Chapter 11

Managing Contamination Risks From Packaging Materials

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11.1 INTRODUCTION

Food contact materials (FCMs) have very specific safety requirements, in most cases established by standards and regulations, and in some cases, when they are lacking, by industry specifications. FCMs constitute a group of materials and articles that comprise mainly:

1. Food packaging (FP) materials (ie, primary and secondary packages);
2. Packages accessories (eg, caps, stoppers, drinking devices as plastic straws, dispensing valves);
3. Promotional articles (eg, toys, cards, labels) included in the primary package;
4. Utensils and containers for the domestic preparation, containment, and consumption of foods (eg, kitchenware, drinking water plastic dispensers, coffee sticks);
5. Equipment, devices, utensils, and containers for the transport of raw materials and the industrial manufacture, storage, and packaging of foods;
6. Surfaces of food vending machines intended to come into contact with foods;
7. Fixed installations for the distribution and storage of drinking water in households and factories (eg, pipes, containers).
8. Reparation materials for domestic or industrial use (eg, epoxy/amine-based resins for reparation of industrial coated food containers or domestic water pipes).

This chapter refers mainly to contamination risks, and their management, arising from the first three above-mentioned categories, as they are articles used by food manufacturers to package foods in definite units, to put them onto the market, and to provide in some cases convenience of use to consumers. "Food packaging (FP)" seems then to be an adequate short way to refer to them in general in this chapter. Several chapters in Part II of this handbook deal more specifically with the contamination risks, and their management, associated with other categories of FCMs. In this chapter, foods also include beverages. Section 11.5 deals with the regulatory aspects of FP and other types of FCMs.

The most important functions that FP must fulfill are food containment and protection (also against human tampering), convenience to consumers, product sale promotion, and useful communications for consumers (Restuccia et al., 2010; Robertson, 2013).

In general, the hygiene requirements for FP are similar to the other categories of FCMs, with exceptions. For instance, kitchenware and utensils are included in the scope of the FCMs regulations in the EU and the Common Market of the South (MERCOSUR), but they are not covered by the US FDA FCMs regulations (Ariosti, 2015a). Fixed public or private drinking water supply equipment is excluded from the scope of the FCMs regulations in these three jurisdictions (Ariosti, 2015a), but is covered in general by specific standards.

The extensive and updated references are useful sources for further reading. Useful website links are also provided at the end of this chapter.

11.2 INTERACTIONS BETWEEN FP, FOODS, AND THE ENVIRONMENT

All stakeholders in the food supply chain are interested in ensuring the safety of foods and their packaging, thus protecting the consumers' health. It is a well-known fact that FP (primary and secondary packages), foods, and the surrounding

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environment can interact between them (Katan, 1996; Catalá and Gavara, 2002; Barnes et al., 2007; Brandsch and Piringer, 2008; Kopper and Ariosti, 2010; Robertson, 2013; Barone et al., 2015; Barp et al., 2015; Eicher et al., 2015).

Conventional FP aims at minimizing these interactions during the product's shelf life. However, in the case of equilibrium modified atmosphere packaging (EMAP) for fruits and vegetables, or antimicrobial active packaging, a high permeability to gases and an enhanced migration of the antimicrobial agent, respectively, are desired (Brody et al., 2001; Ahvenainen, 2003; Dainelli et al., 2008; Restuccia et al., 2010; Pereira de Abreu et al., 2012; Robertson, 2013; Realini and Marcos, 2014).

Each type of FP has specific interactions that must be assessed. For instance, in the case of plastic FP, the main Fickian diffusive processes involved are (Kopper and Ariosti, 2010) (see Fig. 11.1):

1. Permeability of water vapor, gases (eg, oxygen, carbon dioxide, nitrogen) and aromas, through the plastic package wall, from the external medium to food or vice versa, depending on the partial pressure of the permeants at both sides of the plastic package wall;
2. Migration of FP components from the plastic package wall to food;
3. Sorption (scalping) of food components (or foreign substances from nonfood products in case of misuse) by the FP; and
4. Desorption of sorbed components from the FP to the new food in contact.

Permeability evaluation is important for packaging design, prediction of shelf life of packaged foods, or FP quality control, but in general it has not been regulated by legislation. Migration tests or its prediction by mathematical models are necessary to establish compliance with FCMs regulations (see a detailed discussion in Section 11.4). Sorption and desorption are the phenomena of interest in the case of refillable plastic FP, and of FP manufactured with decontaminated postconsumer recycled (PCR) plastics (Kopper and Ariosti, 2010).

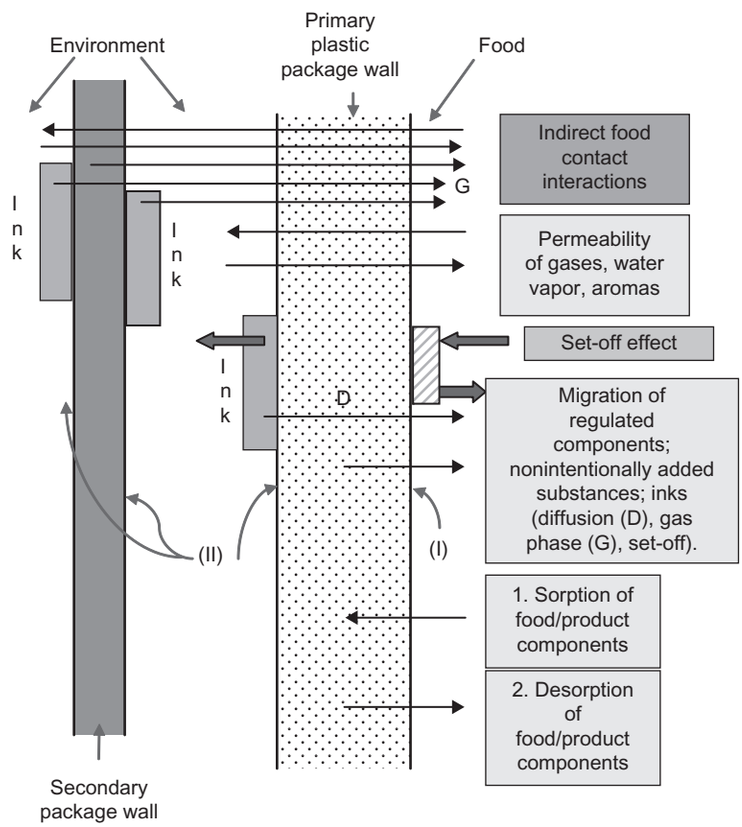

FIGURE 11.1 Examples of possible interactions between environment, primary plastic package (with and without secondary package), and food. (I) "Food-contact side" is the packaging material surface that is directly in contact with food; and (II) "nonfood-contact side" is the packaging material surface that is not directly in contact with food (EU, 2006).

In addition, the physical-mechanical properties and integrity of FP can be modified by migration (eg, flexible plastics stiffening due to loss of plasticizers), by sorption (for instance, swelling of hydrophilic or hydrophobic plastics by excessive absorption of food components such as water or oil, respectively), by corrosion (for instance, perforation (pitting) of tinplate cans due to depolarization and advanced dissolution of iron acting as the anode, with tin acting as the cathode, in contact with the canned food), etc.

11.3 MAIN CONTAMINATION HAZARDS IN FOOD DUE TO FP

Contamination problems in food due to FP can be associated with:

1. Physical hazards;
2. Insect infestation hazards;
3. Microbiological hazards;
4. Chemical hazards;
5. Allergen hazards.

In general, FP manufacturers establish internal standards for microbiological hazards, while physical hazards are more detailed in regulations and international standards. Chemical hazards are widely regulated worldwide. Due to their low prevalence, allergens in FP are not fully addressed yet in standards and legislation.

The Canadian Fact Sheets (Government of Manitoba, 2015a–e) are good introductory guidelines, especially recommended for small and medium-sized enterprises (SMEs). They summarize briefly the different types of hazards associated with foods and FP, and their characterization and management.

11.3.1 Physical Hazards

Physical contaminants in foods are a serious concern for the food industry, as they are the most obvious to consumers, in general due to their macroscopic nature that makes them very visible, hard or sharp, and thus they are a cause of a major number of complaints (UNL, 2005a; de la Cruz García et al., 2014). However, when present in a packaged food, and irrespective of their origin (food or FP), these contaminants tend to affect smaller numbers of consumers than chemical or microbiological contaminants, whose action can be more widespread in the population (UNL, 2005a).

The two main categories of physical hazards due to FP are (UNL, 2005a; Wilm, 2012; CFIA/ACIA, 2013; de la Cruz García et al., 2014; Goodwin, 2014; Government of Manitoba, 2015a; Mason, 2015):

1. Physical features of FP that can produce injuries to consumers before or during food consumption, for instance:
   - **a.** sharp or hard finishes of FP;
   - **b.** badly cut plastic scrap that remains in the FP;
   - **c.** sharp excrescences, defects, or broken material in threads of plastic or glass bottle necks, produced during molding, manipulation, cleaning, or filling of the containers;
   - **d.** sharp edges of metal can bodies or ends (of conventional or easy-opening packages) formed during opening by the consumer;
2. Foreign bodies present in food by detachment from FP materials, for instance:
   - **a.** small pieces of plastics, glass, paper, metals, rubbers, or wood of the primary FP;
   - **b.** paper, board, or plastic wraps from secondary packaging adhered to the primary FP surface;
   - **c.** fragments of plastic straps;
   - **d.** fragments of paper or plastic labels inside bottles after cleaning operations in washing machines;
   - **e.** filth from insects, birds, or rodents (feces, feathers, hair);
   - **f.** mite and insect eggs, larvae, and adult forms, dead or alive;
   - **g.** workers' hair, fingernails, band-aids, cigarettes, jewelry, and other personal objects.

Recently interesting research performed at the Chemical and Veterinary Analytical Institute (CVUA-MEL, Münster, Germany) was reported by Brauer (2014) on table salt packages with plastic millworks. During employment, the millworks plastic teeth were abraded and foreign particles contaminated the salt. The research group developed a gravimetric method to quantify the mass of abraded plastic present in the product, and recommended that in the design of the millworks, the plastic material used must be harder than the salt, in order to avoid teeth abrasion. The same precautions apply in the case of packages with millworks for different peppers.

BOX 11.1 Points to Consider—Management of Physical Hazards

Physical hazards must be assessed and managed within the Hazard Analysis Critical Control Point (HACCP) system, for instance by means of (Wilm, 2012; CFIA/ACIA, 2013; de la Cruz García et al., 2014; Government of Manitoba, 2015a; Mason, 2015):

- Proper equipment design, selection, calibration, and maintenance;
- Exclusion of potential sources of foreign material within the establishment;
- Effective detection systems (eg, online human visual inspection, machine vision, metal detectors, X-ray detection, low power microwaves-based food radar systems (FRS));
- Effective elimination systems (eg, magnets, sieves, filters, extruders, filters);
- Screening assessment of raw materials and FP components;
- End-product screening (eg, electronic bottle (glass, plastic) inspection (EBI));
- Personnel hygiene and training program;
- Consumer feedback or complaint analysis.

Problems involving physical contamination usually reflect potential microbiological concerns, and are indicators of the overall sanitation level of the establishment. Furthermore, foreign body identification (for instance by Fourier transform infrared (FT-IR) spectrometry, light microscopy, scanning electron microscopy (SEM), compound microscopy, X-ray microanalysis, etc.) usually provides useful information on the source of the contamination that can help to correct the problem (CFIA/ACIA, 2013).

Wilm (2012) discusses the regulatory status of physical contamination of foods in Canada, the EU, and the United States. See also the US FDA (2015) considerations on hard or sharp foreign objects that measure less than 7 mm, between 7 and 25 mm, and over 25 mm in length (Box 11.1).

11.3.2 Insect Infestation Hazards

Several authors have studied insect infestation of packaged foods and its control, providing also interesting bibliography reviews, for instance in the case of plastics films (eg, polyethylene (PE), polypropylene (PP), polyethylene terephthalate (PET)), cellophane, and laminates (Navarro et al., 2007; Allahvaisi et al., 2010; Chung et al., 2011; Mullen et al., 2012; Allahvaisi, 2012, 2013); paper (Hou et al., 2004); and plastic inner liners (PE, PP, polyvinyl chloride (PVC)) for jute bags for grains (Marouf and Momen, 2007). Paper and cellophane are less resistant to insect attack than plastic films and laminates.

In warehouses and retail stores where packaged foods remain during long storage periods, insect infestations can spread between different products. Insect infestation originating in packaged feed (eg, pet foods, birdseeds) can contaminate food if both types of products are stored together in the same warehouse. Infestations can also be produced during shipment of goods or during home storage of the packaged food.

Dead or alive adult moths can sometimes be seen trapped inside FP (eg, dried aromatic herbs, dried mushrooms). Flying insects (eg, flies, moths) are attracted by illuminated locations where FP is manufactured, mainly during night shifts. In the absence of good pest control programs, the insects can reach the proximity of the converting machines, and can get trapped between the plastic film surfaces when winding the material into reels, or between plastic trays or cups when stacking them. Low-voltage traps that have an attracting light and a replaceable, sticky board are used to attract flying insects to become attached to the sticky board.

Packaged foods can suffer attack by two main types of insects (Mullen et al., 2012):

1. *Invaders*, which are those insects that cannot perforate the packaging wall, but can enter into it through already-existing openings. For instance, they can access food through unintentional pinholes in FP due to mechanical damage, defective seals, seams and closures, holes made by other insects, etc. This category accounts for 75% of the infestations, and some examples of these insects are the flat grain beetle (*Cryptolestes pusillus*), rice moth larvae (*Corcyra cephalonica*), square-necked grain beetle (*Cathartus quadricollis*), and so on;
2. *Penetrators*, which are those insects that have developed strong mouthparts that allow them to chew small holes into FP. Penetrators tend to be most dangerous at the larval stage, and some examples of these insects are the warehouse beetle (*Trogoderma glabrum*), rice weevil (*Sitophilus oryzae*), cadelle (*Tenebroides mauritanicus*), etc. The warehouse beetle may pose an additional problem, as the larval cast skins can cause allergic reactions to consumers.

BOX 11.2 Points to Consider—Management of Insect Infestation Hazards

Insect infestation hazards must be assessed and managed within the HACCP system. Besides, some basic actions to deal with insect infestation hazards are (Mullen et al., 2012; Government of Manitoba, 2015b):

- Use polished FP surfaces as they are difficult for insect adherence and displacement;
- Perform a sound FP design to avoid unnecessary holes, folds, or other features that can be possible points of penetration or niches for insects to lay eggs;
- Apply good manufacture practices (GMPs) to avoid damage (eg, pinholes or cracks) in the FP material during production, handling, and storage;
- Make strong seals (eg, heat seals) without discontinuities, as they are good barriers to insects;
- Use materials with adequate thickness and with barrier (ie, very low permeability) to food aromas that can attract insects (eg, polyvinylidene chloride (PVDC), ethylene-vinyl alcohol copolymer (EVOH), laminates with aluminum foil);
- Use adequate vent holes or valves;
- Maintain good hygiene in facilities during FP manufacture, storage, and shipping;
- Use FP materials with repellents or IGRs approved in the jurisdiction;
- Apply an efficient pest control program in all the facilities involved.

Both types of insects can enter FP through intentionally designed perforations, as in the case of EMAP used to extend the shelf life of fresh vegetables and fruits. Tiny holes are made on the plastic films by mechanical puncture or laser perforation, to facilitate the exit of water vapor by a convective mechanism (which is not the diffusive permeability mentioned in Section 11.2), through them. The materials used (eg, PE, PP) have a high permeability to oxygen and carbon dioxide (gases involved in the aerobic respiration of the product), and a very low permeability to water vapor. Thus, if the material is not perforated, water vapor remains inside the package, condenses on its inner cold surface (due to refrigeration), the product is not clearly seen by the consumer due to the "fog" effect, and the water drops in contact with the product can favor microbial development. EMAP can be also achieved with nonperforated packages, if the internal surface is coated with antifog additives. Besides, maintaining the cold chain helps, as good refrigeration diminishes insect activity.

Another example of intentionally designed perforations is vent holes that allow equalization of gas pressures, due to changes in air pressure or temperature during storage and transportation, thus avoiding package swelling or shrinking. These vent holes can be used by insects to enter the packaged food, unless a tortuous path can be designed, for instance using double heat seals, that ensure the vent while limiting the insects' entrance (Mullen et al., 2012). Vent holes or valves are also used on sealed plastic packages for cooking refrigerated fresh vegetables or chicken in the microwave oven, or to allow the exit of carbon dioxide produced by the Strecker reaction (a step in the Maillard reaction) in the case of roasted coffee in plastic packages.

Studies have been performed in order to assess the use of chemical repellent coatings on FP materials, but this is a field where more research is needed. Several synthetic and natural substances were tested (eg, neem oil and other plant extracts, turmeric powder, methyl salicylate, DEET derivatives, insect growth regulators (IGRs)). Possible taints in foods due to the migration of these chemicals, or pending clearance for food contact, have rendered most of these substances commercially unfeasible (Navarro et al., 2007; Mullen et al., 2012). Recently, the repellent methyl salicylate was approved by the US EPA and the US FDA, and the IGR methoprene was approved by the US EPA and is being assessed for use in FP (Mullen et al., 2012).

Navarro et al. (2007) described the development of a natural nontoxic insect repellent for packaging materials, based on turmeric essential oil, obtained by extraction of the turmeric (*Curcuma longa* L.) dried powdered rhizome. The research was the basis for US and European patents. The authors also discussed other studies on the repellent action of other plant extracts (eg, eucalyptus, mandarin orange peel, cinnamon oil) and the repellency tests and penetration prevention bioassays performed (Box 11.2).

