CHAPTER III

PACKAGING REGULATIONS

INDIA

Rule 49 of the Prevention of Food Adulteration Rules, 1955 lays down the food packaging requirements.

The requirements are as follows:

1. Every utensil or container used for manufacturing, preparing or containing any food or ingredient of food intended for sale shall be kept at all times in good order and repair and in clean and sanitary condition. No such utensil or container shall be used for any other purpose.

2. No person shall use for manufacturing, preparing or storing any food or ingredient of food intended for sale any utensil or container which is imperfectly enameled or imperfectly tinned or which is made of such materials or is in such a state as to be likely to injure such food or render it noxious.

3. Every utensil or container containing any food or ingredient of food intended for sale shall at all times be either provided with a tight fitting cover or kept closed or covered by a properly fitting lid or by a closed fitting cover or gauze, net or other material of a texture sufficiently fine to protect the food completely from dust, dirt and flies and other insects.

4. No utensil or container used for the manufacture or preparation of or containing any food or ingredient of food intended for sale shall be kept in any place in which such utensil or container is likely by reason of impure air or dust or any offensive, noxious or deleterious gas or substance or any

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noxious or injurious emanations, exhalation, or effluvium, to be contaminated and thereby render the food noxious².

5. A utensil or container made of the following materials or metals, when used in the preparation, packaging and storing of food shall be deemed to render it unfit for human consumption

   a. Containers, which are rusty.

   b. Enamel containers, which have become chipped and rusty.

   c. Copper or brass containers which are not properly tinned³.

   d. Containers made of aluminium not conforming in chemical composition to BIS: 20 specification for Cast Aluminum and Aluminium Alloy for utensils or BIS: 21 specification for wrought Aluminium and Aluminium Alloy for utensils; and

   e. made of plastic materials not conforming to the following Indian Standards Specification, used as appliances or receptacles for packing or storing whether partly or wholly, food articles, namely:-

   i. IS :10146 (Specification for Polyethylene in contact with foodstuffs);

   ii. IS :10142 (Specification for styrene Polymers in contact with foodstuffs);

   IS: 10151 (Specification for Polyvinyl Chloride (PVC), in contact with foodstuffs);

   iii. IS: 10910 (Specification for Polypropylene in contact with foodstuffs).

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2 Ibid.
3 Ibid.
4 Id. at 132
iv. IS: 11434 (Specifications for ionomer resins in contact with foodstuffs).

v. IS: 11704-[Specification for Ethylene Acrylic Acid (EAA) copolymer].

vi. IS: 12254 -[Specification for Poly alkylene terephthalates (PET)].

vii. IS: 12247-[Specification for Nylon 6 Polymer]);

viii. IS 13601-Ethylene Vinyl Acetate (EVA)

ix. IS 13576- Ethylene Metha Acrylic Acid (EMM)\textsuperscript{5}

f. Tin and plastic containers once used shall not be reused for packaging of oils and fats. (Provided that utensil or containers made of copper though not properly tinned may be used for the preparation of sugar confectionery or essential oils and mere use of such utensils or containers shall not be deemed to render sugar confectionery or essential oils unfit for human consumption)\textsuperscript{6}

6. Rule 50 of the PFA Rules, 1955 further requires that Tin Plate used for the manufacture of tin containers for packaging edible oils and Fats shall conform to the standards of prime grade quality contained in B.I.S. Standards No. 1993 or 13955 or 9025 or 13954 as amended from time to time or in respect of Tin containers for packaging edible oils and fats shall conform to IS No. 10325 or 10339 as amended from time to time\textsuperscript{7}.

But all the above provisions have failed to curb litigation as the important task of interpretation has to be done by the judiciary due to vague regulations regarding packaging.

\textsuperscript{5} Ibid.
\textsuperscript{6} Ibid.
\textsuperscript{1} Id. at 136.
EUROPEAN UNION

European Regulation

On 13 November 2004 the new Framework Regulation on materials and articles intended for food contact was published in the Official Journal.

The **Framework Regulation (EC) 1935/2004** states that food contact materials shall be safe. They shall not transfer their components into the food in quantities that could endanger human health, change the composition of the food in an unacceptable way or deteriorate the taste and odor of foodstuffs.

