Chapter 3

FOOD GRADE QUALITY OF PLASTICS AND REGULATIONS

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ROLE OF ADDITIVES IN PLASTICS

In addition to the basic polymers, plastics also contain additional chemical components called additives, which are added in small amounts to alter the properties of the polymers in the desired way and/or simplify their processing. Only fillers and softeners (plasticizers) are used at high concentration to increase volume and/or weight to improve softening, flexibility, elasticity, malleability and processability. Other additives are mostly low molecular weight components like stabilizers, anti-oxidants, antistatic agents, light stabilizers (UV absorbers), lubricants (slip agents), optical brighteners, etc. Polymer packaging materials may also contain small quantities of monomers, oligomers as well as polymerization catalysts and regulators, cross-linking agents, emulsifer agents, etc. These additives along with low molecular weight non-polymeric components, which occur from plastic packaging materials, possess high mobility. It is likely that some transfer of low-molecular weight non-polymeric components will occur from the plastic packaging material into the packaged content, thereby contaminating the product with the risk of toxic hazard to the consumer. However, it is to be remembered that useful properties of the plastics are not manifested without the addition of these additives. Therefore, guidelines for proper use of plastics for food packaging applications have been formulated all over the world, which are necessary to safeguard health of the consumer.

Concern over the safety-in-use of plastics as food packaging materials arises principally from the possible toxicity of other low molecular weight constituents that may be present in the package and hence, get leached into the foodstuff during storage. As stated above, such constituents arise from two sources:

Polymerisation residues including monomers, oligomers (with a molecular weight up to about 200), catalysts (mainly metallic salts and organic peroxides), solvents, emulsifiers and wetting agents, raw material impurities, plant contaminants, inhibitors, decomposition and side reaction products.

The more volatile gaseous monomers, such as ethylene, propylene and vinyl chloride, usually fall in concentration with time, but very low levels may persist in the finished product almost indefinitely. Styrene and acrylonitrile residues are more difficult to remove.

Processing aids such as antioxidants, antiblock agents, antistatic agents, heat and light stabilizers, plasticisers, lubricants and slip agents, pigments, fillers, mould release agents and fungicides are added to assist production processes or to enhance the properties and stability of the final product. They may be present in amounts varying from only a few parts per million up to several parts per cent.

Since compounds of the first group are present inadvertently, there is not much that can be done to remove them. However, the efforts made by the industry to reduce vinyl chloride monomer levels in particular, illustrates the advantages of optimum manufacturing processes on the purity of the final product. Chemicals added deliberately during formulation to alter the processing, mechanical or other properties of the polymer are likely to be present in greater amounts than polymerization residues and should be subjected to strict quality control. They are normally restricted to compounds appearing on an approved list for food contact use. A brief account of the functions of some major additives is presented below:

Antiblock Agents

These are added to roughen the surface of thin films and, hence, prevent them sticking together during machine processing. Silica is most commonly used because its poor solubility in most polymers helps to increase the surface concentration and so introduces irregularity. Similarly, slip additives such as fatty acids and amides are used to reduce mobility.

Antioxidants

These prevent degradation of the polymer by reacting with atmospheric oxygen during moulding operations at high temperatures or when used in contact with hot foods and to prevent deterioration during storage. Derivatives of phenols and organic sulphides are the most frequently used antioxidants. Some of these compounds are classified as heat stabilizers.

Antistatic Agents

Since all plastics are good electrical insulators (and are in fact used on a large scale for this purpose) they will retain electrostatic charges produced by friction from contact with processing machinery. Accumulation of static electricity can cause problems through the pick-up of dust, adhesion between layers or particles of plastics, sparking, electrical shock and possibly fire hazards. Most antistatic agents are glycol derivatives or quaternary ammonium compounds; both increase the electrical conductivity and plate-out onto the surface of plastic.

Lubricants

These are added to reduce frictional forces and are usually low to medium molecular weight hydrocarbons. They should possess good solubility with the plastic, low volatility and be relatively stable compounds.

Plasticizers

These are added to make the product more flexible and less brittle. They are usually high molecular weight esters. The plasticizer also gives the material the limp and tacky qualities found in "cling" films. About 80% of all plasticizers are used in PVC. Typically phthalic esters such as dioctyl phthalate (DOP), also known as di-2-ethylhexyladipate (DEHA) are used as plasticizers.

UV Stabilizers

These are needed to protect the product from deterioration by sunlight or even supermarket lighting. Products containing vitamin C are particularly susceptible to this form of deterioration.

Optical Property Modifiers

The optical properties of a material from a technological aspect are normally described in terms of their ability to transmit light, to exhibit colour and reflect light from the surface (i.e, gloss). The majority of food packaging films are unpigmented, but some are coloured by the addition of colorants. The principal pigments used as colourants in packaging are carbon black, white titanium dioxide, red iron oxide, yellow cadmium sulfide, molybdate orange, ultramarine blue, blue ferric ammonium ferric ammonium, ferrocyanide, chrome green, and blue and green copper phthalocyanines.