11.3.3 Microbiological Hazards

FP is generally not considered to be a source of microbiological hazards of concern, and there are no published cases where pathogenic microorganisms present in FP have migrated from it to food, proliferated in it, and caused illness in consumers, though there are cases of FP-borne spoilage microorganisms causing food alteration, including sensory problems (Raaska, 2005; de la Cruz García et al., 2014). Though food itself is always a more important source of

microorganism contamination than FP, the later microbiological hazards must be assessed according to the type of food to be packaged (Raaska, 2005).

Though FP-borne microorganisms may not compromise food safety in most cases, special attention must be paid in the case of aseptic or retortable packaging technologies (Raaska, 2005). In these products microbes can penetrate from the external environment through FP mechanical defects into foods, and as the natural flora is thermally inactivated to attain a long shelf life, the invader microorganisms face no biological competition and can grow very quickly, and be a serious risk to food safety. FP does not need to be commercially sterile for most applications (except in the case of aseptic packaging), but must be reasonably clean, with a low microbial charge compatible with the food to be packaged. This can be achieved applying GMPs under the HACCP system.

At present, not only is there a certain lack of scientific and technical information on the microbiological quality of FP, but microbiological requirements for FP are also usually missing in regulations if compared with requirements for FP chemical contaminants (Raaska, 2005; Hennlich, 2010, 2011; Steinka, 2015).

Paper and board are the FP materials most affected by microbial activity, as the main components (cellulose fibers and lignin) are naturally biodegradable. Raaska (2005) gives a detailed description of microbiological problems in the paper and paper packaging industry:

1. Microorganisms that spoil raw materials breaking down cellulose fibers, starch, casein, and rosin sizing agents (eg, *Pantoea agglomerans* and *Bacillus subtilis*);
2. Microorganisms acting during the manufacture of paper and board, producing lime and deposits (eg, *Burkholderia cepacia*, *Deinococcus* spp., *Bacillus* spp.);
3. Potential pathogenic microorganisms that can pose a risk to human health, present in raw materials, process environment, and final products (eg, *Bacillus cereus*, *Klebsiella pneumoniae*, *Staphylococcus aureus*; coliforms and molds);
4. Microorganisms that reduce the quality of the final products (for instance causing color defects) (eg, *Bacillus cereus*, coliforms, and molds);
5. Microorganisms that can produce taste and smell taints in the final product (eg, *Clostridium* spp., *Desulfovibrio* spp., actinobacteria).

Microorganisms can contaminate paper and board in two main ways (Raaska, 2005):

1. Those present in the raw materials (eg, primary fibers, recycled fibers, additives, fillers, coatings, starches) and those that contaminate pulps during the manufacturing process (for instance by recirculation water or equipment biofilms), and thus remain in the whole mass of final products; and
2. Those that colonize the final product's surface during handling and storage (eg, airborne microorganisms, microorganisms present in environmental aerosols, handling by personnel).

The pioneer studies on FP microbiology performed by Hartman et al. (1963) at the University of Georgia, Atlanta, United States, indicated that the different FP materials under evaluation (cellophane, cellulose acetate, PE, multilayer vacuum bags), as was expected, were not sterile, and the colony-forming unit (CFU) counts usually ranged between nondetectable and 50 CFU/in^2 (8 CFU/cm^2), with samples occasionally presenting more than 50 CFU/in^2 (8 CFU/cm^2).

Detailed results of several studies on FP microbial content, microbial activity in and biodegradation of FP, and penetration biotests of microorganisms through FP to foods, have been presented, for instance, by Hurme et al. (1997) (for semirigid aseptic and retortable containers), Suominen et al. (1997) (for paper and board), Raaska (2005) (for paper and board), Ravishankar et al. (2005) (for plastic trays), Guzińska et al. (2012) (for paper and board), and Steinka (2015) (for different FP materials, for instance paper and board, polystyrene (PS) trays, PP, PE/PA coextrusions, perforated PE for produce, cellophane, metal and glass containers, etc.).

Aerobic and anaerobic spore-forming bacteria, which are common in mill water recirculation, can contaminate end-products. The main contaminants in FP paper and board are aerobic spore-forming bacteria of the *Bacillus*, *Paenibacillus*, and *Brevibacillus* genera (Raaska, 2005; Steinka, 2015). The persistence of these bacilli in paper and board has many causes, for instance, the recycling of bacilli-rich broke (ie, scrap), resistance to heat during drying of paper and board, possibility of growth on the cellulosic matrix due to their cellulolytic activity, and resistance to many slimicide additives. On the other hand, anaerobic spore-forming bacteria, like *Clostridium*, produce gases and organic acids (eg, butyric, acetic, propionic) due to anaerobic fermentation, that can generate taint problems in the end-products (Raaska, 2005). In PE-coated paperboard, aerobic spore-forming bacteria are generally 10 times more abundant than the anaerobic ones, and occasionally *Enterobacteriaceae* have been detected (Steinka, 2015).

Fungi can also cause problems in paper and board end-products. Under storage conditions of low illumination and high moisture, fungi can ferment cellulosic substrates, producing organic metabolites of high sensory activity that cause

taint problems in food, and also dangerous mycotoxins. *Aspergillus*, *Cladosporium*, *Fusarium*, *Mucor*, and *Penicillium* species have been detected in cartons (Raaska, 2005; Steinka, 2015).

A special problem is the formation of 2,4,6-trichloroanisole (TCA) and other chloroanisoles in cork stoppers by fungi, that along with many other compounds, produce a musty/moldy/earthy taint (in French: goût à bouchon) in bottled wines. Several studies have been performed on this sensory problem, apparently originated by fungi from chlorinated phenolic compounds present in cork (Sefton and Simpson, 2005; Teixeira et al., 2006; Gardner, 2008; Maggi et al., 2008). Maggi et al. (2008) could reproduce the formation of TCA from 2,4,6-trichlorophenol (TCP) by *Penicillium*, *Aspergillus*, and *Trichoderma* (isolated from cork), and by *Botrytis cinerea* (isolated from grapes), growing on cork. Apart from traditional or refined cork boiling, several commercial treatments can help to reduce or eliminate this taint problem, for instance, cork decontamination by steam, supercritical fluid extraction, enzymatic action, microwave heating, and the use of cork stopper coatings as functional barriers that diminish migration of TCA and related compounds to wines (Sefton and Simpson, 2005).

The musty/moldy/earthy taint was one of the reasons that induced industry in the last decade to develop plastic stoppers, formulated with low-density polyethylene (LDPE), LDPE-based thermoplastic elastomer (TPE), styrene-butadiene-styrene (SBS) copolymer, styrene-ethylene/butadiene-styrene (SEBS) copolymer, etc. (Gardner, 2008).

Actinobacteria are Gram-positive bacteria that present diverse morphological diversity, from micrococci to branched filament-forming species. The most common in paper and board are *Actinomyces*, *Mycobacterium*, *Frankia*, *Nocardia*, *Micrococcus*, and *Streptomyces*, all of which are the most prevalent microbes to cause taint problems, for instance due to production of geosmins. Furthermore, many streptomycetes can produce antibiotics and *Streptomyces anulatus* can generate genotoxins (Raaska, 2005).

Steinka (2015) presents results of several studies on the survival period of viruses on the external surface of FP, for instance:

- Up to 2 months for hepatitis A viruses on aluminum cans;
- Up to 12 days for rotaviruses on glass;
- Up to 2 days for polio and hepatitis A viruses on plastic FP;
- Up to 2 days for *Orthomyxoviridae* on steel.

The stages of biofilm formation on the inner surface of FP are: settling (ie, the microbial deposition on the FP surface); adhesion to the surface; proliferation and development of the biofilm by populations of microorganisms interacting with food. Some examples are: biofilms of mesophilic aerobes on LDPE; *Listeria monocytogenes* on glass; *Escherichia coli* on PS; *Staphylococcus* ssp. on PE, PP, and PVC; *Pseudomonas* ssp. on PP and PVC; and so on (Steinka, 2015). The characterization of biofilms and their development is important for food safety reasons and to assess the shelf life of the product. Biofilms can also develop on the outer surface of FP.

Penetration of microbes through packages into food depends on several factors, for instance, the presence of physical damage (discontinuities) in FP (eg, pinholes, pores or micropores, cracks, delamination, badly performed heat seals), their size (diameter or length), and the material wettability (FP material surface energy that determines its angle of moistening, θ); the difference in pressure at both sides of the FP wall; the type of food (eg, water content, viscosity) and the pressure they exert on the discontinuities; the storage conditions (eg, time and temperature); and the characteristics of the microbes (eg, morphology, motility), and their quantity. According to several studies, the minimum discontinuity radius reported as necessary for the penetration of microorganisms is 1 μm for metal cans, 5 μm for rigid boxes, 5–15 μm for rigid bottles, 5–10 μm for semirigid plastic containers, 22 μm for flexible plastic laminates, etc. The studied microorganisms with penetration capability include the bacteria *Pseudomonas* spp., *Staphylococcus* spp., *Bacillus* ssp., *Escherichia coli*, *Enterobacter cloacae*, *Enterobacter aerogenes*, the yeast *Candida albicans*, and the fungi *Aspergillus brasiliensis* (Steinka, 2015).

Microorganisms can also penetrate FP through intentionally performed pinholes (as in the case of EMAP), or through holes performed by penetrator insects, and on the bodies of larval or adult forms of both penetrator and invader insects.

Two examples of food preservation technologies where the evaluation of microbial penetration is necessary when performing microbiological hazard characterization, related to aseptic and retortable FP, are discussed below.

In aseptic packaging, FP and food are commercially sterilized in separate ways, and then packages are filled in sterile conditions, that is, foods are not thermally treated inside their packages. In these cases, pinholes, micropores, cracks, and defective heat seals are the main causes of external microbial contamination. In the case of ultrahigh-temperature (UHT) sterilized milk packaged in cartons, the packages are sterilized by evaporation of an aqueous solution of hydrogen peroxide with hot air that inactivates vegetative microbes and their spores. An alternative system for aseptic packaging of UHT sterilized milk is the use of high-density polyethylene (HDPE) bottles with a middle layer of EVOH as a barrier material

(HDPE/EVOH/HDPE), manufactured by coextrusion blow molding; the bottles are sterilized with sanitizing solutions. Another example of aseptic packaging is the use of bag-in-box systems for drinking water, table wine, concentrated tomato and fruit pulps, soda syrups, etc. In this case, the double plastic bags, intended to contain the food, are sterilized (when empty) by gamma-radiation or accelerated electron beam.

In retortable packaging, in contrast to aseptic packaging, nonsterile food is packaged in nonsterile FP, in nonsterile conditions, and the product is then subjected to steam sterilization in retorts. In retortable packaging such as tinplate, tin-free steel (TFS) and aluminum cans, the main external contamination problems can arise due to perforated metals by corrosion, defective side seams, or can-end double seams. Glass containers or jars need good metallic caps with rubber- or plastic-based liners to ensure air-tightness. Pinholes, micropores, cracks, and defective heat seals are important in the case of semirigid packages, for instance retortable pouches (PET/aluminum foil/PP laminates); retortable coextruded and thermoformed trays (PP/EVOH/PP) with heat-sealed lids (PET/aluminum foil/PP laminates or PP/EVOH/PP coextruded films); and retortable cartons.

Microbial contamination in FP is rarely regulated. For instance, in the case of paper for one-way cartons for "Grade A" pasteurized milk and milk products, the US FDA (2007) established in the Pasteurized Milk Ordinance (PMO) (2007 Revision) the following requisites:

1. Paper stock prior to lamination shall have not more than 250 CFU/g of paper, as determined by the disintegration test;
2. When a rinse test is used, the residual microbial count shall not exceed 50 CFU/container for containers with a capacity of 100 mL or greater, or 10 CFU/container for containers with a capacity of less than 100 mL;
3. When the swab test is used, the count shall be not over 50 CFU/8 in^2 (1 CFU/cm^2) of product-contact surface in three out of four samples taken at random on a given day;
4. All single-service containers and closures shall be free of coliform organisms.

As an example of the minimal contribution of FP-borne microorganisms, if compared with the normal food flora, as mentioned before, it is worth mentioning that the US FDA also established in Section 7 of the PMO (Revision 2007) for "Grade A" pasteurized milk and milk products, the following requirements:

1. Total count of samples maintained at 7°C: not more than 20,000 CFU/mL or g of product;
2. Coliform count of samples maintained at 7°C: not more than 10 CFU/mL of product (not more than 100 CFU/mL of product, in the case of bulk milk transport tank shipments).

Specific values for microbiological contamination of FP after manufacture and before filling are mainly established by internal standards of food or FP manufacturers. Since 2002, the German Industrial Association for Food Technology and Packaging (in German: Industrievereinigung für Lebensmitteltechnologie und Verpackung e.V.) (IVLV), in a joint project with the Fraunhofer Institute for Process Engineering and Packaging (in German: Fraunhofer Institut für Verfahrenstechnik und Verpackung) (Fraunhofer-IVV) in Freising, Germany, began establishing guideline values for microbiological contamination on FP and packaging systems. Part I of the project deals with packaging materials and packaging systems made of nonabsorbent materials, while Part II deals with glass and plastic bottles, and Part III with paper and board laminates (Hennlich, 2010, 2011). For instance, some of the microbiological reference values presented are:

1. For films and lids manufactured with plastic and aluminum foil (Part I): total surface colony count (mesophilic aerobic microorganisms) ≤2 CFU/100 mL; molds and yeasts ≤1 CFU/100 mL; enterobacteriaceae: not detectable;
2. For glass bottles (volumes from 20 mL to 2.5 L) (Part II): average total surface colony number (20 samples minimum) ≤20 CFU/container (internal surface; sampling directly prior to the packaging process of the container to be delivered);
3. For plastic/PET bottles (Part II) (20 samples minimum):
   a. Complete parison (ie, internal and external surfaces), sampling prior to blow molding: average ≤10 CFU/parison, maximum 50 CFU/parison;
   b. Complete bottle (both surfaces), sampling prior to sterilization: average ≤20 CFU/bottle, maximum 100 CFU/bottle;
   c. Bottle (only internal surface), sampling prior to sterilization: average ≤10 CFU/bottle, maximum 50 CFU/bottle;
   d. Closure, sampling prior to sterilization: average ≤10 CFU/closure, maximum 50 CFU/closure.

These guide values for plastic/PET bottles coincide with the requirements for FP intended for aseptic packaging of beverages, established by the Association of the Beverage Machinery Industry (Zürich, Switzerland) (ABMI, 2015), but in this last case, the tests must be carried out with 10 samples (Box 11.3).

BOX 11.3 Points to Consider—Management of Microbiological Hazards

Microbiological hazards must be assessed and managed within the HACCP system. Prevention is essential to keep microbiological hazards under control. Besides, some basic actions to deal with microbiological hazards are (de la Cruz García et al., 2014; Government of Manitoba, 2015c):

- Applying effective cleaning and sanitizing procedures (sanitation standard operating procedures, SSOPs) to minimize cross-contamination due to facilities and improper equipment sanitation;
- Effective pest control (insects, birds, rodents);
- As enterobacteriaceae and coliform counts reflect potential contamination from fecal sources, human contamination due to poor personal hygiene must be prevented;
- Training personnel also to avoid failure in reporting personnel illness, open sores or wounds;
- Use of adequate technologies to sterilize FP involved in aseptic packaging.

11.3.4 Chemical Hazards

Chemical hazards are by far the most studied and regulated aspects of FP (and of other FCMs) safety. They are the main focus of FCMs regulations worldwide, though only recently have standards that deal with prerequisite programs (PRPs) specifically related to FP manufacturing (eg, PAS 223:2011, ISO/TS 22002-4:2013), begun mentioning chemical migration as a point to assess and control.

Migration is the generic word used to denominate the transference of substances (ie, migrants) originally present in FCMs to foods. Several mechanisms have been proposed to explain this phenomenon (eg, Fickian diffusive migration in plastics, rubbers, and can coatings; corrosion in metallic cans; lixiviation of alkaline ions in glass, lead in crystal glass, and lead and cadmium in ceramic; extraction of paper and board components, by water or oil that enter the cellulosic matrix by capillarity) (Katan, 1996; Catalá and Gavara, 2002; Brandsch and Piringer, 2008; Kopper and Ariosti, 2010; Robertson, 2013; Montanari, 2015).

Combinations of these mechanisms can be found in complex multimaterial systems, for instance, in the case of metallic cans for preserves, where the basic metals (tinplate, TFS, or aluminum) are usually internally coated with polymeric plastic enamels or varnishes (colored with pigments or not), and the can-ends are double-seamed with the addition of can-end polymeric cements (basically rubber-based). Diffusive migration of substances may happen from the internal coatings and from the can-end cements. Corrosion is also expected in the case of the basic metals, with release of tin, iron, chromium, and aluminum ions, and also heavy metals (Buculei et al., 2012; Kassouf et al., 2013; Montanari, 2015).

The Council of Europe (CoE) has issued Resolution CM/Res (2013)9 of June 11, 2013, on metals and alloys used in FCMs and articles (nonmandatory). The Resolution has been published along with the "Technical guide on metals and alloys used in food contact materials and articles" (EDQM-CoE, 2013). These FP materials have not been harmonized at the EU level. Chapter 3 of the Technical Guide is a guideline on analytical methods for testing migration from FCMs made from metals and alloys, while Chapter 4 deals with the Declaration of Compliance (DoC) for this type of materials.

Castle (2007) reports that migration from FCMs translates in general in a chronic (ie, long-term) exposure of consumers to migrants, with two exceptions of acute (ie, short-term) exposure: a high tin ion (Sn^{2+}) concentration in canned foods due to advanced tinplate corrosion that can cause gastric problems, and the migration of latex proteins from rubber articles that can cause allergic reactions in consumers. Allergens, being a special case of chemical hazards, are discussed in Section 11.3.5.