The Regulation also includes the following provisions:

1. If an article is intended for food contact it shall be labelled for food contact or bear the symbol with a glass and fork. In cases where the intention for food contact is obvious by the nature of the article e.g. knife, fork, wine glass, this labelling is not obligatory.

2. Labelling, advertising and presentation of food contact materials shall not mislead the consumer.

**Special requirements for Active and Intelligent materials and articles**

Active food contact materials and articles are designed to deliberately incorporate ‘active’ components intended to be released into the food or to absorb substances from the food. They should be distinguished from materials and articles which are traditionally used to release their natural ingredients into specific types of food during the process of their manufacture, such as wooden barrels. Active food contact materials and articles may change the composition or the organoleptic properties of the food only if the changes comply with the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC (4) on food additives. In particular, substances such as food additives deliberately incorporated into certain active food contact materials and articles for release into packaged foods or the environment surrounding such foods, should be authorised.

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under the relevant Community provisions applicable to food and also be subject to
other rules which will be established in a specific measure.

Active and intelligent food contact materials and articles should not change the
composition or the organoleptic properties of food or give information about the
condition of the food that could mislead consumers. For example, active food
contact materials and articles should not release or absorb substances such as
aldehydes or amines in order to mask an incipient spoilage of the food. Such
changes which could manipulate signs of spoilage could mislead the consumer
and they should therefore not be allowed. Similarly, active food contact materials
and articles which produce colour changes to the food that give the wrong
information concerning the condition of the food could mislead the consumer and
therefore should not be allowed either\(^9\).

'Intelligent food contact materials and articles means materials and articles which
monitor the condition of packaged food or the environment surrounding the
food'\(^10\).

The specific Directive dealing with food contact plastics is Commission Directive
2002/72/EC, this repealed and at the same time re-enacted Commission Directive
permitted monomers and approved additives, and overall and specific migration
limits. In addition, Directive 82/711/EEC, as amended, and 85/572/EEC set out the
78/142/EEC, as amended by Directives 80/766/EEC and 81/432/EEC, deals
specifically with food contact materials and articles containing vinyl chloride
monomer.


\(^10\) Ibid.
Scope of the plastics legislation

Directive 2002/72/EC states that the plastics legislation applies to materials and articles made exclusively of plastic which, in their finished state, are intended for use in contact with food. It also applies to materials and articles made of bonded layers of plastic. If a non-plastic layer is incorporated the material or article is not covered by the Directive. This excludes, for example, plastic coatings on paper or metal cans, but these must meet the general requirements of the European Regulation, (EC) number 1935/2004\textsuperscript{11}.

General requirements for plastic food contact materials and articles

Directive 2002/72/EC sets a limit on the maximum quantity of constituents allowed to transfer (or migrate) out of plastic materials and articles into food. This 'overall migration limit' is 10 milligrams per square decimeter of plastic surface area, in general, or 60 milligrams per kilogram of food for containers, or similar receptacles, with a capacity of from 0.5 to 10 litres, or which have a contact area that cannot be determined, and for sealing devices such as caps, gaskets and stoppers\textsuperscript{12}.

Permitted monomers and starting substances

The first step in establishing a suitable status in the EU for a food package composed entirely of plastic is to ensure that each monomer used in the production of the package is listed in the Monomers Directive. As mentioned above, the Monomers Directive’s positive list of monomers is considered to be exhaustive; thus, this part of the legislation is considered to be ‘fully harmonized’ in the EU. Unlisted monomers simply are not permitted for use in the production of food contact articles made entirely of plastic\textsuperscript{13}.

\textsuperscript{11} Food Standards Agency,“Legislation controlling materials and articles intended to be brought into contact with food”, 10, July (2006).