Fire Retardants

Although most packaging materials are combustible, their lack of flame resistance is disregarded in most food packaging applications. For example, thermoformed polystyrene cups and plates are combustible; the risk of fire must be balanced against the possible toxicity of flame retardant additives.

Foaming Agents

Foaming or blowing agents are used for the production of cellular products and are normally classified into physical and chemical types, according to whether the generation of gases to produce the cells takes place through a physical transition i.e. evaporation or sublimation or by a chemical process i.e. decomposition reactions which result in evolution of gases. In food packaging applications, physical blowing agents are normally used. For example, expanded and extruded polystyrene foams use a fluorocarbon or light aliphatic hydrocarbon such as pentane as the blowing agent.

Antimicrobial Agents

Antimicrobials such as algicides, bactericides and fungicides can be added to polymers to prevent the growth of microorganisms. However, their use in food packaging is rare because of the possibility of migration into the food itself.

MIGRATION OF ADDITIVES

The ingredients in the plastics packaging materials may cause toxicity as a result of their migration to the foodstuffs in which the latter are packed. Therefore, positive lists of constituents (additives) to be used in respective plastics in contact with foodstuffs, pharmaceuticals and drinking water have been specified. The manufacturer has to follow a Good Manufacturing Practice (GMP) using only those additives listed in the positive list. Prior to categorizing any plastics as toxic, evidence regarding degree of migration of their constituents has to be ascertained. In general, migration and extraction studies need to be simultaneously conducted on actual foodstuffs under conditions, which are slightly more stringent than those encountered in normal usage. It is, however, not always possible to analyse actual foodstuffs for the nature and quantity of migrants from the plastics. In order to simplify such assessment, food simulants/ extractants have to be substituted for the actual foodstuffs. Further, it is also very difficult to estimate all the migrants individually. Hence, as a good measure, the overall migration of all the migrants put together is considered for safe use, unless they are especially toxic and their limits are fixed.

Migration Model

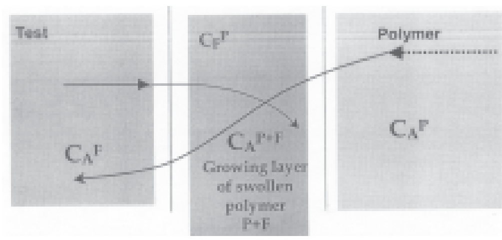
The extent of migration of a substance depends on its concentration in the material, the extent to which it is bound or mobile within the matrix of the material, the thickness of the packaging material, the nature of the food with which the material is in contact (dry, aqueous, fatty, acidic, alcoholic), the solubility of the substance in the food, the duration of contact and temperature.

In a system of polymer/food as presented in the figure below, we have the food on the left which can migrate into the polymer layers on the right side, along with an intermediate layer of swollen polymer with a profile of the migrating food component. On the other hand, we have a concentration gradient of the considered additives, where we assume that we have a certain diffusion in the undisturbed polymer layer and a much improved mobility of the additive in the swollen layer and concentration jump at the interfaces.

Rudolph particularly considered the consequence of the model. The following general formula relates the migration of an additive. In a system where a cut of the plastic P into a food F at a certain time t, is kept at constant temperature, the model predicts direct proportionality of migration of the concentration C^P_A of the considered additive in the polymer and to the square root of time (t).

$$M^F_A (T) = \alpha C^P_A \sqrt{t}$$

M^F_A (T) is concentration of migrating additive A into test food F, at a temperature T and α is is a proportionality constant.



where, C_A^F is concentration of additives in food

C_F^P is concentration of food in polymer

C_A^{P+F} is concentration of additive in polymer and food, which has penetrated into polymer.

C_A^P is concentration of additive in polymer

INDIAN STANDARDS FOR OVERALL MIGRATION (IS: 9845-1998)

CFTRI drafted IS:9845-1998 for "Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs - method of analysis (second-revision)" which is now implemented to be followed for overall migration of plastics constituents for their food grade quality in the country. This standard is the result of R & D work on the study of various factors affecting the migration of additives in food simulants, in the laboratory and is at par with other International standards like US-FDA, ECC Directives, etc. A collection of data regarding the main composition and overall extractable amount of plastic constituents can help with