Migration of components from FP manufactured with all types of materials (eg, plastics, metals, glass and ceramic, paper and board, cellophane, rubbers, silicones, can coatings, cork, printing inks, adhesives, recycled plastics, recycled paper and board, nanomaterials) has been widely described, for instance, in:

1. Books (Katan, 1996; Catalá and Gavara, 2002; Barnes et al., 2007; Brandsch and Piringer, 2008; Forrest, 2009; Kopper and Ariosti, 2010; Oldring, 2010; Veraart, 2010; Robertson, 2013; de la Cruz García et al., 2014; Ariosti, 2015b; Barone et al., 2015; Baughan, 2015);
2. Reports (FSANZ, 2010; Mahinka et al., 2013); and:
3. Research articles and reviews (Six and Feigenbaum, 2003; Sendón García et al., 2006; Poças and Hogg, 2007; Begley et al., 2008; Bradley et al., 2009, 2013; Paseiro-Cerrato et al., 2010; Zülch and Piringer, 2010; Welle, 2011; Buculei et al., 2012; Zhang et al., 2012; Bhunia et al., 2013; Kassouf et al., 2013; Bott et al., 2014a,b; Jung et al., 2014; Jung and Simat, 2014; Oldring et al., 2014a; Hanušová et al., 2015; Kim et al, 2015).

In general, migrants from FP to food can be intentionally added substances (IAS) and nonlisted substances (NLS). IAS, which have been the focus of interest of regulators and scientists for decades, are regulated components (eg, polymers, monomers, additives, starting substances, cellulosic fibers), included in positive lists of regulations in different jurisdictions, that can be used in FP formulations. Some additives, called "dual-use additives," can be used in food and in its FP. If there is a maximum limit for the concentration of this type of additive in food, its migration from FP to food during the expected shelf life must be also considered, and added to the quantity of the additive used in the food formulation, in order to compare the sum of both figures with the maximum limit.

On the other hand, NLS can be:

1. Components expressly not included in the positive lists, but that are recognized to be present in FP by regulations, for instance: aids to polymerization (AP) (eg, catalysts in the case of plastics) (MERCOSUR, 2007; EU, 2011a); polymer production aids (PPAs) (ie, substances used to provide a suitable medium for polymer or plastic manufacturing, such as emulsifiers, pH regulators, surfactants, etc.) not listed in the EU list, but subject to EU Member State (MS) national regulations (EU, 2011a); colorants and solvents subject to EU MS national regulations (EU, 2011a);
2. Known components (except carcinogenic, mutagenic, and toxic to reproduction (CMR) substances) used in a plastic layer separated from food by another layer, called a functional barrier, that minimizes their migration to food up to a maximum limit of 0.01 mg/kg of food (Franz et al., 1996, 1997; Kopper and Ariosti, 2010; EU, 2011a; Guazzotti et al., 2014, 2015; Genualdi et al., 2015).
3. Nonintentionally added substances (NIAS).

NIAS comprise several types of substances, for instance (Gallart-Ayala et al., 2013; Nerín et al., 2013; Koster et al., 2014; Parisi et al., 2015a):

1. Impurities of IAS and NLS or their degradation/reaction products (eg, reaction products of BADGE (Petersen et al., 2008), *m*-xylylenediamine (MXDA) (Paseiro-Cerrato et al., 2015), and melamine (Magami et al., 2015); nonylphenol (NP) (Fernandes et al., 2008); polyolefin oligomeric saturated hydrocarbons (POSH) (Biedermann-Brem et al., 2012), and poly alpha olefin (PAO) (Barp et al., 2015; Eicher et al., 2015) from PE, PP, hot melts, and pressure-sensitive adhesives; perfluorocarboxylic acids (PFCAs) and perfluoroalkyl sulfonates (PFASs) in fluorochemical additives for paper and board (Xu et al., 2013));
2. Residual contaminants from recycled plastics (Bayer, 2002; Franz et al., 2004; Barthélémy et al., 2014; Dutra et al., 2014), and recycled paper and board (Lorenzini et al., 2010, 2013; Biedermann et al., 2013);
3. Substances formed as reaction or breakdown products during the manufacture of FP materials (eg, formaldehyde and acetaldehyde in PET (Mutsuga et al., 2006));
4. Substances formed during the application of industrial preservation technologies to packaged foods (eg, primary aromatic amines (PAAs) in retortable laminates (Aznar et al., 2009), radiolysis products in irradiation (Chytiri et al., 2005, 2010; de Oliveira et al., 2012; Driffield et al., 2014));
5. Substances formed during use by consumers (eg, microwave (Alin and Hakkarainen, 2011, 2013) and conventional oven heating at home).

For a long time NIAS were not considered when assessing FP safety, but since 2003 several of these migrants have been found in foods, as well as unexpected migration into foods of known UV-printing ink photoinitiators (PIs). Cases that attracted attention from regulators, scientists, the public, and the media were, for instance, migration of:

1. Semicarbazide from lids gaskets (Baty et al., 2004; Stadler et al., 2004; EFSA, 2005);
2. Mineral oil (mineral oil aromatic hydrocarbons (MOAH) and mineral oil saturated hydrocarbons (MOSH)), PIs, and certain phthalates from recycled paper and board (Lorenzini et al., 2010, 2013; Biedermann et al., 2013);
3. PIs like isopropylthioxanthone (ITX), benzophenone (BP), and 4-methylbenzophenone (4-MBP) from UV-printing inks (Koivikko et al., 2010; Campioli et al., 2010; Jung et al., 2010; Lago et al., 2015).

These findings, among other reasons, obliged authorities to take regulatory action (Gallart-Ayala et al., 2013; Nerín et al., 2013; de la Cruz García et al., 2014; Koster et al., 2014). For instance, the EU Commission sanctioned Regulation (EC) 2023/2006 (EU, 2006) on GMP for the manufacture of FP. In the Annex, it established that printing inks must be applied to the nonfood-contact side of FCMs, and must be formulated and applied in such a way that their components are not transferred to their food-contact side through the FCMs or by set-off in the stack or the reel, at levels not admitted by regulatory requirements (ie, those set in Article 3 of Regulation (EC) 1935/2004 (EU, 2004)). Subsequently, scientific groups developed methods to detect nonvisible transference of substances from printing inks by set-off (Bradley et al., 2005; Bentayeb et al., 2013).

Later, Regulation (EU) 10/2011 on plastic FCMs (EU, 2011a) recognized that NLS (including NIAS) may be present in FP. According to Article 19 of this Regulation, NLS must be risk-assessed by the FP manufacturer. The findings of the NLS risk assessment should be documented in the internal supporting documentation for the DoC.

This is a challenging task in the case of the NIAS, as no official guidance exists at the EU level, and their identification is difficult and time-consuming. The Netherlands Organization for Applied Scientific Research (TNO) proposed a pragmatic analytical approach based on the threshold of toxicological concern (TTC) concept. According to this proposal, that needs harmonization, NIAS below the exposure threshold of 90 μg/person/day need not be identified, as long as they do not belong to several well-defined categories of highly toxic substances not suitable for the TTC approach (Cheeseman, 2013; Nerín et al., 2013; Koster et al., 2014; Gergely and Cheeseman, 2015). Recently, Plastics Europe (2014) has issued a document on guidelines for the risk assessment of NLS and NIAS under Article 19 of Regulation (EU) 10/2011 for plastic FCMs. The TTC concept applies to NIAS at low-exposure levels, and therefore, not to regulated substances (eg, monomers and additives with specific migration limits (SMLs) or other restrictions).

On the other hand, according to the conclusions and recommendations of the draft document of the Joint EFSA/WHO Expert Workshop on TTC, launched for public consultation on February 2015 (EFSA/WHO, 2015), the TTC is a methodology that could be used to assess potential human health concerns for a substance, based on its chemical characteristics and estimated exposure, when specific toxicity data are scarce or absent.

Another approach to assess exposure to chemical migrants from FP is the new modeling tool called FACET (Flavors, Additives and Food Contact Materials Exposure Task). This was the result of a 4-year project (2008–12), partly funded by the European Commission, under the EU 7th Framework Program for Research and Technological Development (EU FP7). It was coordinated by University College Dublin, and it involved 20 research partner organizations (from academia, industry, research centers, and SMEs). The present maintenance and update of the database, and further development of the tool, are performed by the EU Joint Research Center (JRC) (Ispra, Italy). It is claimed that the FACET tool can provide more realistic data on exposure than the present EU conventional approach (Oldring et al., 2014b). Another tool to measure exposure to NIAS, NLS, mixtures, etc., from plastic FP, was developed by the European Exposure Matrix Project (2005–11). It was financially supported by EuPC, FCA-CEFIC, FPE, and PlasticsEurope, and made use of food consumption data (associated with the packaging surface to which consumers are exposed per plastic materials) from France, Germany, Italy, Spain, and the United Kingdom (Eisert, 2011).

Several substances with high sensory activity can cause taint problems (see definition 3.5 on "taints" of BS ISO 13302:2003 (BS ISO, 2003)) in food, which can be detected by consumers, depending on their odor detection threshold (ODT) and taste detection threshold (TDT). Some examples are, for instance (Tice, 1996; Lord, 2003; Chytiri et al., 2005, 2010; Torri et al., 2008; Ridgway et al., 2010; Robertson, 2013):

1. Solvents for printing inks, adhesives, and coatings; certain UV-printing ink components;
2. Residual monomers (eg, styrene in PS);
3. NIAS (eg, olefins in PE and PP, acetaldehyde in PET, radiolysis products);
4. Chlorophenols used in the treatment of wood storage pallets;
5. Chloroanisoles (eg, TCA in cork);
6. Painted toys and printed cards used as promotions inside FP;
7. Fatty acids and esters from lubricants used in the production of two pieces (2P) metallic cans;
8. Lubricants from compressors in compressed air used in the cooling of plastic film blown bubbles, or in blow molding of plastic bottles or containers (eg, extrusion blow molding (EBM), injection-blow molding (IBM), and injection-stretch-blow molding (ISBM));
9. Contaminants present in cooling water for plastic blown film production;
10. Bacteria and molds activity, auto-oxidation of residual resins, and degradation of processing additives in paper and board;
11. Cleaning products and disinfectants used in FP manufacture plants; etc.

Taint problems due to FP are usually assessed by applying to samples several extraction techniques (eg, solvent extraction, steam distillation, thermal desorption, static or dynamic headspace, solid phase microextraction (SPME)), with subsequent analysis by GC-MS, HPLC, or olfactometry (GC-O); sensory analysis; electronic nose; and combinations of these methods. The identification of the substances involved is a key step for detecting the source of the problem and its subsequent solution (Box 11.4).

11.3.5 Allergen Hazards

Food allergies are adverse immune responses developed by some consumers in response to certain food components (generally a protein). Food allergies can be mediated by immunoglobulin E (IgE) antibodies to proteins, or not (for instance the celiac disease, which is a non-IgE-mediated immunological reaction to gluten protein found in wheat, oats, barley, and rye) (FoodDrinkEurope, 2013; Ariosti and Olivera Carrión, 2014).

BOX 11.4 Points to Consider—Management of Chemical Hazards

Chemical hazards must be assessed and managed within the HACCP system, for instance by means of (de la Cruz García et al., 2014; Plastics Europe, 2014; Government of Manitoba, 2015d; Montanari, 2015; Parisi et al., 2015b):

- Ensuring compliance with FCMs regulations in each jurisdiction, not only with respect to regulated substances (ie, IAS), but also in the case of NLS (and in particular NIAS);
- Ensuring that regulated components (eg, additives) with special restrictions (ie, maximum content in FP) are correctly measured according to the FP formulation;
- Periodic re-evaluation of all FP formulations to ensure that they comply with regulations (including updates and amendments);
- Consolidating traceability all along the supply chain, by means of FP certificates of conformity, approvals/clearances or DoCs, depending on the jurisdictions;
- Controlled storage temperature of the packaged foods, as migration and corrosion accelerate with increasing temperature;
- Storage of correctly labeled chemicals (eg, cleaning agents, disinfectants, biocides) in designated areas away from food, ingredients, FP, and food contact surfaces;
- An adequate maintenance program for equipment, compressor filters, etc.;
- Minimizing the use of lubricants and grease in FP production machines;
- Control contamination of cooling water and compressed air in FP production;
- Taking preventive, rather than corrective, measures against taint problems;
- Following good storage practices (fungi can grow and produce mycotoxins on FP paper and board stored in warehouses with uncontrolled high relative humidity).

BOX 11.5 Points to Consider—Management of Allergen Hazards

Allergen hazards must be assessed and managed within the HACCP system.

Risk management of allergen residues in food is described in chapter "Managing Risks from Allergenic Residues" of this handbook. For details concerning handling of raw materials (including packaging materials) by the food manufacturer and incorrect advisory labeling or lack of it, see also FoodDrinkEurope (2013) and Government of Manitoba (2015e). For instance:

- Precaution must be taken as certain FP materials, though not containing allergens in their composition, could be stored (even for a short time) in areas of the plant where allergenic raw materials were placed before, or in processing areas where such raw materials are used, with the consequent risk of cross-contact and contamination;
- Allergenic raw materials must be clearly labeled, and either stored and processed in specific areas, or when this is not possible (for instance, for some SMEs), an effective cleaning program must be implemented to avoid cross-contact with nonallergenic raw materials or FCMs.

Examples of FCMs containing potential allergens that can migrate to foods are, for instance: rubber articles with allergenic latex proteins (Castle, 2007); wheat flour in cardboard packaging release agents (FoodDrinkEurope, 2013); rubber latex used in cold seal adhesives, nipples for baby bottles and pacifiers (de la Cruz García et al., 2014); novel bio-based biodegradable FCMs from gluten, peanuts' husks, milk whey, egg, soybean, rice, chitosan/chitin of crustaceans shellfish origin (with about 1% (m/m) protein) (Cutter, 2006; Peelman et al., 2013; Rhim et al., 2013), etc. In these cases advisory labeling is justifiable on the basis of a risk analysis (FoodDrinkEurope, 2013).

Topping et al. (2004, 2006) studied the presence of four allergens from latex in articles for food contact (food handlers' gloves, natural rubber cold seal adhesives for wrappers (confectionery/chocolate, ice cream, cheese) and stickers for fruits, rubber nets for meats, elastic bands for onions, cartons with pourer for fruit juices, bakery release films). Modified FITkit ELISAs were developed to quantify low levels (range: 2–5 ng/mL) of the four allergens in the FCMs and in the foods in contact with them. The study confirmed the possibility of latex allergen migration to a limited number of the tested foods. Further research on the validation of ELISAs and their applications to FCMs and foods was reported by Topping and Haines (2008).

Several methods (eg, qualitative and quantitative ELISAs, DNA-based polymerase chain reaction assay) for allergen detection in foods, their scopes, comparison, applications, and validation have been widely described in this handbook (see chapter "Managing Risks from Allergenic Residues") and other sources (Nollet and van Hengel, 2011; Sheehan et al., 2012; Flanagan, 2015) (Box 11.5).

11.4 REGULATORY ASPECTS

11.4.1 Global Summary Situation

Regulatory bodies put great effort into establishing requirements to control migration, as migrants from FP may not (MERCOSUR, 1992a,b; EU, 2004, 2011a):

1. Change the nutritional composition of foods;
2. Pose a risk to human health, depending on the exposure of consumers to these substances;
3. Cause taint problems in foods, with undesirable changes of their sensory characteristics (eg, aroma, taste, flavor, color).

FP GMPs and chemical migration are regulated by FCMs legislation worldwide, but there are several differences in their diverse approaches. There is regulatory harmonization between countries in some politico-economic blocks that have been consolidated in the last decades. Some examples of selected FCMs regulations that apply to FP are described in this section. Some FCMs regulations are very general, and focusing mainly on FP, establish a few requirements for them (eg, in some Latin American and Caribbean countries) (Padula, 2010; Ariosti, 2012, 2013, 2015a,c). Even the Codex Alimentarius (though being an internationally recognized reference in food matters), scarcely mentions FCMs and FP (eg, Code of Practice for the Prevention and Reduction of Tin Contamination in Canned Foods, various codes of hygienic practices for the processing of foods) (Kopper and Ariosti, 2010).

Other legislations (eg, China, EU, Japan, MERCOSUR, US FDA) establish more specific requirements, for instance, depending on the jurisdictions:

1. Substances used in FCMs formulations must be included in positive lists;
2. FCMs must comply with overall migration limits (OMLs);
3. Several listed substances must comply with SMLs;
4. Several listed substances must be used up to established concentration limits (quantity in material, QM) in FP;
5. Certain elements (including heavy metals) must comply with SMLs, and the sum of PAAs released (if not included in the positive list) must not exceed a migration limit of 0.01 mg/kg (EU Regulation 10/2011 for plastics) (EU, 2011a);
6. Pigments and colorants, and several components, must comply with certain purity specifications.

A full description of the EU FCMs regulations and updates has been recently presented by Kopper and Ariosti (2010), Schäffer (2010, 2011), Schupp (2012), Kernoghan (2013), Irvine (2014), Rossi (2014), and Cooper and Irvine (2015). All FCMs must comply with the Framework Regulation (EC) 1935/2004 (EU, 2004) and Regulation (EC) 2023/2006 (EU, 2006) on FCMs GMPs. Regulation (EC) 2023/2006 applies to FCMs in all sectors of the supply chain, except in the production of starting substances. The harmonized regulations directly related to FP are:

1. Directive 84/500/EEC (ceramic);
2. Regulation 1895/2005/EC (restriction for certain epoxy derivatives);
3. Directive 2007/42/EC (regenerated cellulose (cellophane) films);
4. Regulation (EC) 282/2008 (recycled plastics);
5. Regulation (EC) 450/2009 (active and intelligent materials, AIMs);
6. Regulation (EU) 10/2011 and its six amendments up to February 2015 (plastics).