\textsuperscript{12} Article 2, Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

Directive 2002/72/EC establishes a ‘positive list of approved monomers and starting substances. Food contact plastics can only be manufactured using those monomers and other starting substances on the list and in compliance with any restrictions placed on their use. These restrictions are expressed in one of the following forms:

1) Specific migration limit (SML);

2) Specific migration limit as a total moiety of substance(s) indicated (SML(T));

3) Limit on the residual quantity left in the finished material or article (QM);

4) Limit on the residual quantity left in the finished material or article expressed as a total moiety of substance(s) indicated (QM(T));

5) Limit on the residual quantity left in the finished material or article expressed as milligrams per 6 decimeters squared of the surface in contact with the food (QMA);

6) Limit on the residual quantity left in the finished material or article expressed as milligrams of the total of the moiety of substances indicated per 6 decimetre squared of the surface of the material or article in contact with the foodstuff (QMA(T))14.

However, at present, the list does not include monomers and starting substances used only in the manufacture of surface coatings obtained from resinous or polymerized products such as vanishes, lacquers paints etc., epoxy resins, adhesives and adhesion promoters and printing inks. As a result, these substances can only be used if they comply with the general requirements of the European Regulation15.

14 Supra note 11.
15 Ibid.
Vinyl chloride monomer


Specific Measures – Ceramics

Council Directive 84/500/EEC deals with the migration into food of lead and cadmium from ceramic and articles intended to brought into contact with the food. It defines ceramic articles as those manufactured from a mixture of inorganic materials with a very fine grained material, such as clay or a silicate to which inorganic materials may have been added, which are shaped and fired. They may be glazed, enamelled and/or decorated.

Specific Measures - Regenerated Cellulose Film

Commission Directive 93/10/EEC, amended by Directive 93/111/EEC, established a ‘positive list of substances that can be used in the manufacture of coated and uncoated regenerated Cellulose film. Some of the substances have conditions or restrictions. In particular, uncoated film must not transfer adhesives or colorants at detectable quantities, and coated film must not transfer ethylene glycol or di(ethylene) glycol, by themselves or together, in quantities exceeding 30 milligrams per kilogram of food. Synthetic casings made of regenerated cellulose and cellulose films that have coatings on the food contact side of greater than 50 milligrams per square decimeter of film are, at present, excluded from the scope of

16 Supra note 13 at 115.
17 Supra note 11.
the legislation. These Directives were implemented by The Materials and Articles in Contact with Food Regulations 1987, and the 1994 amending Regulations18.

Commission Directive 2004/14/EC further amends Directive 93/10/EEC. It was adopted in December 2003 and published in January 2004 (OJ L 27/48-51 of 30.1.2004). This amendment provides that the uncoated, cellulose coated and plastics coated regenerated cellulose films are subject to the conditions laid down and to manufacture from only the substances in the positive list. It also applies the conditions laid down in Directive 2002/72/EC (the plastics Directive) to those regenerated cellulose films coated with plastics19.

Specific Measures - Nitrosamines in Babies' Dummies

While specific Directives are still to be drafted for elastomers and rubbers, Directive 93/11/EEC. exists to restrict the amount of release of N-nitrosamines and N-nitrosatable substances in the rubber of babies teats and dummies. This Directive has been implemented by the N-Nitrosamines and N-Nitrosatable Substances in Elastomer or Rubber Teats and Dummies (Safety) Regulations 199520.

Specific Measures - Lead From Metal Coatings

While the EC has yet to introduce specific legislation for food contact metals, the Cooking Utensils (Safety) Regulations 1972, made under powers of the Consumer Protection Act 1961, restrict the lead content of tin or other metallic coatings for kitchen utensils21.

Specific measures - epoxy derivatives in all plastics, adhesives and Surface coatings

Regulation (EC) Number 1895/2005 now permits the use of BADGE in all food contact plastics, as well as in adhesives and surface coatings. This is providing that any migration is within a Specific Migration Limit (SML) of 9 milligrams per kilogram of food or food simulant, including the hydrolysed derivatives of

18 Ibid.
19 Ibid.
20 Ibid.
21 Ibid.
BADGE. This limit can be taken as 9 milligrams per six decimetres squared in certain cases where articles are containers, or are comparable to containers, which can be filled with a capacity of less than 500 millilitres or more than 10 litres. It also applies to sheet film or other material, which cannot be filled, or for which it is impracticable to estimate the relationship between the surface area and the quantity of food with which the material is in contact. Where BADGE migration occurs with particular chlorohydrins the sum of the BADGE and chlorohydrin derivative migration may not exceed 1 milligram per kilogram of food or food simulant or 1 milligram per six decimetres squared in the specific cases above. The EC Regulation permits trade in the use of materials and articles containing BADGE throughout the EU from 1 January 2006 and re-affirms the ban on the use of BFDGE and NOGE.