Table 3.1. Classification of foods and selection of simulants

Type	Description	Examples	Simulants
I	Aqueous, non acidic foods (pH>5) without fat.	Honey, mineral water, sugar syrups, molasses, skimmed milk, rasgulla, murabba, paste etc.	'A' (Water)
II	Aqueous, acidic foods (pH<5) without fat	Fruit juices, squashes, fruit chunks or puree or paste, vinegar, jams, jellies, carbonated beverages, lemonde, processed vegetables, preparation of soups, broths, sauces, RTS beverages, etc.	'B' (3% Acetic acid)
III	Alcoholic beverages:		
	i) Alcohol concentration less than 10%.	Beer and some pharmaceutical syrups.	'C1' (10% Ethanol)
	ii) Alcohol concentration above 10%	Wine, brandy, whiskey, arrack and other alcoholic drinks.	'C2' (50% Ethanol)
IV	Oils, fats and processed dry foods with surface fat or volatile oils	Vegetable oils, ghee, vanaspati cocoa butter, lard, dry products with a surface fat such as biscuits, spice powder, snacks and savory, chocolate, caramels, malted foods egg powder, tea coffee powder, confectionery, fried and roasted nuts, etc.	'D' (n-Heptane)
V	Non-acidic foods (pH>5) or high fat and having high moisture content	Butter, bread, pastry, cakes, milk-based sweets, ice-cream, moist and fatty confectionery products.	'A and D'
VI	Acidic foods (pH<5) or high fat and having high moisture content	Pickles, ketchup, cheese, curd, fresh and processed meat and fish products, sauces having fat, frozen foods, etc.	'B and D'
VII.	Dry processed foods without fat	Cereals and pulses, dehydrated vegetable and fruits, dried yeast, corn flakes, salt, sugar, milled products, barley powder, oats, vermicelli, grain, etc.	Only 'A'

the estimation of migration. This can be a considerable asset to both the producers of such articles and for quality control laboratories. Much time and money may also be saved if studies are made on the evaluation of laminates containing layers of recycling material with unknown impurities which can migrate through the virgin plastic layer (functional barrier) in contact with food.

The choice of simulating solvents and test conditions (time-temperature) depends on the type of foods and conditions of use of food products. Food products have been now classified into seven major groups as shown in Table 3.1. This table has been prepared on the lines of accepted classification of foodstuffs for such purpose. The table also gives suitable simulants to be used for different types of foods.

Table 3.2 lists the simulants and test conditions (time-temperature) for extractability studies to be carried out depending on the type of food and conditions of use.

Selection of Samples

Minimum triplicate samples representing the lot/batch have to be selected. Samples in each replicate shall consist of a number of containers (preformed or converted products) with nearest exposed area of 1,000 cm^2. In the case of sealable films representative sample shall be of sufficient size to convert into 2 pouches of size 125 mm width and 200 mm length (inner dimension excluding seal area) and non-heat sealable films of size 50 cm × 10 cm to be exposed over both the sides with 1,000 cm^2 surface area coming in contact. In case of lids/wads, ten pieces are to be sealed to glass bottles of smallest size, in actual use to be placed inverted in position during the test period.

Preparation of Test Specimen

The containers/pouches/film/lids used shall be carefully rinsed with water (25-30°C) to remove extraneous materials prior to actual migration test.

Simulant Quantity

Equal to nominal filling capacity or at least 1 ml/cm^2 of contact area.

Procedure

Fill the container/pouch to their filled capacity or non-heat sealable film to be exposed both sides with preheated simulant at test temperature and close it. In case of pouches, exclude air as much as possible before sealing and expose the filled container/pouch to specified temperature maintained in oven/water bath/autoclave for the specified duration. Remove the container/pouch and transfer the contents immediately into a clean Pyrex beaker along with three washings of the specimen with small quantity of the fresh simulant.

Determination of Amount of Extractive

Evaporate/distill the contents in Pyrex beaker/round bottom flask to about 50-60 ml and transfer into a clean tared stainless steel dish along with 3 washings with small quantity of fresh simulant and further evaporate the concentrate in the dish to dryness in an oven at 100±5°C. Cool the dish with extractives in a desiccator for 30 minutes and weigh to nearest 0.1 mg till constant weight of residue is obtained. Calculate the extractives in mg/dm^2 and mg/kg or ml/l or ppm of the foodstuff with respect to the capacity of container/pouch to be used. Blank shall also be carried out without the sample for adjustment, if necessary.

Table 3.2. Simulating solvents for different types of foods and temperature-time conditions

Conditions of use	Type of Food	Migration Test Wiw Food simulants- Temperature, Time Conditions (°C)				
		Water (A)	3% acetic acid (B)	10% alcohol (C^1)	50% alcohol (C^2)	n-Heptane* (D)
High temperature heat sterilized (Retorting)	I, II, IV, V & VI	121°C/2h		-	-	66°C/2h
Hot filled or pasteurized above 66°C, below 100°C	I, II IV, V & VI	100°C/2h		-	-	49°C/0.5h
Hot filled or pasteurized below 66°C	I to IV	70°C/2h				38°C/0.5h
Room temperature filled and stored and also in refrigerated and frozen condition (no thermal treatment in container)	I to IV	40°C/10 dyas				38°C/0.5h

Heptane extractivity results must be divided by a factor of five in arriving at the extractivity of a food product.