A limited number of additives, not yet harmonized at the EU level, listed in the Provisional List of Additives for Plastics (EU, 2011b), and that are being assessed by EFSA, can be used in the formulation of FP, subject to EU MS national regulations, until a decision on their inclusion or noninclusion into the Union positive list of Regulation (EU) 10/2011 is taken.

Directive 94/62/EEC and its amendments (eg, Directive 2004/12/EC) establish environmental requirements for FP and FP waste (ie, postconsumer FP). For instance, the sum of concentration levels of heavy metals (lead, cadmium, mercury, and hexavalent chromium) shall not exceed 100 mg/kg of FP (except for lead crystal glass). EU biocide regulation changed recently, so now FCMs must comply with the requisites of Regulation (EC) 528/2012 (Biocidal Product Regulation (BPR)), and its amendment Regulation (EU) 334/2014.

For the transposition status of EU FCMs regulations into EU MS national legislations, other EU legislation related to FCMs, additional EU MS and non-EU MS national FCMs legislations, see Working Document References of the European and National Legislations (updated version February 2015) (EU, 2015). In addition, validated analytical methods to assess compliance of FCMs with regulations can be found at the website of the EU JRC—Institute for Health and Consumer Protection (IHCP).

In the EU, and according to the mutual recognition principle, FCMs manufactured with nonharmonized materials at the Union level in one EU MS can be imported into another EU MS, if the FP is lawfully marketed in the origin country, subject to acceptance by the destination country.

The CoE has issued many recommendations, several of them on FCMs not harmonized at the EU level (eg, paper and board, metals and alloys, rubbers, silicones, glass, cork, coatings, printing inks) (Kopper and Ariosti, 2010; Rossi, 2010).

In Switzerland, the main FCMs regulation in force is the Ordinance on Materials and Articles (SR 817.023.21) (Swiss DFI, 2014). The latter includes the most advanced legislation on printing inks (Annexes 1 and 6), which have not been harmonized at the EU level. The German safety authorities have been working on a draft document on printing inks for FP, based on the Swiss regulation (last version as of July 14, 2014).

The essential characteristics of the US FCMs regulations issued by the US FDA and updates have been recently described by Baughan and Attwood (2010), Kopper and Ariosti (2010), Bailey (2012), Irvine and Kernoghan (2013), Greenberg and Rost (2014), and Rossi (2014). In these regulations, FCMs are considered indirect food additives. The most relevant requirements for FCMs can be found at the US FDA website, for instance, at the Code of Federal Regulations—Title 21 (21 CFR): Parts 175 (adhesives and coatings), 176 (paper and board), 177 (polymers), 178 (adjuvants, production aids, and sanitizers), 179 (irradiation), 181 (prior sanctioned (ie, cleared before 1958) food ingredients), 182 (substances generally recognized as safe (GRAS)), 184 (direct food substances affirmed as GRAS), 186 (indirect food substances affirmed as GRAS), and 189 (substances prohibited from use in human food).

The following sections of the US CFR are also of interest:

1. Part 171 describes the petition process for indirect food additives approval before their use (Food Additive Petition (FAP) process);
2. Section 174.5 sets requirements for GMP in the production of FCMs;
3. Section 170.39 exempts certain substances used in FCMs from the requirement of an authorizing regulation before its use (under the threshold of regulation (TOR) exemption system), if the substances have an estimated daily intake (EDI) less than or equal to 1.5 μg/person/day (or an equivalent of 0.5 μg/kg of food consumed).

Also, the "no migration" concept can be used in certain cases to avoid special regulation for a substance. In 1997, the Food Contact Notification (FCN) process was introduced to replace the FAP process as the primary and simplified means for authorizing new uses of indirect food additives. The clearance under the FCN process is proprietary to each company that files the notification. For postconsumer plastics decontamination technologies, whose capability is well assessed, the FDA issues no objection letters (NOLs) to their use. The lists of FCNs and NOLs can also be found at the FDA website.

A full description of the MERCOSUR FCMs regulations and updates has been done by Padula (2010), Kopper and Ariosti (2010), Ariosti (2012, 2013, 2015a,c), and Ariosti and Olivera Carrión (2014). The Common Market of the South (in Spanish: MERCOSUR; in Portuguese: MERCOSUL) was founded by the Treaty of Asunción (Paraguay) in 1991. The present MS are Argentina, Bolivia (since July 2015), Brazil, Paraguay, Uruguay, and Venezuela. The Common Market Group (GMC), the maximum body politic, has sanctioned several GMC Resolutions on different FCMs (plastics, paper and board, glass and ceramic, rubbers, regenerated cellulose films and casings, metals, refillable PET bottles, PCR-PET for FP, etc.), taking as the main international references the EU and US FDA regulations. Also, the German Federal Institute for Risk Assessment (BfR) Recommendations for paper and board and the Council of Europe Resolution AP (89)1 on pigments and colorants for plastics were followed. The GMC Resolutions in force can be found (in Spanish and Portuguese) at the recommended websites below. To be valid in the MERCOSUR MS, GMC Resolutions must be transposed into their national regulations, for instance, in Argentina, into chapter IV of the Argentine Food Code (available at the National Food Commission (CONAL) website), and in Brazil, into the Brazilian federal regulation (available at the National Agency of Sanitary Surveillance (ANVISA) website). The US Plastics Industry Trade Association (SPI) (Washington DC) has recently published unofficial translations into English of three of the GMC Resolutions related to plastic FCMs (on: the positive list of monomers, other starting substances and polymers; the positive list of additives for plastics materials; and the criteria for the selection of conditions of overall and specific migration tests).

Details on the Canadian FCMs regulations have been summarized by Mattu (2014) and Rulibikiye (2015), and can be found at the websites of Health Canada/Santé Canada (HC/SC) and the Canadian Food Inspection Agency/Agence Canadienne d'Inspection des Aliments (CFIA/ACIA), which are official agencies involved in FCMs regulation and control. All FCMs must comply with the basic requirements established in Division 23 "Food Packaging Materials" of the Food and Drugs Act and Regulations (last update, April 7, 2016). Section B.23.001.

The Japanese FCMs regulatory situation has been described by Mori (2010), Kopper and Ariosti (2010), Ettinger and Clark (2012), Rossi (2014), and Kawamura (2015). In addition, the Japan External Trade Organization (JETRO) has published two guidelines on the Japanese regulatory requirements for FCMs in English (JETRO, 2009, 2011). In Japan,

FCMs manufacturers also apply several voluntary standards issued by very active industrial hygienic associations, such as the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA), the Japan Hygienic PVC Association (JHPA), and the Japan Hygienic Association of Vinylidene Chloride (JHAVC).

The two basic mandatory regulations are:

- The Food Sanitation Act (Act 233 of December 24, 1947, Amendment Act 53 of 2006), which is under the jurisdiction of the Ministry of Health, Labor, and Welfare (MHLW, 2015);
- The Food Safety Basic Act (Act 48 of May 23, 2003), of the Food Safety Commission, which is under the jurisdiction of the Japan Cabinet Office (FSC, 2015).

The essential features of the Chinese FCMs regulations and updates have been recently described by Li and Bian (2010), Zhu (2013), Bian (2013), Baughan (2013), Rossi (2014), Zhang (2015) and Clark (2015). The Food Safety Law, which became effective on June 1, 2009, regulates FCMs.

A draft revision to the Food Safety Law was proposed, which was preliminary approved by the People's Republic of China State Council on May 14, 2014, and became effective on October 1, 2015. The Law requires that FCMs comply with an applicable food safety standard. There is a wide variety of standards applicable to FCMs, for instance, national mandatory standards (GB), national voluntary standards (GB/T), local or provincial standards (DB), and professional or industry standards (QB, BB, HG, etc.). China's "Hygienic Standard for Uses of Additives in Food Containers and Packaging Materials" (GB 9685-2008) includes a list of additives allowed in FCMs, and became effective on June 1, 2009.

The basic aspects of the Australia and New Zealand FCMs regulations and updates have been described by Steele (2010), Magnuson et al. (2013), and Stanley (2015). The updates, regulations, and summaries of standards related to FCMs can be found at the Australia and New Zealand official websites indicated below. The Australia New Zealand Food Standards Code establishes only general requisites for FCMs in "Standard 1.4.3 Articles and materials in contact with food." On the other hand, though standard AS 2070-1999 is a voluntary guide for industry for the manufacture of plastic FCMs, it refers to the EU and US regulations in force.

The EU and US FDA FCMs regulations are the ones that are most frequently taken as international references, but their approaches to FCMs safety assessment are different. In principle, according to the EU regulation, all the stakeholders in the supply chain share responsibility for the product, while the US FDA focuses the responsibility on the FP manufacturer, and the Canadian legislation on the food seller (producer or distributor) (de la Cruz García et al., 2014; Mattu, 2014). According to the MERCOSUR regulation, which is rather eclectic and takes both legislations as the main references, the FP manufacturer must submit the final FP to a premarket approval process, the national safety authorities issue the clearances, and the food producer is obliged to buy only approved FP.

For the clearance of substances used in the formulation of FP, in order to include them in the positive lists, the US FDA approach is an exposure-based risk assessment of the substances, taking into account consumption factors (CFs), food-type distribution factors (f_Ts), dietary concentrations (DCs), EDIs, and cumulative estimated daily intakes (CEDIs). The EU approach is a toxicological-based risk assessment, which involves the determination of the no-observed effect level (NOEL) and the tolerable daily intake (TDI) of the substance. More detailed comparisons between these two regulations (and those of Canada, China, Japan and MERCOSUR) can be found in Kopper and Ariosti (2010), Ariosti (2012, 2013, 2015a,c), de la Cruz García et al. (2014), Mattu (2014), and Rossi (2014).

11.4.2 Declarations of Compliance

To ensure food safety, FP operators all along the supply chain in different stages of production (eg, raw materials manufacturer, primary or secondary converter), must verify that FP placed on the market is safe and complies with regulations in force, providing adequate information downstream. One means to perform this is to issue DoCs, which are documents that are envisaged to ensure traceability (Dainelli, 2007), and that are mandatory in some jurisdictions (eg, the EU).

In the EU, DoCs are required for materials harmonized at the EU level (ceramics, regenerated cellulose films, plastics, recycled plastics, AIMs), and for nonharmonized materials, according to the requirements of EU MS (Regulation (EC) 1935/2004, Regulation (EU) 10/2011). While some EU MS (eg, Belgium, the Czech Republic, Denmark, Finland, France, Italy) also require DoCs for nonharmonized materials, others (eg, the United Kingdom) consider that DoCs should be provided to customers (Semail, 2014).

Article 16 of Regulation (EC) 1935/2004 establishes that FCMs covered by harmonized measures must be accompanied by a written declaration stating that they comply with the rules applicable to them (DoC), that supporting documentation for the DoC is needed, and that it must be available for the safety authorities on demand. Annex IV to Regulation (EU) 10/2011 establishes the basic information required in a DoC for plastic FCMs. To facilitate the interpretation and

BOX 11.6 Checklist for DoCs for Plastic FCMs According to the EU Regulations, Using the EasyDoc (FSAI) Online Program (http://easydoc.fsai.ie/Home/Index)

1. *Example for final material 1* (without a functional barrier): Plastic material or article or plastic component (Yes)/In multimaterial multilayer (Yes)/Acting as a functional barrier or used behind (No)/Contains only substances listed in Annex I or II (No)/Contains substances with SML in Annex I or II (Yes)/Proof that SML can never be exceeded (No)/Specification in Annex I (Yes)/Restriction in Annex I (Yes)/Dual use additive (Yes).
2. *Example for final material 2* (with a functional barrier): Plastic material or article or plastic component (Yes)/In multimaterial multilayer (Yes)/Acting as a functional barrier or used behind (Yes)/Contains only substances listed in Annex I or II (No)/Contains substances with SML in Annex I or II (Yes)/Proof that SML can never be exceeded (No)/Specification in Annex I (Yes)/Restriction in Annex I (Yes)/Dual use additive (Yes).

implementation of certain aspects of the DoC for plastic FCMs, the European Commission issued a guidance document (EU, 2013). Though focusing only on plastic FCMs, it may be used as a guide for DoCs for other FCMs.

EU MS safety authorities have reported in several cases that necessary information is missing from DoCs for commercial FCMs (eg, undeclared components with limitations in the positive lists, target type of food, conditions of use of FCMs) (Oesterreicher, 2012 (Austria); Hegarty, 2013 (Ireland); Brauer, 2014 (Germany)). To write an acceptable DoC is a complex task. To help FP manufacturers to take into account all the information needed for the DoC to be complete, some EU MS have developed guidelines, as the Nordic checklist for supporting documentation and traceability (NORDEN, 2008).

In the case of DoCs for plastic FCMs covered by Regulation (EU) 10/2011, the Food Safety Authority of Ireland (FSAI), developed in 2013 the online checklist EasyDoc, which is available from: http://easydoc.fsai.ie/Home/Index. After several steps, in each of which the user can select options, the program delivers a final checklist report. The reader is invited to follow two proposed scenarios online, and to retrieve their corresponding checklists (see Box 11.6). At the time of writing, regulation updates were as of October 2013, so the reader must take into account further amendments of Regulation (EU) 10/2011 (see the disclaimers in the checklist reports).

In the United States, the Plastics Industry Trade Association (SPI)—Food, Drug, Cosmetic Packaging Materials Committee (FDCPMC), issued in February 2015 a guideline for risk communication along the global food contact supply chain (SPI, 2015). It is the result of the work group called Project Passport, convened by the FDCPMC, functioning for more than 3 years, and representing different stages of the supply chain, for instance plastics resins and additives manufacturers, converters, brand owners, etc. Project Passport addresses the compliance challenges that FP manufacturers must confront in the US and European markets, with different FCMs regulations in force. The document provides: a form to organize data in a Food Contact DoC, designed in such a general way that it can be adapted to different FP intended to be marketed in different jurisdictions; instructions and basic explanations to fill the form; and several topic guides to clarify the instructions.

11.5 FP HYGIENE AND SAFETY MANAGEMENT SYSTEMS

Though several safety authorities worldwide began setting requirements for FCMs in the 1960s and 1970s, it was during the early 1980s that FP manufacturers began to acknowledge how the packaging materials' chemical composition could be involved in food safety, apart from the traditional control of more known and conventional physical hazards. In those years, monomers like vinyl chloride and styrene (in PVC and PS, respectively) began to attract the attention both of the safety authorities and industry. In the following decades, the main FP materials began to be regulated in detail. Thus, food and FP manufacturers developed a new view on food and FP safety and how they are linked to the consumers' health protection. From the early days of quality control concepts, industry has continuously improved up to the adoption of total quality management (TQM) tools.

During the last few decades, some of the driving forces behind these global changes were the development of standards and regulations following international references (based on new and sound scientific advancements), the requirements of local food producers and global brand owners, the exigencies of very competitive markets, and better training of officials and industry personnel. Last but not least, the consumers' new conscience on their health protection, their concerns and demands on food safety, and their perception of FP as a source of potential risks are being taken into account by safety authorities and industry (Raaska, 2005; de la Cruz García et al., 2014). This proactive attitude is helping in some cases to enhance the scientific, regulatory, and technological efforts aimed at addressing new safety challenges, for instance in the case of NIAS, allergens, printing inks, etc., during recent years.

TABLE 11.1 Generic PRPs Established by ISO/TS 22002-4:2013

4. Generic PRPs
4.1 Establishment
4.2 Layout and workplace
4.3 Utilities
4.4 Waste disposable
4.5 Equipment suitability, cleaning, and maintenance
4.6 Management of purchased materials and services
4.7 Measures for prevention of contamination
4.8 Cleaning
4.9 Pest control
4.10 Personnel hygiene and facilities
4.11 Rework
4.12 Withdrawal procedures
4.13 Storage and transport
4.14 Food packaging information and customer communication
4.15 Food defense and bioterrorism
Annex A: Comparison of food packaging design and development relevant items

The key to control hazards in FP is preventive action, thus a high commitment to safety from all the stakeholders in the supply chain is essential. In order to ensure food quality and safety it is necessary to perform an adequate FP design based on clear specifications, control of raw materials and FP components, proper maintenance of plant buildings, warehouses, processing equipment and shipping facilities, adequate personnel hygiene and training, pest control, etc., following PRPs (see Table 11.1). These PRPs include GMPs (which are directly linked to food safety), standard operating procedures (SOPs), SSOPs, etc. Once hazards have been correctly identified and assessed at all these stages, a control program must be designed to manage risks. This control program includes the implementation of an effective HACCP system. The HACCP system consists of the preexistent PRPs and a HACCP plan. The HACCP system is compatible with the implementation in a company of a TQM system based on the ISO 9000 series standards (Raaska, 2005; UNL, 2005b; CFIA/ACIA, 2013; de la Cruz García et al., 2014; Parisi et al., 2015a).

In some jurisdictions, GMPs are mandatory for FCMs in a general way (for instance in MERCOSUR), and in others, there are more specific requirements (eg, EU, United States) (see Section 11.4.1). Safety authorities and industrial associations are working together to establish guidelines on GMP on several FP materials. For instance, the CAST (Food Contact Safety and Technology) Project in Italy (Milana et al., 2011, 2013), on guidelines for GMPs in the FCMs supply chains, is being coordinated by the ISS (Italian National Institute of Health, Rome).

EU Regulation (EC) 2023/2006 on GMPs recognizes that business operators should establish an effective quality management system at their facilities, which should be adapted to their position in the supply chain, and that the rules on GMPs should be applied proportionately to avoid excessive burden to SMEs (EU, 2006). This clearly aims to facilitate the adoption of hygiene concepts, practices, and tools during the operation of FP businesses. This adequacy may require special help and follow-up by safety authorities or companies specialized in providing technical support for SMEs (FSAI, 2010; Scherzinger, 2013).