EC Directives

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22 Ibid.
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**FOOD CONTACT PLASTICS – TESTING FOR MIGRATION**

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**OTHER SPECIFIC FOOD CONTACT MATERIALS AND ARTICLES**

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**Labelling and Traceability Requirements**

The labelling provisions of the European Regulation require that food contact materials and articles not already in contact with food when they are sold, should be accompanied by either the words 'for food contact, or a specific indication as to their use. This indication can take the form of an easily recognizable symbol such as a coffee machine, wine bottle, soup spoon etc. that is appropriate to the material or article. Alternatively the symbol may be the wineglass and fork symbol long permitted by previous Directives. However, this wording or symbol isn't necessary for articles whose characteristics make them clearly intended for use in contact with food. If necessary, special instructions for the safe and appropriate use of the material or article must also be given and the name or trade name and the address of the manufacturer, processor or seller who places the goods on the market must be included. The information provided must be in a language easily understood by purchasers, conspicuous, clearly legible and indelible. There are rules about the siting of this information at the marketing and retail stages.

All materials and articles shall be traceable at all stages of manufacture, processing and distribution to enable them to be controlled, if necessary.
recalled if they are defective and to facilitate the provision of consumer information and the attribution of responsibility for any problems that arise. Business operators are required to have systems and procedures in place to allow the identification of the business from which and to whom materials and articles, substances or products used in their manufacture have been supplied. The measure also requires that the information is made available to competent authorities on demand.  

**Substance authorization**

In time, all substances used for the manufacture of food contact materials and articles, as well as some specific types of articles such as functional barriers, and some processes, like those that mechanically recycle food contact plastics, will have to be assessed for risk and authorized. The assessment will be carried out by the European Food Safety Authority (EFSA) who will then publish their opinion. The process for that risk assessment is outlined in the provisions of the European Regulation, as are time limits for the process and the duty of notification of the parties involved. That opinion will be taken into account by the European Commission who will then make a proposal to authorize, or not, the substance in question. Proposals for authorization will be adopted by a specific measure that will have to be agreed by the Standing Committee on the Food and Animal Health. Once authorized, the substance will be included in a positive list of substances and in a register of substances maintained by the Commission. Authorizations may be modified, suspended or revoked by means of an application that will again be assessed for risk by EFSA.

The European Regulation requires that specific measures provided for the materials and articles that they deal with to be accompanied by written declaration of compliance with the rules that apply to them. This compliance

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23 *Supra* note 11 at 7.
will be demonstrable through appropriate documentation that shall be made available to the authorities on demand\textsuperscript{24}.

UNITED KINGDOM

United Kingdom is being a member state of the European Union, the European regulation is directly applicable and therefore does not need to be implemented in the United Kingdom.

Given this fact and that the Regulation revoked the Directive that had been in force since 1989, the U.K. legislation, namely The \textit{Materials and Articles in Contact with Food Regulations 1987} (SI No. 1987/1523), that had implemented that Directive has been repealed. However, some parts of those 1987 regulations implemented other Directives on the use of vinyl chloride monomer and regenerated cellulose film in materials and articles in contact with food.

The Directive on vinyl chloride monomer (78/142/EEC as amended) remains in force and the one on regenerated cellulose film (93/10/EEC) has been amended (by Directive 2004/14/EC), thus their implementing provisions from the 1987 regulations have been re-enacted in each part of the United Kingdom, with modification in the case of regenerated cellulose film\textsuperscript{25}.