Migration Limits

The material shall comply with the overall migration limit when tested by the method prescribed in IS: 9845-1998, mg/kg, Max, of foodstuff. In the case of liquid foodstuffs or of simulants, the limit shall be 60 mg/l or ppm., Max. However, the value of the overall migration limit shall be equal to 10 mg/dm^2, Max, of the surface of the material or article. In case of lids/wads the results can be expressed only as mg/kg, 60 mg/l or ppm.

$$\text{Amount of extractive (Ex)} = \frac{M}{A} \times 100 \text{ mg/dm}^2,$$

$$\frac{M}{V} \times 1000 \text{ mg/kg or mg/l and/or ppm}$$

where,

M = mass of residue in mg minus blank value

A = total surface area in cm^2 exposed in each replicate, and

V = total volume in ml of simulant used in each replicate

Indian Standards for plastics suitable for use in contact with food-stuffs, pharmaceuticals and drinking water are listed below:

IS No.	Title
10171:1999	Guide on suitability of plastics for food packaging (second-revision).
9833:1981	List of pigments and colorants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water.
9845:1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with food-stuffs — method of analysis (second-revision).
10141:1982	Positive list of constituents of polyethylene in contact with foodstuffs, pharmaceuticals and drinking water (first-revision).
10142:1999	Polystyrene (crystal and high impact) for its safe use in contact with foodstuffs, pharmaceuticals and drinking water (first-revision).
10146: 1982	Polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water.
10148:1982	Positive list of constituents of polyvinyl chloride and its copolymers for safe use in contact with foodstuffs, pharmaceuticals and drinking water.
10149:1982	Positive list of constituents of polystyrene (crystal and high impact) in contact with foodstuffs, pharmaceuticals and drinking water.

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10151:1982	Polyvinyl Chloride (PVC) and its copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
10909:1984	Positive list of constituents of polypropylene and their copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water (first-revision).
10910:1984	Polypropylene and its copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
11434:1985	Ionomer resins for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
11435:1985	Positive list of constituents of ionomer resins for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
11704:1986	Ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
11705:1986	Positive list of constituents of Ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
12229:1987	Positive list of constituents of polyalkylene terephthalates (PET & PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
12247:1998	Nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water.
12248:1998	Positive list of constituents of Nylon-6 polymer for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
12252:1987	Polyalkylene terephthalates (PET & PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
13449:1992	Positive list of constituents of ethylene vinyl acetate (EVA) for their safe use in contact with food stuffs, pharmaceuticals and drinking water.
13576:1992	Ethylene methacrylic and (EMMA) copolymer and terepolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
13557:1992	Positive list of constituents of ethylene methacrylic (EMMA) copolymer and terepolymers in contact with foodstuffs, pharmaceuticals and drinking water.

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13601:1993	Ethylene vinyl acetate (EVA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
Doc: PCD 12(1328)	Positive list of constituents of polycarbonate resins in contact with foodstuffs, pharmaceuticals and drinking water.
Doc: PCD12 (1329)	Polycarbonate resins for their safe use in contact with foodstuffs, pharmaceuticals and drinking water.
Doc: PCD 12(1331)	Positive list of constituents of Melamine-Formaldehyde resins in moulded articles in contact with food stuffs, pharmaceuticals and drinking water.
Doc: PCD 12(1332)	Melamine-Formaldehyde resins in moulded articles in contact with foodstuffs, pharmaceuticals and drinking water.
Doc: PCD 12(1375)	Positive list of constituents of Modified Poly (Phenylene Oxide) (PPO) in contact with food stuffs, pharmaceuticals and drinking water.
Doc: PCD 12(1375)	Modified Poly (Phenylene Oxide) (PPO) resins in contact with foodstuffs, pharmaceuticals and drinking water.
Doc: PCD 12(1516)	Positive list of constituents of unsaturated polyester resins in contact with foodstuffs, pharmaceuticals and drinking water.

FOOD AND DRUGS ADMINISTRATION, UNITED STATES

In the United States of America all the packaging materials are evaluated for food contact application as per the **Code of Federal Regulations 21, Parts 170 to 199, Revised as of April1, 2001 Food and Drugs. (Table 3.3 and 3.4).**

Indirect Food Additives: General

Regulations prescribe that food additive substances may be safely used under conditions of good manufacturing practice. 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 the regulations.