Industrial associations that have issued guidelines for GMPs are, for instance: British Glass for glass (2009); CEPE for coatings (2009); EMPAC for metals (2009); CEPI for paper and board (2010); EuPIA for printing inks (2011); Plastics Europe, EuPC, and FCA-CEFIC for plastics (2011); FPE and CITPA for flexible and fiber-based FP (2011); CEFIC, CEPI, CITPA, and FPE for paper and board (2012); EAA for aluminum (2012); SPI for plastics (2012); ECMA for cartons (2013); FoodDrinkEurope for recycled paper and board, and printed cartons (2014); FEICA for adhesives and sealants (2015); etc.

The Food Safety Alliance for Packaging (FSAP), a technical committee of the Institute of Packaging Professionals (IoPP) (United States) issued in 2009 a document with a list of possible hazards for different FP materials and suggested measures of control. Some of these hazards can be controlled by means of PRPs, but some may be considered as Critical Control Points (CCPs) in a HACCP plan. This document and several HACCP plan models for different FP (issued between 2010 and 2012) can be found at the IoPP website.

Historically, it has been usual practice for customers to audit suppliers' FP safety management systems against different international standards, for instance, EN 15593:2008 (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), etc. Some disadvantages were that any FP manufacturer could be subjected to multiple audits from different customers or certification bodies, sometimes with different interpretation criteria, and the lack of specific PRPs for FP. In recent years great emphasis has been placed by food manufacturers, food services industry, and retailers on FP suppliers' third-party certification against international standards with global recognition (Sansawat and Terry, 2011; de la Cruz García et al., 2014; Marasco, 2014; Prevendar, 2014).

The Global Food Safety Initiative (GFSI), launched in 2000, is a nonprofit organization which is managed by The Consumer Goods Forum. The GFSI Board of Directors is composed of representatives of major global retailers, food manufacturers, and food service operators.

One of the objectives of the GFSI is to establish criteria to benchmark any food and FP standard developed to certify safety management systems (ie, "the scheme"). Once the schemes are recognized by the GFSI, the third-party companies can certify against them, acting as certification bodies. These certifications are widely accepted and required in the market, and avoid multiple audits (GFSI, 2013). At the time of writing, four such schemes have been recognized by the GFSI in the case of FP design and manufacture (GFSI, 2015):

- *BRC-IoP*—Global Standard for Packaging and Packaging Materials, Issue 4 (February 2011), developed by the British Retail Consortium (BRC) and the former Institute of Packaging (United Kingdom);
- *FSSC 22000*—October 2011 Issue, based on ISO 22000:2005 plus PAS 223:2011 (PRPs for FP design and manufacture), and developed by the Foundation for Food Safety Certification (the Netherlands);
- *IFS PACsecure*, Version 1 (October 2012), developed by the International Featured Standards (Germany) and the PAC—Packaging Consortium (Canada);
- *SQF Code* 7th Edition—Level 2 (July 2014): Modules 2 and 13—Food Sector Categories (FSC) 27 Food Packaging; developed by the Safe Quality Food Institute (United States).

As of April 2016, there exist updates of two of these schemes. The BCR published the Global Standard for Packaging and Packaging Materials, Issue 5 (February 2015); and the FSSC published FSSC 22000 version 3.2 (February 2015).

The ISO 22000 family of international standards that addresses food safety management is used by organizations to identify and control food safety hazards, and comprises eight standards. For instance, central to the FSSC 22000 scheme, the standards of this family of interest for the FP supply chain are (www.iso.org):

- *ISO 22000:2005* "Food safety management systems—Requirements for any organization in the food chain" that contains overall guidelines for food safety management; it was updated in 2009, is at present under revision, and the final document is expected early in 2017;
- *ISO/TS 22002-4:2013* "Prerequisite programs on food safety—Part 4: Food packaging manufacturing" that is based on PAS 223:2011 and EN 15593:2008, establishes specific PRPs for FP manufacturing (see Table 11.1), and is intended to be used in conjunction with ISO 22000:2005; and
- *ISO 22004:2014* "Food safety management systems—Guidance on the application of ISO 22000" that provides generic advice on the application of ISO 22000:2005, but that does not create, alter, or replace any of its requirements, therefore its guidelines are not to be considered as requirements.

Sansawat and Terry (2011), Marasco (2014), Prevendar (2014), and de la Cruz García et al. (2014) present descriptions and comparisons of the four schemes. In 2014 the FSSC announced that after November 1, 2014, ISO/TS 22002-4:2013 will replace PAS 223:2011 in its scheme, according to its policy that FSSC 22000 must be a fully ISO-based certification scheme, and that all certificates already issued must be updated no later than October 31, 2015.

In France, the research network ACTIA and experts from several technical institutions (Adria Dévelopment, Critt Agroalimentaire Poitou-Charentes, Critt Agroalimentaire Provence Alpes-Côte d'Azur, CTCPA, and LNE) designed an interactive website (http://referentiel.actia-asso.eu/), operative since 2011, that can be used as an online tool for comparing requirements for food and FP safety management systems, according to different references. Of interest in the case of FP are these references: Codex Alimentarius, regulations, standards as ISO 9001, ISO/TS 22002-4 and NF EN 15593, and a private repository (BRC-IoP 4). The website provides comparative tables and case studies in French. In the case of food manufacture, there are more references available (ISO 22000, ISO 22002-1, IFS 6, and BRC 6).

The comparative tables provide information on 49 items divided into six chapters (quality management, PRPs, HACCP, control of production, traceability/noncompliance, and continuous improvement), according to selected scenarios and choices by the user. As the reports provided are backed by the information at the data base, the authors of the tool alert the users to review all the original texts of the regulations, standards, and repositories considered, and their updates. The reader is invited to follow two proposed examples online and to retrieve their corresponding comparative tables (see Box 11.7).

BOX 11.7 Comparative Tables of Requirements for FP Manufacturing According to Different References, Using the ACTIA Online Program (http://referentiel.actia-asso.eu/)

- *Example 1* (choose three items of the HACCP chapter and three references): comparison of items Microbiological risk management, Chemical risk management, and Allergen risk management, according to the Codex Alimentarius, ISO/TS 22002-4 and EN 15593. Click on the corresponding six options, and edit the report in the form of a comparative table.
- *Example 2* (choose three items of the Quality Management chapter and three references): comparison of items Documentation, Review by the Direction, and Customer, according to regulations, ISO 9001 and BCR-IoP 4. Click the corresponding six options, and edit the report in the form of a comparative table.

(The system only allows 3 × 3 choices each time. Operative language is French.)

Among the case studies presented, the following are of interest for FP:

- *Case study 1*: a NF EN 15593-certified FP manufacturer wants a BCR-IoP 4 certification; enter the Case studies section, and retrieve the corresponding report in.pdf version.
- *Case study 2*: an ISO 9001-certified FP manufacturer wants a BCR-IoP 4 certification; enter the Case studies section, and retrieve the corresponding report in.pdf version.

Access to the Case studies section requires a very simple preregistration online.

11.6 CONCLUSIONS AND TRENDS

FP is both an essential part of complex food preservation technologies and a tool of modern food marketing. Thus during recent decades, it was necessary to develop hygiene risk assessment and quality management systems for the FP industry equivalent to those applied by the food manufacturing industry.

Physical and insect infestation risks are the most evident to consumers and are the most frequently addressed by regulations and standards. Microbiological risks are scarcely regulated and standardized, and the available specifications are issued mainly in the orbit of private companies. Allergen risks due to FP, though potentially of low impact at present, are beginning to be taken into account in standards and regulations. Chemical risks have been widely studied by scientists and have been regulated worldwide at least since the 1970s. Nevertheless they appear to have been recognized publicly only very recently, with some cases attracting wide consumer and media attention (eg, ITX, BP, bisphenol A (BPA)).

FP GMPs are regulated in the main jurisdictions (eg, China, EU, United States), and several industrial associations in the EU and United States have issued guidelines for FP of different materials, which need regular updating. It is of interest to also consider the further developments of the CAST Project in Italy, and its approval by the EU Commission.

DoCs are issued as a means of ensuring the flux of information along the supply chain. Multiple regulations worldwide, new scientific discoveries (as the NIAS), lack of harmonization of several FP materials in the EU, different approaches for safety assessment in the EU and United States, etc., can complicate the issuing of clear and complete DoCs, as noted recently by some safety EU MS authorities. The European Commission Guidance Document, online tools such as the FSAI EasyDoc, the NORDEN guidelines, and the Passport Project in the United States, among others, can help suppliers to fulfill this task.

Global brand owners and retailers, along with FP manufacturers are working to establish the different certification schemes of FP safety management systems, recognized by the GFSI, as replacements for the traditional multiple customer audits procedures applied, and to bring confidence in suppliers to a wider scale. This institution has recognized four of these schemes to date for FP. One important trend here is fitting such schemes to ISO standards (as the FSSC 22000, with the replacement of PAS 223:2011 by ISO/TS 22002-4:2013). Central to the schemes are the HACCP systems, which are beginning to be applied widely by FP manufacturers. The problems faced by SMEs in their implementation need further work and reasonable flexibility, as recognized by safety authorities.

As the Codex Alimentarius has traditionally addressed food hygiene and safety, with scarce mention of FP chemical risks, different countries and blocks began developing their FP safety regulations separately, and so no global harmonization exists in this field. At present there is a multiplicity of such regulations, but a few of them appear to be taken notice of as international references by other jurisdictions, when developing their own regulations and standards, or when accepting imported FP cleared against those references.

For instance, it can be said that in general, in China and in the Association of South-East Asian Nations (ASEAN), the EU's, Japan's and US FDA's regulations are recognized as references; similarly, in MERCOSUR and in Australia and New Zealand, the EU's and US FDA's; in Colombia and other MS of the Andean Community of Nations (CAN), the EU's, MERCOSUR's, and US FDA's; in Turkey, some Northern African countries and South Africa, the EU's; in some Caribbean Community (CARICOM) MS, the US FDA's; etc. So future trends of convergence toward a few of these regulations can be perceived in the long run.

Additionally, further developments of the principle of mutual recognition of FP cleared against foreign regulations and standards can be expected. All these convergent approaches can help to ensure a globally equivalent level of consumer health and food quality protection, and remove technical barriers to trade. Several regulatory and standardization bodies, industrial associations, and the scientific networks and individual scientists, that constitute the Global Harmonization Initiative (GHI, based in Vienna, Austria), are among the institutions working worldwide toward this goal.

LIST OF ACRONYMS

ABMI Association of the Beverage Machinery Industry (Switzerland)
ACTIA Association of Technical Coordination for Agribusiness (in French: Association de Coordination Technique pour l'Industrie Agro-Alimentaire) (France)
AIM Active and intelligent material
ANVISA National Agency of Sanitary Surveillance (in Portuguese: Agência Nacional de Vigilância Sanitária) (Brazil)
AP Aid to polymerization
ASEAN Association of South-East Asian Nations
BADGE Bisphenol A diglycidyl ether
BfR German Federal Institute for Risk Assessment (in German: Bundesinstitut für Risikobewertung)
BP Benzophenone
BPA Bisphenol A
BPR Biocidal Product Regulation (EU)
BRC British Retail Consortium
CAN Andean Community of Nations (in Spanish: Comunidad Andina de Naciones)
CARICOM Caribbean Community
CAST Food Contact Safety and Technology (in Italian: Contatto Alimentare Sicurezza e Tecnologia)
CCP Critical control point
CEDI Cumulative estimated daily intake
CEPE European Council of Paints, Printing Inks and Artist's Colors Industries (in French: Conseil Européen des Producteurs de Peintures, d'Encres d'Imprimerie et de Couleurs pour Artistes)
CEPI Confederation of European Paper Industries
CF Consumption factor
CFIA/ACIA Canadian Food Inspection Agency/Agence Canadienne d'Inspection des Aliments
CFR Code of Federal Regulations (United States)
CFU Colony-forming unit
CITPA International Confederation of Paper and Board Converters in Europe (in French: Confédération Internationale des Transformateurs de Papier et Carton en Europe)
CMR Carcinogenic, mutagenic, and toxic to reproduction
CoE Council of Europe
CONAL National Food Commission (in Spanish: Comisión Nacional de Alimentos) (Argentina)
CTCPA Technological Center for the Conservation of Agricultural Products (in French: Centre Technique de la Conservation des Produits Agricoles) (France)
CVUA-MEL Chemical and Veterinary Analytical Institute (in German: Chemische und Veterinäruntersuchungsamt)—Münsterland-Emscher-Lippe (Germany)
DC Dietary concentration
DEET *N*,*N*-diethyl-meta-toluamide = *N*,*N*-diethyl-3-methyl-benzamide
DFI Federal Department of Home Affairs (In French: Département Fédéral de l'Intérieur) (Switzerland)
DoC Declaration of Compliance
DVFA Danish Veterinary and Food Administration
EAA European Aluminum Association
EBI Electronic bottle inspection
EBM Extrusion blow molding
ECMA European Carton Makers Association
EDI Estimated daily intake
EDQM European Directorate for the Quality of Medicines and HealthCare
EFSA European Food Safety Authority (Parma, Italy)
ELISA Enzyme-linked immunosorbent assay
EMAP Equilibrium modified atmosphere packaging
EMPAC European Metal Packaging
EPA Environmental Protection Agency (United States)

EU European Union
EU FP7 EU 7th Framework Program for Research and Technological Development
EuPC European Plastics Converters
EuPIA European Printing Ink Association
EVOH Ethylene vinyl alcohol copolymer
FACET Flavors, Additives and Food Contact Materials Exposure Task
FAP Food Additive Petition (US FDA)
FCA-CEFIC Food Contact Additives Group—European Chemical Industry Council
FCM Food contact material
FCN Food Contact Notification (US FDA)
FDA Food and Drug Administration (United States)
FDCPMC Food, Drug, Cosmetic Packaging Materials Committee (US SPI)
FEICA Association of the European Adhesive and Sealant Industry (in French: Fédération Européenne des Industries de Colles et Adhésifs)
FP Food packaging
FPE Flexible Packaging Europe
Fraunhofer-IVV Fraunhofer Institute for Process Engineering and Packaging (in German: Fraunhofer-Institut für Verfahrenstechnik und Verpackung) (Freising, Germany)
FRS Food Radar Systems
FSAI Food Safety Authority of Ireland
FSANZ Food Standards Australia New Zealand
FSAP Food Safety Alliance for Packaging (United States)
FSC Food Safety Commission (Japan)
FSSC Food Safety System Certification
$\mathbf{f_T}$ Food-type distribution factor
FT-IR Fourier transform infrared (spectrometry)
GC-MS Gas chromatography—mass spectrometry
GC-O Gas chromatography—olfactometer
GFSI Global Food Safety Initiative
GHI Global Harmonization Initiative (Vienna, Austria)
GMC Common Market Group (MERCOSUR)
GMP Good manufacture practice
GRAS Generally recognized as safe
HACCP Hazard Analysis Critical Control Point
HC/SC Health Canada/Santé Canada
HDPE High-density polyethylene
HPLC High performance liquid chromatography
IAS Intentionally added substances
IBM Injection-blow molding
IFS International Featured Standards (Germany)
IGR Insect growth regulator
IoP Institute of Packaging (at present The Packaging Society) (United Kingdom)
IoPP Institute of Packaging Professionals (United States)
ISBM Injection-stretch-blow molding
ISO International Organization for Standardization
ISS Italian National Institute of Health (In Italian: Istituto Superiore di Sanità)
ITX Isopropylthioxanthone
IVLV Industrial Association for Food Technology and Packaging (in German: Industrievereinigung für Lebensmitteltechnologie und Verpackung e.V.) (Germany)
JETRO Japan External Trade Organization
JHAVC Japan Hygienic Association of Vinylidene Chloride
JHOSPA Japan Hygienic Olefin and Styrene Plastics Association
JHPA Japan Hygienic PVC Association
JRC-IHCP EU Joint Research Center—Institute for Health and Consumer Protection (Ispra, Italy)
LDPE Low-density polyethylene
LNE National Laboratory of Metrology and Testing (in French: Laboratoire National de Métrologie et d'Essais) (France)
4-MBP 4-Methylbenzophenone
MERCOSUR (in Spanish)/MERCOSUL (in Portuguese) Common Market of the South
MHLW Ministry of Health, Labor, and Welfare (Japan)

MOAH Mineral oil aromatic hydrocarbons
MOSH Mineral oil saturated hydrocarbons
MS Member State
MXDA *m*-Xylylenediamine
NIAS Nonintentionally added substances
NLS Nonlisted substances
NOEL No-observed effect level
NOL No Objection Letter (US FDA)
NORDEN Nordic Council of Ministers
NP Nonylphenol
ODT Odor detection threshold
OML Overall migration limit
PA Polyamide
PAA Primary aromatic amine
PAO Poly alpha olefin
PCR Postconsumer recycled
PE Polyethylene
PET Polyethylene terephthalate
PFAS Perfluoroalkyl sulfonate
PFCA Perfluorocarboxylic acid
PI Photoinitiator
PlasticsEurope Association of Plastics Manufacturers
PMO Pasteurized Milk Ordinance (US FDA)
POSH Polyolefin oligomeric saturated hydrocarbons
PP Polypropylene
PPA Polymer production aid
PRP Prerequisite program
PS Polystyrene
PVC Polyvinyl chloride
PVDC Polyvinylidene chloride
QM Quantity in material
SBS Styrene-butadiene-styrene copolymer
SEBS Styrene-ethylene/butadiene-styrene copolymer
SEM Scanning electron microscopy
SME Small and medium-sized enterprise
SML Specific migration limit
SOP Standard operating procedure
SPI The Plastic Industry Trade Association (United States)
SPME Solid phase microextraction
SQF Safe Quality Food
SSOP Sanitation standard operating procedure
TCA 2,4,6-Trichloroanisole
TCP 2,4,6-Trichlorophenol
TDI Tolerable daily intake
TDT Taste detection threshold
TFS Tin-free steel
TNO the Netherlands Organization for Applied Scientific Research (in Dutch: Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek)
TOR Threshold of regulation (United States, MERCOSUR)
TPE Thermoplastic elastomer
TQM Total quality management
TTC Threshold of toxicological concern
UHT Ultra-high temperature
UNL University of Nebraska-Lincoln (United States)
WHO World Health Organization (Geneva, Switzerland)