It is an offence to sell, use in the course of business import materials or articles intended for contact with food, which do not comply with the food contact material and articles legislation. There is no system of Government or other official approval for food contact material and articles. Instead, the responsibility for ensuring compliance with the legislation lies with the manufacture, retailer and importer. They have to take all reasonable precautions, and exercise all due diligence, to avoid committing an offence. The court decides what is reasonable, but for those who produce or use food contact materials and articles in the course

\textsuperscript{24} \textit{Ibid.}
\textsuperscript{25} \textit{Supra} ncte 23.
of their business, this may involve materials tests to ensure compliance with the law and maintain documentary evidence. The legislation is enforced by Trading Standards Officers and Environmental Health Officers as applicable locally.

AUSTRALIA

Definition

Articles and materials means any materials in contact with food, including Packaging material, which may enclose materials such as moisture absorbers, mould inhibitors, oxygen absorbers, promotional materials, Writing or other graphics.

The Food Standards Code does not specify details of materials to be added to or used to produce food packaging materials or articles in contact with food. It is the responsibility of food manufacturers and retailers to ensure that their products are safe and that they comply with all relevant legislations.

Articles and materials may be placed in contact with food, provided such articles or materials, if taken into the mouth, are not:-

1. Capable of being swallowed or of obstructing any alimentary or respiratory passage; and
2. Otherwise likely to cause bodily harm, distress or discomfort26.

A food business must, when packaging food:

a) only use packaging material that is fit for its intended use;

A food business should not place packaging materials in contact with food until it has established that the material is appropriate to be used for this purpose. The food business should establish the following27 :-

26 Standard 1.4.3, “Articles and Materials in contact with food”, Food Standards Code Australia New Zealand.
- That the packaging material is appropriate for food contact use;
- The types of foods that can safely come into contact with the packaging material, for example a packaging material may not be appropriate for acidic foods;
- What the packaging material is suitable to be used for, for example dry storage, refrigeration, freezing and microwaving; and
- Whether the packaging material is reusable.

b) only use material that is not likely to cause food contamination; and

‘Contaminant’ means any biological or chemical agent, foreign matter, or other substance that may compromise food safety or suitability. Hence, a packaging material must not compromise the safety and suitability of food that comes into contact with it. A packaging material may contaminate food in three ways:

- By leaching chemical substances into the food
- By transferring micro-organisms, dirt or other foreign material that may be
- Contaminating the packaging material itself
- If parts of the packaging itself break off into the food, for example glass.

There are some legal limits specified in the Food Standards Code for chemical contaminants in food. These must not be exceeded.

Standard 1.4.1 Contaminants and Natural Toxicants specifies maximum permitted concentrations for metals as well as vinyl chloride and acrylonitrile. Packaging materials must not leach into the food more than the specified limit for the contaminant in the standard.

Packaging materials contain many other chemicals that may contaminate food. These chemicals have no legal limit. Where no limit is specified, the manufacturer...
of the packaging material must ensure packaging material will not endanger the safety and suitability of the food in contact with it. Specifically, it is essential to minimize any migration of substances into the food from the packaging material. If migration occurs, there should be no known toxic hazards to the consumer of the food. The manufacturer of the packaging material must consider the likelihood of substance migration for both the type of food that will come into contact with the packaging material and the conditions to which the food and packaging material may be subjected.

Australian Standard 2070-1999 Plastic materials for food contact use, produced by Standards Australia is not mandatory but does provide-useful guidance. It refers to relevant international standards from Europe and the United States on manufacturing plastic materials for food contact use. \(^{32}\)

The clause does not specifically prohibit the use of packaging materials manufactured from recycled materials. Packaging materials manufactured from recycled materials may be used provided they are suitable for food contact use and will not contaminate food that comes into contact with the material. \(^{33}\)

A packaging material may contaminate food if it is not clean and free from foreign matter. Therefore packaging materials must be protected from contamination before they are used. Contamination may occur from dust, dirt and pests. A packaging material that may be contaminated must not be in contact with food. \(^{34}\)

This clause does not prevent the use of glass or other packaging materials prone to breakage. However, if these materials are used they should be able to withstand reasonable handling, to avoid breakages.

Packaging materials that have been used to store non-food items such as cleaning or agricultural chemicals must never be used in contact with food. Even if the packaging material were to be thoroughly cleaned, harmful chemical residues could remain and contaminate the food.