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

The existence of a regulation prescribing safe conditions for the use of substance as an article or component of articles that contact food shall not be construed as implying that such substance as an article or component or articles that contact food shall not be

Table 3.3. Types of raw and processed foods (US FDA)

I.	Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both.
II.	Acid (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III.	Aqueous, acid or nonacid products containing free oil or fat; may contain salt and including water-in-oil emulsions of low- or high-fat content.
IV.	Dairy Products and modifications A. Water-in-oil emulsions, high - or low - fat B. Oil-in-water emulsions, high - or low -fat.
V.	Low-moisture fats and oil.
VI.	Beverages: A. Containing up to 8% alcohol. B. Non alcoholic C. Containing more than 8% alcohol.
VII.	Bakery products other than those included under types 8^{th} or 9^{th} of this table.
	a) Moist bakery products with surface containing free fat or oil.
	b) Moist bakery products with surface containing no free fat or oil.
VIII.	Dry solids with the surface containing no free fat or oil (no end-test required).
IX.	Dry solids with the surface containing free fat or oil.

construed as implying that such substance may be safely used as a direct additive in food. Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following subjects to any prescribed limitations:

- ❖ Substances generally recognized as safe in or on food
- ❖ Substances generally recognized as safe for their intended use in food packaging
- ❖ Substances used in accordance with a prior sanction or approval

Threshold of the Regulation for Substances Used in Food-contact Articles

Substances used in food-contact articles (e.g., food-packaging or food-processing equipment) that migrate, or that may be expected to migrate, into food at negligible levels may be reviewed under the regulation. The Food and Drug Administration will exempt substances whose uses it determines meet the criteria.

Migration Limits

In the finished form in which it is to contact food, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions or its intended use as determined from Tables 3.3 and 3.4, the extractives shall not exceed 0.5 milligram per square inch of food-contact surface nor exceed 50 parts per million of the water capacity of the container in general or otherwise limits specified for specific

Table 3.4. Test procedures with time-temperature conditions for determining amount of extractives from the food contact surface or uncoated or coated paper and paper-board, using solvents simulating types of foods and beverages (USFDA)

Code	Conditions of use	Type of Food	Extractant			
			Water, time and temp.	n-Heptane, time and temp.	8% alcohol, time & temp.	50% alcohol, time & temp.
A	High temperature heat sterilized (eg., over 212°F)	I, IV B, VII B	250°F, 2h	-	-	-
		III, IV-A, VII A	-do-	150°F, 2h	-	-
B	Boiling water sterilized	I, VII B	212°F, 30 min	-	-	-
		III, VII A	-do-	120°F, 30 min	-	-
C	Hot filled or pasteurized above 150°F	II, IV B, VII B	Fill boiling Cool to 100°F	-	-	-
		III, IV A VII A	-	120°F, 15	-	-
		V, IX	-	-do-	-	-
D	Hot filled or pasteurized below 150°F	II, IV B, VI B	-	-	-	-
		VII B	150°F, 2h	-	-	-
		III, IV A, VII A	-	100°F, 30 min	-	-
		V, IX	-	-do-	150°F, 2h	-
		VI A	-	-	-	-
		VI C	-	-	-	150°F, 2h
E	Room temperature filled & stored (no thermal rated & frozen treatment in container) & also in refrige- rated & frozen condition	I, II, IV B, VI B, VII B	120°F, 24hr	-	-	-
		III, IV A, VII A	-do-	70°F, 30 min	-	-
		V, IX	-	-	120°F, 24 h	-
		VI A	-	-	-	120°F, 24hr
		VI C				

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F	Refrigerated storage (no thermal treatment in the container)	III, IV A, VII A	70°F, 48 hr	70°F, 30 min	-	-
		I, II, IV B, VII B	-do-	-	-	-
		VI A	-	-	70°F, 48 h	-
		VI C	-	-	-	70°F, 48 h
G	Frozen storage (no thermal treatment in the container)	I, II, IV B VII B	70°F, 24 hr	-	-	-
		III, VII B	-do-	70°F, 30 min	-	-

material when tested as per the prescribed method.

Further, most of the indirect food additives used as adjuvant, production aids and sanitizers for the manufacture of polymers coming in contact with food stuffs are covered under part 178 of Code of Federal Regulations 21 (Food and Drugs). Similarly, irradiation in the production, processing and handling of food and packaging materials for irradiated foods have been covered under part 179 of the US-FDA regulation.

EEC DIRECTIVES ON PLASTIC CONTAINERS FOR FOODS

At the European level, Framework Directive 89/109/ECC defines comparable general requirement for Plastic Container. In the early 1980's, corresponding separate directives in the field of plastic utensils were adopted at the European level, which also included procedures for carrying out such migration tests. European regulations have been harmonized to a large extent at least with regard to admissible monomers and starting substances (positive lists) as well as

The various specifications of US-FDA for plastic polymers coming in contact with foodstuffs are listed below (Indirect food additives):

Substances for Use Only as Components of Adhesives:	
175.105	Adhesives.
175.125	Pressure-sensitive adhesives.
	Substances for Use as Components of Coatings:
175.210	Acrylate ester copolymer coating.
175.230	Hot-melt strippable food coatings.
175.250	Paraffin (synthetic).
175.260	Partial phosphoric acid esters of polyester resins.
175.270	Poly (vinyl fluoride) resins.
175.300	Resinous and polymeric coatings.