WEBSITES OF INTEREST

FCMs Regulations

- **Australia/New Zealand:**
  www.comlaw.gov.au
  http://www.comlaw.gov.au/Search/Australia New Zealand Food Standards
  www.foodstandards.gov.au
  www.foodsafety.govt.nz
- **Canada:**
  a. Health Canada/Santé Canada (HC/SC): www.hc-sc.gc.ca
  b. Canadian Food Inspection Agency/Agence Canadienne d'Inspection des Aliments (CFIA/ACIA): www.inspection.gc.ca
- **Council of Europe Resolutions:**
  www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/presentation.asp#TopOfPage
  www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/COE%27s%20policy%20statements%20food%20contact.asp#TopOfPage
- **Denmark:**
  DVFA: www.dvfa.dk
- **European Union:**
  a. The **European Commission** regulations, guidelines, and complementary information on FCMs can be found at the following websites: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm
  http://ec.europa.eu/food/food/chemicalsafety/foodcontact/eu_legisl_en.htm
  http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm
  http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sci_advice_en.htm
  http://ec.europa.eu/food/food/chemicalsafety/foodcontact/emerging_en.htm
  http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm
  https://webgate.ec.europa.eu/sanco_foods/main/?event=display
  http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/sum_nat_legis_en.pdf
  b. EFSA:
  www.efsa.europa.eu/
  www.efsa.europa.eu/en/panels/fip.htm
  c. EU JRC-IHCP
  http://ec.europa.eu/dgs/jrc/index.cfm
  http://crl-fcm.jrc.it/
  http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m
- **Ireland:**
  FSAI: https://www.fsai.ie/
  EasyDoc: http://easydoc.fsai.ie/Home/Index
- **Italy:**
  ISS: www.iss.it
- **Japan:**
  a. FSC
  www.fsc.go.jp/english/index.html
  b. JETRO
  https://www.jetro.go.jp/en/reports/regulations/
- **MERCOSUR:**
  www.puntofocal.gov.ar (Focal Point, Argentina)
  www.conal.gov.ar (CONAL, Argentina) (see Argentine Food Code—Chapter IV: FCMs)
  http://portal.anvisa.gov.br/wps/portal/anvisa/home (ANVISA, Brazil)
  www.mercosur.int (Technical Secretariat, Montevideo, Uruguay)
- **Swiss Ordinance on FCMs:**
  https://www.admin.ch/opc/fr/classified-compilation/20050179/index.html
  www.bag.admin.ch/encres_emballage
- **US FDA:**
  www.fda.gov

Other Organizations

- **ACTIA** (France): http://referentiel.actia-asso.eu/
- **British Retail Consortium** (United Kingdom): www.brcglobalstandards.com
- **Food Standards Agency** (United Kingdom): www.food.gov.uk
- **FSAP-IoPP** (United States): www.iopp.org/i4a/pages/index.cfm?pageid=2267
- **FSSC** (the Netherlands): www.fssc22000.com
- **GFSI** (France): www.mygfsi.com
- **GHI** (Austria): www.globalharmonization.net
- **ISO**: www.iso.org
- **IFS** (Germany): www.ifs-certification.com
- **IVLV** (Germany): www.ivlv.org/en/about-us/
- **IVV-Fraunhofer** (Germany): www.ivv.fraunhofer.de/en.html
- **PAC—Packaging Consortium** (Canada): www.pac.ca
- **SQF Institute** (United States): www.sqfi.com
- **The Packaging Society** (formerly the IoP) (United Kingdom): www.iom3.org/packaging-society
- **The Plastics Industry Trade Association** (SPI) (United States): www.plasticsindustry.org/
- **TNO** (the Netherlands): www.tno.nl

REFERENCES

ABMI, 2015. Efficiency—Aseptic Validation Protocol—Appendix. Association of the Beverage Machinery Industry, Zürich, Switzerland, Available from: <www.abm-industry.org/technic/efficiency/aseptic-validation-protocol/appendix.html> (accessed 30.04.2015).

Ahvenainen, R. (Ed.), 2003. Novel Food Packaging Techniques CRC Press, Boca Raton, FL.

Alin, J., Hakkarainen, M., 2011. Microwave heating causes rapid degradation of antioxidants in polypropylene packaging, leading to greatly increased specific migration to food simulants as shown by ESI-MS and GC-MS. J. Agric. Food Chem. 59 (10), 5418–5427.

Alin, J., Hakkarainen, M., 2013. Combined chromatographic and mass spectrometric toolbox for fingerprinting migration from PET tray during microwave heating. J. Agric. Food Chem. 61 (6), 1405–1415.

Allahvaisi, S., 2012. Polypropylene in the industry of food packaging. In: Dogan, F. (Ed.), Polypropylene InTech ISBN: 978-953-51-0636-4. Available from: <www.intechopen.com/books/polypropylene/polypropylene-in-the-industry-of-food-packaging> (accessed 18.03.2015).

Allahvaisi, S., 2013. Controlling *Lasioderma serricorne* F. (Col.: Anobiidae) by fumigation and packaging. World Appl. Sci. J. 28 (12), 1983–1988.

Allahvaisi, S., Pourmirza, A.A., Safaralizade, M.H., 2010. The study on polymers permeability for foodstuffs packaging by some serious species of stored pest insects and phosphine gas. J. Agri. Technol. 6 (4), 747–759.

Ariosti, A., 2012. General situation of FCMs regulations in Latin America and an update of the MERCOSUR advancement. In: Proceedings of the Plastics and Paper in Contact with Foodstuffs Conference (Vienna, Austria, 11–14 December). Smithers Pira, Leatherhead, pp. 1–121.

Ariosti, A., 2013. Regulations on plastics in contact with foodstuffs—present situation in MERCOSUR and other Latin American countries. In: Proceedings of the 11th Biennial International Symposium on Worldwide Regulation of Food Packaging (Baltimore, MD, 4–6 June). The Society of the Plastics Industry Inc., Washington, DC, pp. 1–37.

Ariosti, A., 2015a. An update of the MERCOSUR and South American food contact materials regulations. In: Proceedings of the Global Food Contact Conference (Rome, Italy, 19–21 May). Smithers Pira, Leatherhead, pp. 1–36.

Ariosti, A., 2015b. Global legislation for regenerated cellulose materials in contact with food. In: Baughan, J.S. (Ed.), Global Legislation for Food Contact Materials Woodhead Publishing, Cambridge, pp. 109–139.

Ariosti, A., 2015c. Regulation of food packaging in South America. In: Proceedings of the Food Packaging Law Seminar (Arlington, VA, 14–15 October). Keller and Heckman LLP, Washington, DC, pp. 1–52.

Ariosti, A., Olivera Carrión, M., 2014. Argentina. In: Kirchsteiger-Meier, E., Baumgartner, T. (Eds.), Global Food Legislation: An Overview Wiley-VCH, Weinheim, pp. 1–32.

Aznar, M., Canellas, E., Nerín, C., 2009. Quantitative determination of 22 primary aromatic amines by cation-exchange solid-phase extraction and liquid chromatography-mass spectrometry. J. Chromatogr. A. 1216, 5176–5181.

Bailey, A., 2012. An update of the US FDA's Food Contact Notification (FCN) Program. In: Proceedings of the Global Food Contact Conference (Baltimore, MD, 15–17 May). Smithers Pira, Leatherhead, pp. 1–28.

Barnes, K.A., Richard Sinclair, C., Watson, D.H. (Eds.), 2007. Chemical Migration and Food Contact Materials Woodhead Publishing, Cambridge.

Barone, C., Bolzoni, L., Caruso, G., Montanari, A., Parisi, S., Steinka, I., 2015. Food Packaging Hygiene. Springer International Publishing AG, Switzerland. http://dx.doi.org/10.1007/978-3-319-14827-4.

Barp, L., Suman, M., Lambertini, F., Moret, S., 2015. Migration of selected hydrocarbon contaminants into dry pasta packaged in direct contact with recycled paperboard. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 32 (2), 271–283.

Barthélémy, E., Spyropoulos, D., Milana, M.R., Pfaff, K., Gontard, N., Lampi, E., et al., 2014. Safety evaluation of mechanical recycling processes used to produce polyethylene terephthalate (PET) intended for food contact applications. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk

Assess. 31 (3), 490–497. (Proceedings of the 5th ILSI International Symposium on Food Packaging 'Scientific developments supporting safety and innovation', held on 14–16 November 2012 in Berlin, Germany, organized by ILSI Europe).

Baty, S., Castle, L., Ginn, R., Reynolds, S., 2004. LC–MS/MS analysis for semicarbazide in food. Recent Appl. LC-MS 17 (11a), 32–35.

Baughan, J.S., 2013. Food contact regulatory developments in China. In: Proceedings of the Plastics and Paper in Contact with Foodstuffs Conference (London, UK, 9–12 December). Smithers Pira, Leatherhead, pp. 1–34.

Baughan, J.S. (Ed.), 2015. Global Legislation for Food Contact Materials Woodhead Publishing, Cambridge.

Baughan, J.S., Attwood, D., 2010. Food packaging in the United States. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 223–242.

Bayer, F., 2002. Polyethylene terephthalate recycling for food-contact applications: testing, safety and technologies: a global perspective. Food Addit. Contam. 19 (Suppl.), 111–134. (Proceedings of the 2nd ILSI International Symposium 'Food Packaging: Ensuring the Safety and Quality of Foods', held on 8–10 November 2000 in Vienna, Austria, organized by ILSI Europe in collaboration with European Commission, IUPAC and Vienna University of Technology).

Begley, T.H., Hsu, W., Noonan, G., Diachenko, G., 2008. Migration of fluorochemical paper additives from food-contact paper into foods and food simulants. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 25 (3), 384–390.

Bentayeb, K., Ackerman, L.K., Lord, T., Begley, T.H., 2013. Non-visible print set-off of photoinitiators in food packaging: detection by ambient ionisation mass spectrometry. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 30 (4), 750–759.

Bhunia, K., Sablani, S.S., Tang, J., Rasco, B., 2013. Migration of chemical compounds from packaging polymers during microwave, conventional heat treatment, and storage. Compr. Rev. Food Sci. Food Safety 12, 523–545.

Bian, S., 2013. Food contact compliance in China: the view from industry. In: Proceedings of the 11th Biennial International Symposium on Worldwide Regulation of Food Packaging (Baltimore, MD, 4–6 June). The Society of the Plastics Industry Inc., Washington, DC, pp. 1–31.

Biedermann, M., Ingenhoff, J.-E., Zurfluh, M., Richter, L., Simat, T., Harling, A., et al., 2013. Migration of mineral oil, photoinitiators and plasticizers from recycled paperboard into dry foods: a study under controlled conditions. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 30 (5), 885–898.

Biedermann-Brem, S., Kasprick, N., Simat, T., Grob, K., 2012. Migration of polyolefin oligomeric saturated hydrocarbons (POSH) into food. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 29 (3), 449–460.

Bott, J., Störmer, A., Franz, R., 2014a. Migration of nanoparticles from plastic packaging materials containing carbon black into foodstuffs. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 31 (10), 1769–1782.

Bott, J., Störmer, A., Franz, R., 2014b. A model study into the migration potential of nanoparticles from plastics nanocomposites for food contact. Food Pack. Shelf Life 2, 73–80.

Bradley, E.L., Castle, L., Dines, T.J., Fitzgerald, A.G., Gonzalez Tunon, P., Jickells, S.M., et al., 2005. Test method for measuring non-visible set-off from inks and lacquers on the food-contact surface of printed packaging materials. Food. Addit. Contam. 22 (5), 490–502.

Bradley, E.L., Castle, L., Jickells, S.M., Mountfort, K.A., Read, W.A., 2009. Use of overall migration methodology to test for food-contact substances with specific migration limits. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 26 (4), 574–582.

Bradley, E.L., Burden, R.A., Leon, I., Mortimer, D.N., Speck, D.R., Castle, L., 2013. Determination of phthalate diesters in food. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 30 (4), 722–734.

Brandsch, J., Piringer, O.G. (Eds.), 2008. Plastic Packaging—Interactions with Food and Pharmaceuticals, second ed. Wiley-VCH, Weinheim.

Brauer, B., 2014. The German enforcement perspective: case studies from working in enforcement. In: Proceedings of the Plastics and Paper in Contact with Foodstuffs Conference (Munich, Germany, 2–5 December). Smithers Pira, Leatherhead, pp. 1–25.

Brody, A.L., Strupinsky, E.R., Kline, L.R. (Eds.), 2001. Active Packaging for Food Applications CRC Press, Boca Raton, FL.

BS ISO, 2003. British Standard ISO 13302:2003 Sensory Analysis—Methods for Assessing Modifications to the Flavor of Foodstuffs due to Packaging. British Standards Institution, London, pp. 1–36.

Buculei, A., Gutt, G., Sonia, A., Adriana, D., Constantinescu, G., 2012. Study regarding the tin and iron migration from metallic cans into foodstuff during storage. J. Agroalim. Process. Technol. 18 (4), 299–303.

Campioli, E., Zavatti, M., Avallone, R., Puia, G., Losi, G., Baraldi, M., 2010. Evidence that isopropylthioxanthone (ITX) is devoid of anxiolytic and sedative effect. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 27 (3), 389–395.

Castle, L., 2007. Chemical migration into food: an overview. In: Barnes, K.A., Richard Sinclair, C., Watson, D.H. (Eds.), Chemical Migration and Food Contact Materials Woodhead Publishing, Cambridge, pp. 1–13.

Catalá, R., Gavara, R. (Eds.), 2002. Migración de Componentes y Residuos de Envases en Contacto con Alimentos Instituto de Agroquímica y Tecnología de Alimentos (IATA), Valencia.

CFIA/ACIA, 2013. Physical Hazards. Canadian Food Inspection Agency/Agence Canadienne d'Inspection des Aliments., Available from: <http://active.inspection.gc.ca/rdhi-bdrid/english/rdhi-bdrid/introe.aspx?i=8> (accessed 16.04.2015).

Cheeseman, M., 2013. Toxicological threshold of concern: a tool for global food contact material compliance. In: Proceedings of the Global Food Contact Conference (Barcelona, Spain, 14–16 May). Smithers Pira, Leatherhead, pp. 1–29.

Chung, S.K., Seo, J.Y., Lim, J.H., Park, H.H., Kim, Y.T., Song, K.H., et al., 2011. Barrier property and penetration traces in packaging films against Plodia interpunctella (Hübner) larvae and Tribolium castaneum (Herbst) adults. J. Stored. Prod. Res. 47, 101–105.

Chytiri, S., Goulas, A.E., Badeka, A., Riganakos, K.A., Kontominas, M.G., 2005. Volatile and non-volatile radiolysis products in irradiated multilayer coextruded food-packaging films containing a buried layer of recycled low-density polyethylene. Food Addit. Contam. 22 (12), 1264–1273.

Chytiri, S.D., Badeka, A.V., Riganakos, K.A., Kontominas, M.G., 2010. Radiolysis products and sensory properties of electron-beam-irradiated high-barrier food-packaging films containing a buried layer of recycled low-density polyethylene. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 27 (4), 546–556.

Clark, M.N., 2015. Regulation of food packaging in China. In: Proceedings of the Food Packaging Law Seminar (Arlington, Virginia, USA, 14-15 October). Keller and Heckman LLP, Washington, DC, pp. 1–26.

Cooper, I., Irvine, A., 2015. EU guidance documents supporting the PIM Proceedings of the Global Food Contact Conference (Rome, Italy, 19–21 May). Smithers Pira, Leatherhead, pp. 1–16.

Cutter, C.N., 2006. Opportunities for bio-based packaging technologies to improve the quality and safety of fresh and further processed muscle foods. Meat Sci. 74, 131–142.

Dainelli, D., 2007. Traceability and food contact materials. In: Barnes, K.A., Richard Sinclair, C., Watson, D.H. (Eds.), Chemical Migration and Food Contact Materials Woodhead Publishing, Cambridge, pp. 64–83.

Dainelli, D., Gontard, N., Spyropoulos, D., Zondervan-van der Beuken, E., Tobback, P., 2008. Active and intelligent food packaging: legal aspects and safety concerns. Trends Food Sci. Technol. 19, S103–S112.

de la Cruz García, C., Sánchez Moragas, G., Nordqvist, D., 2014. Food contact materials. In: Motarjemi, Y., Lelieveld, H. (Eds.), Food Safety Management—A Practical Guide for the Food Industry Academic Press, New York, NY, pp. 397–419.

de Oliveira, C., Rodríguez, A., Ferreira Soares, N., Nerín, C., 2012. Multiple headspace-solid-phase microextraction as a powerful tool for the quantitative determination of volatile radiolysis products in a multilayer food packaging material sterilized with gamma-radiation. J. Chromatogr. A 1244, 61–68.

Driffield, M., Bradley, E.L., Leon, I., Lister, L., Speck, D.R., Castle, L., et al., 2014. Analytical screening studies on irradiated food packaging. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 31 (3), 556–565.

Dutra, C., Freire, M.T., de, A., Nerín, C., Bentayeb, K., Rodríguez-Lafuente, A., et al., 2014. Migration of residual nonvolatile and inorganic compounds from recycled post-consumer PET and HDPE. J. Brazil. Chem. Soc. 25 (4), 686–696.

EDQM-CoE, 2013. Metals and Alloys Used in Food Contact Materials and Articles. A Practical Guide for Manufacturers and Regulators. Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB)—European Directorate for the Quality of Medicines and HealthCare (EDQM)—Council of Europe, Strasbourg.