\(^{32}\) Ibid.  
\(^{33}\) Ibid.  
\(^{34}\) Id. at 71.
While not an offence under this standard, food packaging materials should never be used to store cleaning or other chemicals, to avoid someone mistakenly thinking the packaging material contains food. The chemical could then be used in food or accidentally served to customers. The storage of poisons in food containers may also breach State and Territory poisons legislation\textsuperscript{35}.

c) ensure that there is no likelihood that the food may become contaminated during the packaging process.

During packaging the food may be exposed to contamination from:

- the packaging equipment itself, for example the equipment may be dirty or a part of the equipment such as machinery oil or grease may contaminate the food;

- foreign matter such as dirt, dust, insects, glass, metal and plastic; and

- food handlers contacting the food directly or indirectly, for example, if items such as jewellery worn by the food handler fall into the food\textsuperscript{36}.

USA

Definitions

FDA’s authority over food derives from the Federal Food, Drug, and Cosmetic Act (FD \& C Act). Thus the definition of “food” in the act has importance in determining the reach and limits of FDA’s jurisdiction and authority.

The statutory definition of “food” in FD \& C Act section 321(f) is a term of art that is clearly intended to be broader than the commonsense definition of food. This creates numerous pitfalls for the unwary. For instance, the definition of “food” includes chewing gum and food additives. “Food additives” can be any

\textsuperscript{35} Ibid.

\textsuperscript{36} Ibid.
substance, the intended use of which results, or may reasonably result, in its becoming a component or otherwise affecting the characteristics of any food.  

Food additives includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food.

Thus, once more, under the Act, the term "food additive" includes not only substances directly added to food, but also substances, such as some packaging materials, that contact and are reasonably expected to migrate into food, unless those substances are GRAS or prior-sanctioned.

"GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

- Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.

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- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

A material used in the production of containers and packages is subject to the above definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. “Affecting the characteristics of food” does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive.

The quantity of any food additive substance that may be added to food as a result of use in articles that contact food shall not exceed, where no limits are specified, that which results from use of the substance in an amount not more than reasonably required to accomplish the intended physical or technical effect in the food-contact article; shall not exceed any prescribed limitations; and shall not be intended to accomplish any physical or technical effect in the food itself, except as such may be permitted by regulations in parts.

Any substance used as a component of articles that contact food shall be of purity suitable for its intended use.

Following is the list of Indirect Additives used in Food contact substances. :-

- General Indirect Food Additives (21 CFR 174)
- Adhesives and Components of Coatings (21 CFR 175)
- Paper and Paperboard Components (21 CFR 176)
- Polymers (21 CFR 177)
- Adjuvants, Production Aids, and Sanitizers (21 CFR 178)

40 Section 74.5, Part 174, Indirect Food Additives, Food and Drug Administration, HHS.
• Irradiation in the Production, Processing and Handling of Food (21 CFR 179)

The complete list on over 3000 substances has been mentioned in Title 21 of the U.S. Code of Federal Regulations (21 CFR) Parts 175, 176, 177, and 178

MALAYSIA

Food Regulations 1985 - Part VI Packages For Food

Use of Harmful Packages Prohibited

Except as otherwise provided in these Regulations, no person shall import, manufacture, advertise for sale or sell, or use or cause or permit to be used in the preparation, packaging, storage, delivery or exposure of food for sale, any package, appliance, container or vessel which yields or could yield, its contents, any toxic, injurious or tainting substance, or which contributes to the deterioration of the food.

Safety of Packages for Food

No person shall import, manufacture, advertise for sale or sell any package, appliance, container or vessel made of enamel or glazed earthenware that is intended for use in the preparation, packaging, storage, delivery or exposure of food for sale and is either capable of imparting lead, antimony, arsenic, cadmium or any other toxic substance to any food prepared, packed, stored, exposed in it, or is not resistant to acid unless the package, appliance, container or vessel satisfies the test described in the Thirteenth Schedule.

Presumption as To the Use of Any Packages

For the purposes of regulations 32 and 33, where a package, appliance, container or vessel containing food bears any mark or label belonging to another food it

41 Food Regulations 1985 (Malaysia) – Part VI.
42 Ibid.
shall be presumed that such package, appliance, container or vessel has been used for that particular food as shown by such mark or label\textsuperscript{13}.

