that the foot pad does not span over cracks, grout lines or other floor imperfections. Whenever anchor bolts have been drilled into the floor, the holes must be sealed with epoxy or similar materials, dependent on the floor, so that water and dirt are not allowed to leak into the hole. Floor fixings should be of stainless steel, and have dome nuts fitted.

Fixed feet should be radiused, free of sharp corners and crevices at the fixing point. Feet ends may have a foot base with flat (not recommended) or sloped surfaces (recommended), or may consist of a pivot-socket arrangement where the pivot-end of the spindle may freely swivel in the socket or internal cavity of a separate load-bearing foot base (Figure 26.27). This type of connection allows relative inclination of the foot stem and foot base as in an articulated bone joint, and is optimal to allow equipment to be repositioned or moved to uneven surfaces without loss of stability. Due to the non-rigid nature of the foot leg–foot base transition and because the load of the supported equipment is more evenly distributed about the surface of the socket, articulated support feet can better cope with the vibratory or oscillatory movements of the process equipment.

Ball feet are not recommended because they leave uncleanable crevices between the floor and the foot. Moreover, mechanically, they will almost destroy the floor, because – due to their very small contact surface with the floor – they exert locally a very high pressure. If the process equipment is heavy and prone to vibration, the floor will break up very quickly.

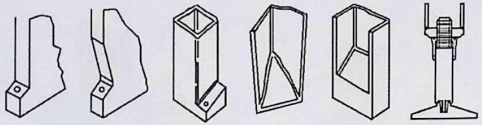

FIGURE 26.27 Feet ends may have a foot base with flat (not recommended) or sloped surfaces (recommended), or may consist of a pivot-socket arrangement where the pivot-end of the spindle may freely swivel in the socket or internal cavity of a separate load-bearing foot base. Feet ends with horizontal flat surfaces are not recommended. For maximum drainability, all surfaces of the feet not in contact with the floor should be sloped, with rounded corners and smooth welds (APV Baker, 2001).

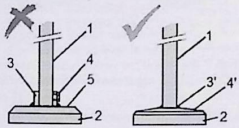

FIGURE 26.28 (a) Foot spindle (1) is inserted into a bush (3) which is welded to a foot base (2). The foot spindle is rigidly fastened to the foot base by means of a screw (4). This foot is not hygienically designed because the upper part of the foot base forms a non-drainable flat surface (5). Debris and water may collect into the crevice formed between the inner surface of the bush and the inserted part of the spindle, and around the fastening (4). (b) The foot spindle (1) is all-around flush welded (3') to the foot base (2) from which the upper surface parts (4') are now sloped to make them drainable (Hauser, 2008b).

All exposed surfaces shall have a smooth finish such that soil may be cleaned from the surface using manual cleaning techniques, and be free of pits, folds, cracks, crevices and other imperfections in the final fabricated form, when installed on the machinery and within the specified load conditions. Hence, feet may not create dirt traps, and further they must be self-draining which means that they shall not have pockets which retain liquids (Figure 26.28b). Feet with fixing holes should be provided only if bolting to the floor is necessary, but avoid the use of extra brackets. Figure 26.29 shows some examples of hygienically designed feet.

Equipment should be adequately located in position, with all its feet having a contact face that is even so as to ensure complete contact with or to allow fixation to the floor. For proper installation on uneven or inclined floors, the use of improvised shimming to level food processing equipment is not allowed. Equipment feet adjustable by min ±75 mm should be used. When adjustable feet with threads are used for this purpose, the threaded spindle for leveling should be completely concealed in closed profiles/pipes or enclosed so as not to cause accumulation of dirt and contaminants in the thread.

The load-bearing foot may also include a rubber layer underneath or rubber can be embedded in the load-bearing foot. The elastomeric material may dampen the vibrations of the operating equipment and may prevent slipping of the foot on the support surface. The