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175.320	Resinous and polymeric coatings for polyolefin films.
175.350	Vinyl acetate/crotonic acid copolymer.
175.360	Vinylidene chloride copolymer coatings for nylon film.
175.365	Vinylidene chloride copolymer coatings for polycarbonate film.
175.380	Xylene-formaldehyde resins condensed with 4,4′-isopropylidene-diphenol - epichlorohydrin epoxy resins.
175.390	Zinc-silicon dioxide matrix coatings.
	Substances for Use Only as Components of Paper and Paperboard:
176.170	Components of paper and paperboard in contact with aqueous and fatty foods.
176.180	Components of paper and paperboard in contact with dry food.
	Polymers : Substance for use as basic components of single and repeated use food contact surfaces:
177.1010	Acrylic and modified acrylic plastics, semirigid and rigid.
177.1020	Acrylonitrile/butadiene/styrene copolymer.
177.1030	Acrylonitrile/ butadiene/styrene methyl methacrylate copolymer.
177.1040	Acrylonitrile/ styrene copolymer.
177.1050	Acrylonitrile/ styrene copolymer modified with butadiene/styrene elastomer.
177.1060	n-Alkylglutarimide/acrylic copolymer.
177.1200	Cellophane.
177.1210	Closures with sealing gaskets for food containers.
177.1211	Cross-linked polyacrylate copolymers.
177.1240	1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isopthalate copolymer.
177.1310	Ethylene-acrylic acid copolymers.
177.1312	Ethylene-carbon monoxide copolymers.
177.1315	Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers.
177.1320	Ethylene-ethyl acrylate copolymers.
177.1330	Ionomeric resins.
177.1340	Ethylene-methyl acrylate copolymers resins.
177.1345	Ethylene/1, 3-phenyle oxygenthelene isophthalate/terephthalate copolymer.

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177.1350	Ethylene-vinly acetate copolymers.
177.1360	Ethylene-vinly acetate-vinly alcohol copolymers.
177.1380	Fluorocarbon resins.
177.1390	Laminate structures for use at temperatures of 250°F and above.
177.1400	Hydroxyethyl cellulose film, water insoluble.
177.1420	Isobutylene polymers.
177.1430	Isobutylene-butene polymers.
177.1440	4, 4-isopropylidene diphenol-epichlorohydrin resins, minimum molecular weight 10,000.
177.1460	Melamine-formaldehyde resins in molded articles.
177.1480	Nitrile rubber modified acrylonitrile-methyl acrylate copolymer.
177.1500	Nylon resins.
177.1520	Olefin polymers.
177.1550	Perfluorocarbon resins.
177.1555	Polyarylate resins.
177.1556	Polyaryletherketone resins.
177.1560	Polyarylsulfone resins.
177.1570	Poly 1-butene resins and butene/ethylene copolymers.
177.1580	Polycarbonate resins.
177.1585	Polyester carbonate resins.
177.1590	Polyester elastomers.
177.1595	Polyetherimide resin.
177.1600	Polyethylene resins, carboxyl modified.
177.1610	Polyethylene, chlorinated.
177.1615	Polyethylene, fluorinated.
177.1650	Polyethylene, oxidized.
177.1630	Polyethylene phthalate polymers.
177.1632	Poly (phenylene terephthalamide) resins.
177.1635	Poly (p-methylstyrene) and rubber modified poly (p-methylstyrene).
177.1637	Poly (oxy-1, 2 ethanediyloxycarbonyl-2, 6-naphthalenediyl) resins.
177.1640	Polystyrene and rubber-modified polystyrene.

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177.1650	Polysulfide polymer-polyepoxy resins.
177.1655	Polysulfone resins.
17731670	Poly (teramethylene terphthalate).
177.1670	Polyvinly alcohol film.
177.1680	Polyurethane resins.
177.1810	Styrene block polymers.
177.1820	Styrene-maleic anhydride copolymers.
177.1830	Styrene-methyl methacrylate copolymers.
177.1850	Textryls.
177.1900	Urea formaldehyde resins in molded articles.
177.1950	Vinyl chloride-ethylene copolymers.
177.1960	Vinyl cloride-hexane-1 copolymers.
177.1970	Vinyl chloride-lauryl vinyl ether copolymers.
177.1980	Vinyl chloride-propylene copolymers.
177.1990	Vinylidene chloride-methyl acrylate copolymer.
177.2000	Vinylidene chloride/methyl acrylate/methyl methacrylate polymers.
Substance for use only as components of articles intended for repeated use:	
177.2210	Ethylene polymer, chlorosulfonated.
177.2250	Filters, microprous polymeric.
177.2260	Filters, resin-bonded.
177.2280	4, 4′ - Isopropylidenediphenol epichlorohydrin thermosetting epoxy resins.
177.2355	Mineral reinforced nylon resins.
177.2400	Perflurocarbon cured elastomers.
177.2410	Phenolic resins in molded articles.
177.2415	Poly (aryletherketone) resins.
177.2420	Polyesterylate/poly (trimethoxysilylpropy) methacrlate co-polymers.
177.2430	Polyester resins, chlorinated.
177.2440	Polyestersulfone resins.
177.2450	Polyamide-imide resins.