**Use of Polyvinyl Chloride Package Containing Excess Vinyl Chloride Monomer Prohibited**

No person shall import, manufacture or advertise for sale or sell or use in the preparation, storage, delivery or exposure of food for sale, any rigid or semi-rigid package, container or vessel, made of polyvinyl chloride which contains more than 1 mg/kg of vinyl chloride monomer.

Food Packaged in Polyvinyl Chloride Container Shall Not Contain Excess Vinyl Chloride Monomer

No person shall import, prepare or advertise for sale or sell any food in any rigid or semi-rigid appliance, container or vessel made of polyvinyl chloride if the food contains more than 0.05 mg/kg of vinyl chloride monomer\textsuperscript{44}.

**Use of Package for Non-Food Product Prohibited**

No person shall use, or cause or permit to be used, in the preparation, packaging, storage, delivery or exposure for sale of any food, any package, appliance, container or vessel that had been used or intended to be used for any non-food product\textsuperscript{45}.

**Recycling of Packages Prohibited**

No person shall use, or cause or permit to be used, in the preparation, packaging, storage, delivery or exposure for sale -

1. of any sugar, flour or meat, any sack that has previously been used for any purpose;
2. of any edible fat or edible oil, any bottle or metal container, other than silos and tankers for edible fat and edible oil, that has previously been used for any purposes;

\textsuperscript{13} Ibid.
\textsuperscript{44} Ibid.
\textsuperscript{45} Ibid.
3. of any food of non-swine origin, any package, appliance; container or vessel that is intended for use or has been used for any product of swine origin (sus scrofa);

4. of any food, other than that packaged in an extra wrapper, any plastic bottle that has previously been used for any purpose;

5. of any food, other than alcoholic beverage and shandy, any bottle that has previously been used or alcoholic beverage or shandy.

Polycarbonate containers of not less than 20 litres in size that has previously been used for natural mineral water may be used for the same purpose\(^{46}\).

**Packages that may be recycled for similar products**

Except as otherwise provided in regulation 33A, no person shall use, or cause or permit to be used, in the preparation, packaging, storage, delivery or exposure for sale -

(a) of any milk, soft drink, alcoholic beverage or shandy, any glass bottle that has previously been for another food;

(b) of any vegetable, fish or fruit, any box or crate that has previously been used for another food;

(c) of any polished rice, any gunny sack that has previously been used for another food\(^ {47}\).

**Use of Damaged Package Prohibited**

1. No person shall import, prepare or advertise for sale or sell any food container in any damaged package or container.

2. For the purposes of subregulation (1), the term "damaged" includes -

\(^{46}\) *Ibid.*

\(^{47}\) *Ibid.*
i) Chipping or distortion that affect the integrity of the package or container, or the wholesomeness of the product or both; or

ii) Perforation, corrosion or leakage or a combination of these.\(^{48}\)

**Toys, Coins, etc. Not To Be Placed In Food**

1. There shall not be placed in food for sale or in packages of such food, any toy, coin or other article.

2. Nothing in subregulation (1) shall prohibit the placing in food or in packages of such food -

   a. any article for measuring the recommended quantity of food to be consumed, provided that such article is sterile;

   b. the label referred to in subregulation (6) of regulation 12; or

   c. any sachet or reduced iron powder for the purpose of absorbing oxygen.\(^{49}\)

**Reduced Iron Powder**

1. The reduced iron powder specified in paragraph (c) of subregulation (2) of regulation 36 shall be enclosed in a sachet in such a manner that the oxygen absorber will not contaminate, taint or migrate into the food.

2. Where the sachet or reduced iron powder is in direct contact with the food, the sachet itself and label shall compose of material that will not contaminate, taint or migrate into the food.

3. The sachet of reduced iron powder may contain one or more of the following:

   i. Calcium chloride;

   ii. Calcium hydroxide;

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\(^{48}\) *Ibid.*

\(^{49}\) *Ibid.*
iii. Carbon, activated;

iv. Gypsum;

v. Salt;

vi. Iron oxide;

vii. Magnesium hydroxide;

viii. Magnesium stearate;

ix. Perlite

x. Talc;

xi. Water;

xii. Zeolite.