EFSA, 2005. Opinion of the scientific panel on food additives, flavourings, processing aids and materials in contact with food on a request from the commission related to semicarbazide in food: question number EFSA-2003-235. EFSA J. 219, 1–36.

EFSA/WHO, 2015. Threshold of toxicological concern approach: conclusions and recommendations of the Joint EFSA/WHO Expert Workshop on TTC (Brussels, Belgium, 3–5 December 2014)—DRAFT for public consultation, pp. 1–31. Available from: <www.efsa.europa.eu/en/consultation-sclosed/call/150212.pdf> (accessed 12.02.2015).

Eicher, A., Biedermann, M., Zurfluh, M., Grob, K., 2015. Migration by 'direct' or 'indirect' food contact? 'Dry' and 'wetting' foods? Experimental data for 'touching' contact of dry foods with paper and board. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 32 (1), 110–119.

Eisert, R., 2011. EU exposure matrix project—results. In: Proceedings of the Global Food Contact Conference (Frankfurt am Main, Germany, 14–16 June). Pira International, Leatherhead, pp. 1–22.

Ettinger, D.J., Clark, M.N., 2012. Special Focus—The Regulation of Food Packaging Materials in Japan. Keller and Heckman LLP, Washington, DC, Available from: <www.packaginglaw.com/3383_.shtml> (accessed 24.06.2014).

EU, 2004. Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, pp. 4–17.

EU, 2006. Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. OJ L 384, 29.12.2006, pp. 75–78.

EU, 2011a. Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, pp. 1–89.

EU, 2011b. Provisional List of Additives. 11th Update 28/10/2011. European Commission, Brussels1–4, Available from: <http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/080410_provisional_list_7_211009.pdf> (accessed 10.5.2015).

EU, 2013. Union Guidance on Regulation (EU) No. 10/2011 on Plastic Materials and Articles Intended to Come into Contact with Food as Regards Information in the Supply Chain. European Commission Health and Consumers Directorate-General—Safety of the Food Chain—Innovation and Sustainability, Brussels, Available at: <http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/guidance_reg-10-2011_without_boxes_en.pdf> (accessed 22.10.2014).

EU, 2015. Working Document References of the European and National Legislations (Updated Version February 2015). European Commission Health and Consumers Directorate-General—Safety of the Food Chain—Innovation and Sustainability, Brussels, Available at: <http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/references-eur-nat-leg_en.pdf> (accessed 10.05.2015).

Fernandes, A.R., Rose, M., Charlton, C., 2008. 4-Nonylphenol (NP) in food-contact materials: analytical methodology and occurrence. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 25 (3), 364–372.

Flanagan, S. (Ed.), 2015. Handbook of Food Allergens—Detection and Control Woodhead Publishing, Cambridge.

FoodDrinkEurope, 2013. Guidance on food allergens management for food manufacturers, Brussels. Available from: <www.fooddrinkeurope.eu> (accessed 29.01. 2015).

Forrest, M., 2009. Food Contact Materials—Rubbers, Silicones, Coatings and Inks. iSmithers, Shawbury.

Franz, R., Huber, M., Piringer, O., Damant, A.P., Jickells, S.M., Castle, L., 1996. Study of functional barrier properties of multilayer recycled poly(ethylene terephthalate) bottles for soft drinks. J. Agric. Food Chem. 44 (3), 892–897.

Franz, R., Huber, M., Piringer, O., 1997. Presentation and experimental verification of a physicomathematical model describing the migration across functional barrier layers into foodstuffs. Food Addit. Contam. 14 (6–7), 627–640.

Franz, R., Mauer, A., Welle, F., 2004. European survey on post-consumer poly(ethylene terephthalate) materials to determine contamination levels and maximum consumer exposure from food packages made from recycled PET. Food Addit. Contam. 21 (3), 265–286.

FSAI, 2010. Guide to Food Law for Artisan/Small Food Producers Starting a New Business. Food Safety Authority of Ireland, Dublin.1–28

FSANZ, 2010. Survey of Chemical Migration from Food Contact Packaging Materials in Australian Food. Food Standards Australia New Zealand., Available from: <www.foodstandards.gov.au/consumer/chemicals/foodpackaging/Pages/default.aspx> (accessed 29.06.2014).

FSC, 2015. Food Safety Basic Act (Act 48 of 23 May 2003). Japan Food Safety Commission, Tokyo, Available from: <www.fsc.go.jp/english/index.html> (accessed 12.05.2015).

Gallart-Ayala, H., Núñez, O., Lucci, P., 2013. Recent advances in LC-MS analysis of food-packaging contaminants. Trends Analytic. Chem. 42, 99–124.

Gardner, D., 2008. Innovative Packaging for the Wine Industry: A Look at Wine Closures. Technical Report. Virginia Tech—Food Science and Technology, Blacksburg, VA1–16, Available from: <www.iopp.org/files/public/GardnerVaTechWineClosures.pdf> (accessed 28.04.2015).

Genualdi, S., Addo Ntim, S., Begley, T., 2015. Suitability of polystyrene as a functional barrier layer in coloured food contact materials. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 32 (3), 395–402.

Gergely, A., Cheeseman, M., 2015. TTC: practical and legally sound approach to evaluate safety and regulatory compliance. In: Proceedings of the Global Food Contact Conference (Rome, Italy, 19–21 May). Smithers Pira, Leatherhead, pp. 1–22.

GFSI, 2013. GFSI Guidance Document, sixth ed., version 6.3. The Global Food Safety Initiative Foundation—The Consumers Goods Forum, Issy-les-Moulineaux, pp. 1–168. Available from: <www.mygfsi.com> (accessed 13.01. 2015).

GFSI, 2015. Recognised schemes. Available from: <www.mygfsi.com/schemes-certification/recognised-schemes.html> (accessed 16.04.2015).

Goodwin, D., 2014. Foreign body contamination and the implications for the food manufacturing sector. New Food Mag. December 19, 2014. Available from: <www.newfoodmagazine.com/advent-calendar/foreign-body-contamination/> (accessed 16.04.2015).

Government of Manitoba, 2015a. Physical hazards in food. Fact Sheet 16. Program for Processors and Distributors, Canada. Available from: <www.gov.mb.ca/agriculture/food-safety/at-the-food-processor/food-safety-program/pubs/fs_16.pdf> (accessed 16.04.2015).

Government of Manitoba, 2015b. Pest control. Fact Sheet 13. Program for Processors and Distributors, Canada. Available from: <www.gov.mb.ca/agriculture/food-safety/at-the-food-processor/food-safety-program/pubs/fs_13.pdf> (accessed 24.04.2015).

Government of Manitoba, 2015c. Biological hazards. Fact Sheet 19. Program for Processors and Distributors, Canada. Available from: <www.gov.mb.ca/agriculture/food-safety/at-the-food-processor/food-safety-program/pubs/fs_19.pdf> (accessed 23.04.2015).

Government of Manitoba, 2015d. Chemical hazards. Fact Sheet 26. Program for Processors and Distributors, Canada. Available from: <www.gov.mb.ca/agriculture/food-safety/at-the-food-processor/food-safety-program/pubs/fs_26.pdf>. (accessed 23.04.2015).

Government of Manitoba, 2015e. Food allergens as chemical hazards. Fact Sheet 17. Program for Processors and Distributors. Canada. Available from: <www.gov.mb.ca/agriculture/food-safety/at-the-food-processor/food-safety-program/pubs/fs_17.pdf> (accessed 23.04.2015).

Greenberg, E.F., Rost, K.T., 2014. Pre-conference workshop—Food contact notifications, GRAS and other key concepts: explanations, comparisons and newest developments. In: Proceedings of the Global Food Contact Conference (Silver Spring, MD, 12–14 May). Smithers Pira, Leatherhead, pp. 1–156.

Guazzotti, V., Marti, A., Piergiovanni, L., Limbo, S., 2014. Bio-based coatings as potential barriers to chemical contaminants from recycled paper and board for food packaging. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 31 (3), 402–413.

Guazzotti, V., Limbo, S., Piergiovanni, L., Fengler, R., Fiedler, D., Gruber, L., 2015. A study into the potential barrier properties against mineral oils of starch-based coatings on paperboard for food packaging. Food Pack. Shelf Life 3, 9–18.

Guzińska, K., Owczarek, M., Dymel, M., 2012. Investigation in the microbiological purity of paper and board packaging intended for contact with food. Fibres Text. East. Eur. 20 (96), 186–190.

Hanušová, K., Vrbík, K., Raichl, A., Dobiáš, J., Sosnovcová, J., 2015. Migration of epoxidised soybean oil from PVC gaskets of commercial lids: simulation of migration under various conditions and screening of food products from Czech markets. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 32 (3), 427–437.

Hartman, M.W., Powers, J.J., Pratt, D.E., 1963. Bacterial permeability of selected food packaging films. Food Technol. September, 92–94.

Hegarty, B., 2013. Food contact controls and compliance—a Member State perspective. In: Proceedings of the Plastics and Paper in Contact with Foodstuffs Conference (London, UK, 9–12 December). Smithers Pira, Leatherhead, pp. 1–60.

Hennlich, W., 2010. Microbiological Guide Values for Food Packaging—A Fraunhofer IVV Initiative. Beverage and Brewing—International Supplier's Guide.108.

Hennlich, W., 2011. Guideline values for microbiological contamination provide increased assurance for assessing the hygienic state of food packaging. Food Market. Technol. April, 54–55.

Hou, X., Fields, P., Taylor, W., 2004. The effect of repellents on penetration into packaging by stored-product insects. J. Stored. Prod. Res. 40, 47–54.

Hurme, E.U., Wirtanen, G., Axelson-Larsson, L., Pacheco, N.A.M., Ahvenainen, R., 1997. Penetration of bacteria through microholes in semirigid aseptic and retort packages. J. Food Protect. 60 (5), 520–524.

Irvine, A., 2014. Food contact update from Europe. In: Proceedings of the Global Food Contact Conference (Silver Spring, MD, 12–14 May). Smithers Pira, Leatherhead, pp. 1–28.

Irvine, A., Kernoghan, N., 2013. Pre-conference workshop—an introduction to US FDA food contact regulations. In: Proceedings of the Global Food Contact Conference (Barcelona, Spain, 14–16 May). Smithers Pira, Leatherhead, pp. 1–110.

JETRO, 2009. Specifications, Standards and Testing Methods for Foodstuffs, Implements, Containers and Packaging, Toys, Detergents 2008. Japan External Trade Organization, Tokyo1–149, Available from: <www.jetro.go.jp/ext_images/en/reports/regulations/pdf/testing2009dec-ep.pdf> (accessed 12 May 2015).

JETRO, 2011. Specifications and Standards for Foods, Food Additives, etc., under the Food Sanitation Act (Abstract) 2010. Japan External Trade Organization, Tokyo1–190, Available from: <www.jetro.go.jp/ext_images/en/reports/regulations/pdf/foodext2010e.pdf> (accessed 12.05.2015).

Jung, T., Simat, T.J., 2014. Multi-analyte methods for the detection of photoinitiators and amine synergists in food contact materials and foodstuffs—Part II: UHPLC-MS/MS analysis of materials and dry foods. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 31 (4), 743–766.

Jung, T., Simat, T.J., Altkofer, W., 2010. Mass transfer ways of ultraviolet printing ink ingredients into foodstuffs. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 27 (7), 1040–1049.

Jung, T., Browatzki, C., Simat, T.J., 2014. Multi-analyte methods for the detection of photoinitiators and amine synergists in food contact materials and foodstuffs—Part I: HPLC-DAD screening of materials. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 31 (3), 512–536.

Kassouf, A., Chebib, H., Lebbos, N., Ouaini, R., 2013. Migration of iron, lead, cadmium and tin from tinplate-coated cans into chickpeas. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 30 (11), 1987–1992.

Katan, L.L. (Ed.), 1996. Migration from Food Contact Materials Blackie Academic & Professional, London.

Kawamura, Y., 2015. Current status of food contact regulations in Japan. In: Proceedings of the Global Food Contact Conference (Rome, Italy, 19–21 May). Smithers Pira, Leatherhead, pp. 1–35.

Kernoghan, N., 2013. Update on harmonized food contact regulations in Europe. In: Proceedings of the Global Food Contact Conference (Barcelona, Spain, 14–16 May). Smithers Pira, Leatherhead, pp. 1–24.

Kim, S.-U., Kim, T.-R., Lee, E.-U., Kim, M.-S., Kim, C.-K., Kim, L.-R., et al., 2015. Formaldehyde and heavy metal migration from rubber and metallic packaging/utensils in Korea. Food Addit. Contam. Part B Surveill. 8 (1), 7–11.

Koivikko, R., Pastorelli, S., Rodríguez-Bernaldo de Quirós, A., Paseiro-Cerrato, R., Paseiro-Losada, P., Simoneau, C., 2010. Rapid multi-analyte quantification of benzophenone, 4-methylbenzophenone and related derivatives from paperboard food packaging. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 27 (10), 1478–1486.

Kopper, G., Ariosti, A., 2010. Food packaging legislation: sanitary aspects. In: Boisrobert, Ch, Stjepanovic, A., Oh, S., Lelieveld, H. (Eds.), Ensuring Global Food Safety—Exploring Global Harmonization Academic Press, New York, NY, pp. 227–261.

Koster, S., Rennen, M., Leeman, W., Houben, G., Muilwijk, B., van Acker, F., et al., 2014. A novel safety assessment strategy for non-intentionally added substances (NIAS) in carton food contact materials. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 31 (3), 422–443.

Lago, M.A., Rodríguez-Bernaldo de Quirós, A., Sendón, R., Bustos, J., Nieto, M.T., Paseiro-Losada, P., 2015. Photoinitiators: a food safety review. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 32 (5), 779–798.

Li, C., Bian, S., 2010. China food contact chemical legislation summary. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 319–335.

Lord, T., 2003. Packaging materials as a source of taints. In: Baigrie, B. (Ed.), Taints and Off-Flavours in Food Woodhead Publishing, Cambridge, pp. 64–111.

Lorenzini, R., Fiselier, K., Biedermann, M., Barbanera, M., Braschi, I., Grob, K., 2010. Saturated and aromatic mineral oil hydrocarbons from paperboard food packaging: estimation of long-term migration from contents in the paperboard and data on boxes from the market. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 27 (12), 1765–1774.

Lorenzini, R., Biedermann, M., Grob, K., Garbini, D., Barbanera, M., Braschi, I., 2013. Migration kinetics of mineral oil hydrocarbons from recycled paperboard to dry food: monitoring of two real cases. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 30 (4), 760–770.

Magami, S.M., Oldring, P.K.T., Castle, L., Guthrie, J.T., 2015. Migration of melamine from thermally cured, amino cross-linked can coatings into an aqueous ethanol food simulant: aspects of hydrolysis, relative reactivity and migration. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 32 (3), 403–409.

Maggi, L., Mazzoleni, V., Fumi, M.D., Salinas, M.R., 2008. Transformation ability of fungi isolated from cork and grape to produce 2,4,6-trichloroanisole from 2,4,6-trichlorophenol. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 25 (3), 265–269.

Magnuson, B., Munro, I., Abbot, P., Baldwin, N., López-García, R., Ly, K., et al., 2013. Review of the regulation and safety assessment of food substances in various countries and jurisdictions. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 30 (7), 1147–1220.

Mahinka, S.P., Reisin Miller, A., Vaughn, J.L., 2013. Compliance of Glass Packaging with Human and Environmental Health and Safety Toxics—in—Packaging Requirements. Glass Packaging Institute, Arlington, VA1–50, Available from: <http://www.gpi.org/sites/default/files/Compliance of Glass Packaging with Human and Environmental Health and Safety Toxics.pdf> (accessed 06.02.2015).

Marasco, J., 2014. Uncloaking the GFSI requirements for food packaging. AIB update, January/February, pp. 8–11. Available from: <www.aibonline.org/aibOnline_/www.aibonline.org/newsletter/Magazine/Jan_Feb2014/Uncloaking.pdf> (accessed 10.03.2015).

Marouf, A., Momen, R.F., 2007. An evaluation of the permeability to phosphine through different polymers used for the bag storage of grain. In: Donahaye, E.J., Navarro, S., Bell, C., Jayas, D., Noyes, R., Phillips, T.W. (Eds.), Proceedings of the International Conference on Controlled Atmosphere and Fumigation in Stored Products (Gold-Coast, Australia, 8–13 August 2004 FTIC Ltd. Publishing, Israel, pp. 1–7. Available from: <http://ftic.co.il/2004gold-coastPDF/7.6.pdf> (accessed 24.04.2015).

Mason, J., 2015. Foreign Material Contamination in Food. NSF International, Ann Arbor, MI, Available from: <www.aig.com/Jan-2015-NSF-Article_3171_659050.html> (accessed 16.04.2015).

Mattu, J., 2014. An overview of food packaging regulations in Canada and Health Canada's safety assessment process. In: Proceedings of the Global Food Contact Conference (Silver Spring, MD, 12–14 May). Smithers Pira, Leatherhead, pp. 1–37.

MERCOSUR, 1992a. Resolución GMC 03/92—Reglamento Técnico MERCOSUR Criterios generales de envases y equipamientos alimentarios en contacto con alimentos. 1 April 1992.

MERCOSUR, 1992b. Resolución GMC 56/92—Reglamento Técnico MERCOSUR Disposiciones generales para envases y equipamientos plásticos en contacto con alimentos. 15 December 1992.

MERCOSUR, 2007. Resolución GMC 32/07—Reglamento Técnico MERCOSUR sobre lista positiva de aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos en contacto con alimentos. 11 December 2007.

MHLW, 2015. Food Sanitation Act (Act 233 of 24 December 1947, Amendment Act 53 of 2006, updated 31 March 2009). Japan Ministry of Health, Labour and Welfare, Tokyo, Available from: <www.japaneselawtranslation.go.jp/law/detail/?ft=2&yo=%E9%A3%9F%E5%93%81%E8%A1%9B%E7%94%9F%E6%B3%95&ia=03&x=25&y=17&ky=&page=1&re=02&id=12&lvm=02> accessed 12.05.2015).