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177.2460	Poly (2, 6-dimethyl-1, 4-phenylene) oxide resins.
177.2466	Polyoxymethacrylate/poly (trimethoxysilylpropy) methacrlate co-polymers.
177.2470	Polyoxymethylene copolymer.
177.2480	Polyoxymethylene homopolymer.
177.2490	Polyphenylene sulfide resins.
177.2500	Polyphenylene sulfone resins.
177.2510	Polyvinylidene fluoride resins.
177.2550	Reverse osmosis membranes.
177.2600	Rubber articles intended for repeated use.
177.2710	Styrene-divinyl benzene resins, cross-linked.
177.2880	Textiles and textile fibers.
177.2910	Ultra-filtration membranes.

maximum admissible migration of ingredients of plastics utensils. This also applies to overall migration limitations, maximum admissible residual content of certain monomers and starting substances in plastic container [so-called QM(A) limits], maximum admissible migration limits of defined specific substances [so-called SML(T)]. EC Directives have laid down procedures for selecting food simulants and also requirements for testing migration based on actual conditions of use (time/temperature combinations). On the other hand, the existing European Directives mentioned above only partly cover the use of plastic additives and, at present, provide no regulations at all with regard to aids to polymerisation and colouring materials in plastics. In practice, the evaluation of plastic container (in particular packages) with regard to compliance with food regulation is a two-step procedure in most cases: at first, the ingredients of the recipe are examined so as to ensure that the materials used are admissible in principle. This examination is based on existing European Directive. If, in this first step, all components of the recipe turn out to be admissible in principle, migration tests are carried out in the next step in order to ensure that individual components of the plastic container in question (e. g., additives, colouring materials, monomers, etc) are not transmitted to the filling material (food stuff) to an inadmissibly great extent. The corresponding tests are preferably carried out directly on the respective containers or on a test specimen taken from it, with specific attention paid to the requirement that the overall migration limit and any specific migration limits be met.

Migration Limits

In any such case, for substances exempt from specific migration limits or other restrictions in the list provided in Annex II, a generic specific migration limit of 60 mg/kg or 10 mg/dm^2, according to the case, is applied. However, the sum of all specific migrations determined shall not exceed the overall migration limit, when tested as per Tables 3.5 and 3.6.

SPECIFIC MIGRATION OF TOXIC ADDITIVES

In addition to creating safety and health problems during production, many chemical additives that give plastic products desirable packaging qualities also have negative environmental and human effects. These effects include direct toxicity as in the case of lead, cadmium and mercury. Most of the colourful pots or kudams, which are locally manufactured by recycling, would have these toxic additives. Plastic containers can contaminate food because some chemicals diffuse from the packaging polymer of which they are made to the foods they contain. Migration potential exists for traces of monomers, oligomers, additives, stabilizers,

Table 3.5. Simulants according to EU Directive 97/48/EC

Simulant A:	
Distilled water	for aqueous foods having a pH of 4.5 or more
Simulant B:	
3% acetic acid (w/v)	for aqueous foods and acidic foods having a pH < 4.5
Simulant C:	
10% ethanol (v/v)	for alcoholic foods
Simulant D:	
Rectified olive oil	for edible oils and fats as well as fatty foods in which fat (is contained in a way that it) comes into direct contact with the utensil in question.

Table 3.6. Migration tests of plastic materials and articles for certain types of foods according to EU Directive 97/48/EC

Food type	Simulant
Only aqueous foods	A
Only acidic foods	B
Only alcoholic foods	C
Only fatty foods	D
All aqueous and acidic foods	B
All alcoholic and aqueous foods	C
All alcoholic and acidic foods	C and D
All fatty and aqueous foods	D and A
All fatty and acidic foods	D and B
All fatty, alcoholic and aqueous foods	D and C
All fatty, alcoholic and acidic foods	D, C and B

plasticizers and lubricants. Such substances may be toxic. A report of the Berkeley (U.S.) Plastics Task Force published in 1996 found that styrene from polystyrene, plasticizers from PVC, antioxidants from polyethylene and acetaldehyde from PET have the potential to contaminate food.