4. The sachet of reduced iron powder shall be labeled with the words 'OXYGEN ABSORBER' or any word or words having the same or similar effect and shall be followed by the words 'DO NOT EAT CONTENTS' and 'CONTAINS IRON POWDER'.

JAPAN

Food Sanitation Law—Chapter 3

The distribution of food in the domestic market is regulated by establishing specifications and standards. There are two categories for specifications and standards. One is those that apply generally to all foods; the other is those that apply specifically to individual foods. Currently, specifications or standards are established for 30 individual food groups including nonalcoholic beverages, meat, and fish and shellfish. Individual specifications are established for heavy metals,
microbial counts, and chemicals\textsuperscript{51}.

It is required under the law that:

1. Any apparatus and container/package used in business shall be clean and sanitary\textsuperscript{52}.

2. No person shall sell, manufacture or import with intent to sell, or use in business any apparatus or container/package which contains or bears toxic or injurious substances and may injure human health or any apparatus or container/package which may injure human health by having harmful influence on foods and food additives through contact therewith.

3. The Minister of Health, Labour and Welfare, from the viewpoint of public health, may establish specifications for apparatus, containers/packages, or raw materials thereof.\textsuperscript{53}

**Voluntary standards**

Aside from the general safety standard and the particular end-tests and specifications under the Food Sanitation Law noted above, a "positive list" of additives that are used to manufacture various plastic materials for food-contact applications is provided in a widely followed set of voluntary standards that were developed by the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)\textsuperscript{54}.

JHOSPA's voluntary guidelines cover 27 basic polymers used to manufacture plastic food-contact materials, organized by categories of base polymers, additives, and colorants, and described by chemical name.

Although voluntary from a strictly legal viewpoint, the standards are widely recognized and followed in Japan. Consequently, a listing by JHOSPA may be a


\textsuperscript{52} Article 8, Chapter 3, Food Sanitation Law in Japan.

\textsuperscript{53} Article 9, Chapter 3, Food Sanitation Law in Japan.

\textsuperscript{54} \url{http://www.packaginglaw.com/2569.shtml}
requirement for satisfying certain customers in the Japanese market. A company that would like to include its "new substance" on the positive list must first become a regular member of the JHOSPA industry group\textsuperscript{55}.

THAILAND

The Thai FDA requires that all packaging and containers of food must comply with the Ministerial Notifications No: 92, B.E.2528 and No: 111, B.E. 2531. The guidelines on packaging and containers are as follows\textsuperscript{56}.

i. A container must:

1. Be clean
2. Not emit other substances to contaminate in volume likely to be harmful to health.
3. Free of germ contamination.
4. Emit not color to contaminate food.

ii. Containers, which are ceramic vessel or enameled metal vessels, must have to conform to not only the quality and standards as above but also the quality or standards with respect lead and cadmium leaching into the food. The official AOAC test methods are required to be followed\textsuperscript{57}.

iii. Containers which are made of plastic must conform to not only the quality but also the quality or standard in Schedule 1 to the notifications.

iv. Plastics in the form of sheets or bags which are used as food containers must not be made from used plastic and must not be added with any color, except:

a) in the case of laminate plastic, only the layer not coming into direct

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\textsuperscript{55} Ibid.

\textsuperscript{56} Section 3 of Global Agriculture Information Network Report No. TH3085, 29 July (2003).

\textsuperscript{57} Ibid.
contact with the food; and b) in the case of plastic which are used for packing shelled fruits.

v. Plastic containers of milk, milk products, and other products similar to milk products (such as soybean milk and coconut milk) must be made from Polyethylene, Polypropylene, Polystyrene, or Polycarbonate.

vi. Use of a container which has previously been used to pack or wrap a fertilizer, poisonous substance, or substance likely to be harmful to health as a food container is prohibited.

vii. Use of a container which is made for packing other thing, which are not food or which bear a design or any statement that may cause a misconception with respect to the material parts of the food contained therein as a food container is prohibited.\footnote{Ibid.}