Milana, M.R., Denaro, M., Feliciani, R., Maggio, A., Maini, A., Padula, G. (Eds.), 2011. CAST Project. Guidelines for the Application of the Regulation (EC) 2023/2006 to the Supply Chain of Materials and Articles Intended to Come into Contact with Food. Rapporti ISTISAN 11/37 Istituto Superiore di Sanità, Rome. Available from: <www.iss.it> (accessed 31.01.2015).

Milana, M.R., Denaro, M., Feliciani, R., Gesumundo, C., Maggio, A., Mannoni, V., Panico, O., Padula, G. (Eds.), 2013. Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Linee guida per il riscontro documentale sull'applicazione del Regolamento (CE) n. 2023/2006. Rapporti ISTISAN 13/14 Istituto Superiore di Sanità, Rome. Available from: <www.iss.it> (accessed 30.01.2015).

Montanari, A., 2015. Inorganic contaminants of food as a function of packaging features. In: Barone, C., Bolzoni, L., Caruso, G., Montanari, A., Parisi, S., Steinka, I. (Eds.), Food Packaging Hygiene Springer International Publishing AG, Switzerland, pp. 17–41. http://dx.doi.org/10.1007/978-3-319-14827-4.

Mori, Y., 2010. Rules on food contact materials and articles in Japan. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 291–317.

Mullen, M.A., Vardeman, J.M., Bagwell, J., 2012. Insect resistant packaging. In: Hagstrum, D.W. Phillips, T.W. Cuperus, G. (Eds.), Stored Product Protection, S156 Kansas State University Agricultural Experiment Station and Cooperative Extension Service, Manhattan, KS, pp. 135–142. ISBN 978-0-9855003-0-6. Available from: <www.ksre.ksu.edu/bookstore/pubs/s156.pdf> (accessed 24.04.2015).

Mutsuga, M., Kawamura, Y., Sugita-Konishi, Y., Hara-Kudo, Y., Takatori, K., Tanamoto, K., 2006. Migration of formaldehyde and acetaldehyde into mineral water in polyethylene terephthalate (PET) bottles. Food Addit. Contam. 23 (2), 212–218.

Navarro, S., Zehavi, D., Angel, S., Finkelman, S., 2007. Natural nontoxic insect repellent packaging materials. In: Wilson, C.L. (Ed.), Intelligent and Active Packaging for Fruits and Vegetables CRC Press/Taylor and Francis Group, Boca Raton, FL, pp. 201–236.

Nerín, C., Alfaro, P., Aznar, M., Domeño, C., 2013. The challenge of identifying non-intentionally added substances from food packaging materials: a review. Anal. Chim. Acta 775, 14–24.

Nollet, L.M.L., van Hengel, A.J. (Eds.), 2011. Food Allergens—Analysis Instrumentation and Methods CRC Press/Taylor and Francis Group, Boca Raton, FL.

NORDEN, 2008. Food Contact Materials—In-house Documentation and Traceability. Nordic Check Lists to Industry and Trade. TemaNord 2008:517. Nordic Council of Ministers, Copenhagen1–87, Available at: <www.foedevarestyrelsen.dk/english/Food/Materials_in_contact_with_Food/Pages/default.aspx> (accessed 03.02. 2015).

Oesterreicher, H.D., 2012. Insights from the host regulator on recent activities relating to FCM. In: Proceedings of the Plastics and Paper in Contact with Foodstuffs Conference (Vienna, Austria, 11–14 December). Smithers Pira, Leatherhead, pp. 1–18.

Oldring, P., 2010. Estimating risks posed by migrants from food contact materials. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 175–195.

Oldring, P.K.T., Castle, L., O'Mahony, C.O., Dixon, J., 2014a. Estimates of dietary exposure to bisphenol A (BPA) from light metal packaging using food consumption and packaging usage data: a refined deterministic approach and a fully probabilistic (FACET) approach. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 31 (3), 466–489.

Oldring, P.K.T., O'Mahony, C.O., Dixon, J., Vints, M., Mehegan, J., Dequatre, C., et al., 2014b. Development of a new modeling tool (FACET) to assess exposure to chemical migrants from food packaging. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 31 (3), 444–465.

Padula, M., 2010. Food packaging legislation in South America and Central America. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 255–282.

Parisi, S., Barone, C., Caruso, G., 2015a. The influence of chemical composition of food packaging materials on the technological suitability: a matter of food safety and hygiene. In: Barone, C., Bolzoni, L., Caruso, G., Montanari, A., Parisi, S., Steinka, I. (Eds.), Food Packaging Hygiene Springer International Publishing AG, Switzerland, pp. 1–16. http://dx.doi.org/10.1007/978-3-319-14827-4.

Parisi, S., Barone, C., Caruso, G., 2015b. Organic food packaging contaminants: new and emerging risks. In: Barone, C., Bolzoni, L., Caruso, G., Montanari, A., Parisi, S., Steinka, I. (Eds.), Food Packaging Hygiene Springer International Publishing AG, Switzerland, pp. 63–77. http://dx.doi.org/10.1007/978-3-319-14827-4.

PAS 223, 2011. Prerequisite Programmes and Design Requirements for Food Safety in the Manufacture and Provision of Food Packaging. British Standards Institution, London, pp. 1–20.

Paseiro-Cerrato, R., Rodríguez-Bernaldo de Quirós, A., Sendón, R., Bustos, J., Santillana, M.I., Cruz, J.M., et al., 2010. Chromatographic methods for the determination of polyfunctional amines and related compounds used as monomers and additives in food packaging materials: a state-of-the-art review. Compr. Rev. Food Sci. Food Safety 9, 676–694.

Paseiro-Cerrato, R., Rodríguez-Bernaldo de Quirós, A., Sendón, R., Bustos, J., Sánchez, J.J., López-Hernández, J., et al., 2015. Instability of an aromatic amine in fatty food and fatty food simulant: characterisation of reaction products and prediction of their toxicity. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 32 (1), 100–109.

Peelman, N., Ragaert, P., De Meulenaer, B., Adons, D., Peeters, R., Cardon, L., et al., 2013. Application of bioplastics for food packaging. Trends Food Sci. Technol. 32, 128–141.

Pereira de Abreu, D.A., Cruz, J.M., Paseiro Losada, P., 2012. Active and intelligent packaging for the food industry. Food Rev. Int. 28 (2), 146–187.

Petersen, H., Biereichel, A., Burseg, K., Simat, T.J., Steinhart, H., 2008. Bisphenol A diglycidyl ether (BADGE) migrating from packaging material 'disappears' in food: reaction with food components. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 25 (7), 911–920.

Plastics Europe, 2014. Risk assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under Article 19 of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, pp. 1–34. Available from: <www.plasticseurope.org/documents/document/20141010141117-ra_for_non_listed_substances_and_nias_under_article_19_sept_2014.pdf> (accessed 04.05.2015).

Poças, M.F., Hogg, T., 2007. Exposure assessment of chemicals from packaging materials in foods: a review. Trends Food Sci. Technol. 18, 219–230.

Prevendar, R., 2014. Thinking Outside the Box: GFSI Certification Options for Food Packaging. NSF International, Ann Arbor, MI, Available from: <www.nsf.org/newsroom_pdf/NSF_GFSI_for_Packaging_White_Paper.pdf> (accessed 16.04.2015).

Raaska, L., 2005. Managing contamination risks from food packaging materials. In: Lelieveld, H.L.M., Mostert, M.A., Holah, J. (Eds.), Handbook of Hygiene Control in the Food Industry Woodhead Publishing, Cambridge, pp. 378–395.

Ravishankar, S., Maks, N.D., Teo, A.Y.L., Strassheim, H.E., Pascall, M.A., 2005. Minimum leak size determination, under laboratory and commercial conditions, for bacterial entry into polymeric trays used for shelf-stable food packaging. J. Food Protect. 68 (11), 2376–2382.

Realini, C.E., Marcos, B., 2014. Active and intelligent packaging systems for a modern society. Meat Sci. 98, 404–419.

Restuccia, D., Spizzirri, U.G., Parisi, O.I., Cirillo, G., Curcio, M., Iemma, F., et al., 2010. New EU regulation aspects and global market of active and intelligent packaging for food industry applications. Food Control 21, 1425–1435.

Rhim, J.-W., Park, H.-M., Ha, C.-S., 2013. Bio-nanocomposites for food packaging applications. Progress Polym. Sci. 38, 1629–1652.

Ridgway, K., Lalljie, S.P.D., Smith, R.M., 2010. Analysis of food taints and off-flavours: a review. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 27 (2), 146–168.

Robertson, G.L., 2013. Food Packaging—Principles and Practice, third ed. CRC Press/Taylor and Francis Group, Boca Raton, FL.

Rossi, L., 2010. Council of Europe resolutions. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 49–66.

Rossi, L., 2014. Plastics regulations in EU, USA, China and Japan: the main different approaches. In: Proceedings of the Plastics and Paper in Contact with Foodstuffs Conference (Munich, Germany, 2–5 December). Smithers Pira, Leatherhead, pp. 1–48.

Rulibikiye, A., 2015. Updates on food packaging regulations in Canada. In: Proceedings of the Global Food Contact Conference (Rome, Italy, 19–21 May). Smithers Pira, Leatherhead, pp. 1–40.

Sansawat, S., Terry, J., 2011. Overview of the standards for food safety management systems and food packaging design and manufacture. SGS S.A. Available from: <www.sgs.com> (accessed 16.03.2015).

Schäffer, A., 2010. EU legislation. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 1–25.

Schäffer, A., 2011. Overview and update on EU legislation for plastic food contact materials—regulation (EU) no. 10/2011 PIM. In: Proceedings of the 10th Biennial International Symposium on Worldwide Regulation of Food Packaging (Baltimore, MD, 7–8 June). The Society of the Plastics Industry Inc., Washington, DC, pp. 1–33.

Scherzinger, M., 2013. The implementation of GMP for SMEs. In: Proceedings of the Plastics and Paper in Contact with Foodstuffs Conference (London, UK, 9–12 December). Smithers Pira, Leatherhead, pp. 1–20.

Schupp, B., 2012. FCM, 2013 and beyond. In: Proceedings of the Plastics and Paper in Contact with Foodstuffs Conference (Vienna, Austria, 11–14 December). Smithers Pira, Leatherhead, pp. 1–29.

Sefton, M.A., Simpson, R.F., 2005. Compounds causing cork taint and the factors affecting their transfer from natural cork closures to wine—a review. Aust. J. Grape Wine Res. 11, 226–240.

Semail, R., 2014. Declarations of compliance. In: Proceedings of the International Conference Food Contact Compliance (Baveno, Italy, 24–25 September). Istituto Italiano Imballaggio, Milan, pp. 1–34.

Sendón García, R., Sanches Silva, A., Cooper, I., Franz, R., Paseiro Losada, P., 2006. Revision of analytical strategies to evaluate different migrants from food packaging materials. Trends Food Sci. Technol. 17, 354–366.

Sheehan, T., Baumert, J., Taylor, S., 2012. Allergen validation: analytical methods and scientific support for a visually clean standard. Available from: <www.foodsafetymagazine.com/magazine-archive1/december-2011january-2012/allergen-validation-analytical-methods-and-scientific-support-for-a-visually-clean-standard/> (accessed 27.03.2015).

Six, T., Feigenbaum, A., 2003. Mechanism of migration from agglomerated cork stoppers. Part 2: Safety assessment criteria of agglomerated cork stoppers for champagne wine cork producers, for users and for control laboratories. Food. Addit. Contam. 20 (10), 960–971.

SPI, 2015. Guideline for Risk Communication for the Global Food Contact Supply Chain. Version 1.0, February. The Plastics Industry Trade Association—Food, Drug, Cosmetic Packaging Materials Committee, Washington, DC, pp. 47. Available from: <www.plasticsindustry.org/IndustryGroups/content.cfm?ItemNumber=13673&navItemNumber=1098> (accessed 04.06.2015).

Stadler, R.H., Mottier, P., Guy, P., Gremaud, E., Varga, N., Lalljie, S., et al., 2004. Semicarbazide is a minor thermal decomposition product of azodicarbonamide used in the gaskets of certain food jars. Analyst 129, 276–281.

Stanley, G., 2015. Regulation of chemical migration from packaging into food—Food Standards Australia and New Zealand. In: Proceedings of the 12th Biennial International Symposium on Worldwide Regulation of Food Packaging (Baltimore, MD, 16–18 June). The Society of the Plastics Industry Inc., Washington, DC, pp. 1–27.

Steele, R.J., 2010. Australia and New Zealand. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 369–378.

Steinka, I., 2015. Chemical and microbiological aspects of the interaction between food and food packages. In: Barone, C., Bolzoni, L., Caruso, G., Montanari, A., Parisi, S., Steinka, I. (Eds.), Food Packaging Hygiene Springer International Publishing AG, Switzerland, pp. 79–104. http://dx.doi.org/10.1007/978-3-319-14827-4.

Suominen, I., Suihko, M.-L., Salkinoja-Salonen, M., 1997. Microscopic study of migration of microbes in food-packaging paper and board. J. Indust. Microbiol. Biotechnol. 19, 104–113.

Swiss DFI, 2014. Ordonnance SR 817.023.21 du DFI (Le Département Fédéral de l'Intérieur) sur les objets et matériaux du 23 novembre 2005 (Etat le 1er avril 2013). Federal Department of Home Affairs, Bern, Available from: <https://www.admin.ch/opc/fr/classified-compilation/20050179/index.html> (accessed 10 May 2015).

Teixeira, M.I.V., San Romão, M.V., Bronze, M.R., Vilas Boas, L., 2006. 2,4,6-Trichloroanisole: a consumer panel evaluation. Ciência Técnica Vitivinícola 21 (2), 53–65.

Tice, P., 1996. Packaging materials as a source of taints. In: Saxby, M.J. (Ed.), Food Taints and Off-Flavours, second ed. Springer Science and Business Media, Dordrecht, pp. 226–263.

Topping, J., Haines, J., 2008. Validation of enzyme linked immunoabsorbant assays (ELISAs) for the determination of latex allergens in food contact materials and associated foods. Food Safety Agency—UK Project A03056 Final Report Draft 3. Available from: <www.foodbase.org.uk/results.php?f_report_id=21> (accessed 04.02.2015).

Topping, J., Gibbons, M., Haines, J., Knellar, S., Angus, F., Patel, P., 2004. Assessment and Quantification of Latex Protein (LP) Transfer from LP Containing Contact Materials into Food and Drink Products. Food Standard Agency—UK Project Code: A03043. Leatherhead Food International Ltd., Leatherhead, Surrey, Available from: <www.foodbase.org.uk/results.php?f_report_id=11> (accessed 04.02.2015).

Topping, J.R., Haines, J., Kneller, S., Patel, P., 2006. A preliminary investigation into the possible transfer of latex allergens from latex protein containing materials in contact with food. J. Sci. Food Agric. 86, 1826–1832.

Torri, L., Piergiovanni, L., Caldiroli, E., 2008. Odour investigation of granular polyolefins for flexible food packaging using a sensory panel and an electronic nose. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 25 (4), 490–502.

UNL, 2005a. Physical Hazards. University of Nebraska-Lincoln—Institute of Agriculture and Natural Resources, USA, Available from: <www.foodsafety.unl.edu/haccp/start/physical.html> (accessed 16.04.2015).

UNL, 2005b. HACCP Prerequisites Programs. University of Nebraska-Lincoln—Institute of Agriculture and Natural Resources, USA, Available from: <www.foodsafety.unl.edu/haccp/prerequisites/preprograms.html> (accessed 25.04.2015).

US FDA, 2007. Grade "A" Pasteurized Milk Ordinance (PMO) (2007 Revision)—Appendix J—Standards: fabrication of single-service containers and closures for milk and milk products. Washington, DC. Available from: <www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm064394.htm> (page updated August 14, 2013) (accessed 09.01.2015).

US FDA, 2015. Compliance Policy Guidance CPG Sec. 555.425 Foods, adulteration involving hard or sharp foreign objects. Available from: <www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm> (accessed 23.04.2015).

Veraart, R., 2010. Compliance testing, declaration of compliance and supporting documentation in the EU. In: Rijk, R., Veraart, R. (Eds.), Global Legislation for Food Packaging Materials Wiley-VCH, Weinheim, pp. 197–221.

Welle, F., 2011. Twenty years of PET bottle to bottle recycling—an overview. Resour. Conserv. Recycl. 55, 865–875.

Wilm, K.H., 2012. Foreign object detection: integration in food production. Food Safety Mag. Available from: <www.foodsafetymagazine.com/magazine-archive1/octobernovember-2012/testing-foreign-object-detection-integration-in-food-production/> (accessed 16.04.2015).

Xu, Y., Noonan, G.O., Begley, T.H., 2013. Migration of perfluoroalkyl acids from food packaging to food simulants. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 30 (5), 899–908.

Zhang, H., 2015. Progress on food contact material regulations in China. In: Proceedings of the Global Food Contact Conference (Rome, Italy, 19–21 May). Smithers Pira, Leatherhead, pp. 1–31.

Zhang, K., Wong, J.W., Begley, T.H., Hayward, D.G., Limm, W., 2012. Determination of siloxanes in silicone products and potential migration to milk, formula and liquid simulants. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 29 (8), 1311–1321.

Zhu, L., 2013. Progress on food packaging material regulation in China. In: Proceedings of the Global Food Contact Conference (Barcelona, Spain, 14–16 May). Smithers Pira, Leatherhead, pp. 1–30.

Zülch, A., Piringer, O., 2010. Measurement and modeling of migration from paper and board into foodstuffs and dry food simulants. Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess. 27 (9), 1306–1324.