Vinyl Chloride

As per mutagenicity and metabolism of VCM, a range of toxic effects has been reported in human case studies. The principal effects observed include lesions of the bones in the terminal joints of the fingers and toes (acro-osteolysis) as well as changes in the liver and spleen. Long-term exposure gives rise to a rare form of liver cancer (angiosarcoma) and the association with exposure to VCM has been reported amongst plant operatives in several countries. In recent years, however, exposure to VCM at production and polymerization plants has been markedly reduced. It is well known that vinyl chloride causes angiosarcomas of the liver as well as tumours of the brain, lung and haemato-lymphopoietic systems in humans.

VCM limits : As per EEC directive, the level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs shall be 1 mg/kg of PVC material and 0.01 mg/kg of food.

As per Indian standard, the vinyl chloride monomer content of PVC suspension resin used for the manufacture shall not exceed 5 ppm, and in the PVC containers/film used for packaging shall not exceed 1 ppm. The

Table 3.7. European framework directives on separate materials in contact with food are as follows:

Council Directive 89/109/ECC of 21 December 1988 (OJ L 040, 11/02/1989)

Directive 2002/72/ECC	Plastic materials and articles.
Directive 90/128/ECC	Plastic monomers.
Directive 82/711/ECC	Basic rules for migration tests.
Directive 85/572/ECC	List of simulants/foodstuffs.
Directive 80/766/ECC	VC in PVC.
Directive 81/432/ECC	Method of analysis for vinyl chloride released into foodstuffs.
Directive 78/142/ECC	Limits of vinyl chloride monomer.
Directive 80/590/ECC	Determining symbols.
Directive 83/329/ECC	Regenerated cellulose film (RCF).
Directive 84/500/ECC	Ceramic articles.
Directive 86/388/ECC	1st amendment to 83/229/ECC.
Directive 92/15/ECC	Amendment to 83/229/ECC.
Directive 93/8/ECC	1st amendment to 82/711/ECC.
Directive 93/11/ECC	Nitrosamines in elastomers and rubber.
Directive 97/48/ECC	2nd amendment to 82/711/ECC.
Directive 2001/61/ECC	Epoxy derivatives.

residual migration of VCM into foodstuffs being packed shall not exceed 10 ppb. The method developed at CFTRI, Mysore, is suitable for estimation of RVCM content in PVC material and foods packed in them upto 0.01 ppm levels.

Vinylidene Chloride

Less is known of toxicology of VDC, both in animals and in humans. The LD value for rats is around 1,500 mg/kg body weight, while in mice the value is 200 mg/kg body weight. VDC affects the activity of several rat liver enzymes and decreases the store of glutathione. Some tumours have been observed after prolonged exposure but no teratogenic effects were seen in rats or rabbits. The main pathway of excretion is via the lungs, with other metabolites being discharged by the kidneys.

Acrylonitrile

AN is considerably more toxic than the chlorinated monomers and has LD value of 80-90 mg/kg body weight in rats and 27 mg/kg body weight in mice. It has also been shown to be mutagenic after metabolic activation with liver enzymes. In animals, AN is metabolized to cyanide, which is converted to thiocyanate and excreted in the urine. There is also some evidence of carcinogenicity in animals and possibly humans too.

As per US-FDA, styrene-maleic anhydride copolymers shall not contain residual styrene monomer more than 0.1 weight percent. In nitrile rubber modified acrylonitrile-methyl acrylate copolymers, the residual acrylonitrile monomer content is not more than 11 parts per million.

Styrene

The LD value of styrene for rats is 5 g/kg body weight. It is metabolized to styrene and its oxide, which is a potent mutagen in a number of test systems. Both styrene and its oxide have been prone to produce chromosomal aberrations under certain conditions. Toxic effects of styrene in humans have been reviewed by IARC. The most frequently observed changes were of neurological and psychological nature.

Limit: The total residual monomers, when present, shall not exceed 0.2 percent by mass of the polymer, as per Indian Standard. As per US-FDA styrene-maleic anhydride copolymers shall not contain residual styrene monomer more than 0.3 weight percent. Polystyrene basic polymers shall contain not more than 1 weight percent of total residual styrene monomer.

Colourants in Plastics

Plastics are increasingly coloured to enhance the attractiveness of packaging, to protect the contents from the adverse effects of light or to differentiate between products. Depending on the type of packaging, the contents and the storage conditions, it is possible that components in the packaging, including colourants, could migrate to the food. It must therefore be ensured that the packaging components, including colourants, do not pose a health hazard to the consumer. This is also the aim of the relevant directives, laws and regulations.

The colouration of plastics, which come into contact with food, is an important application for the colourants industry. The following basic criteria are decisive for the safe use of colourants for the colouration of food contact articles and packaging:

1. Purity criteria of the colourants,
2. Its fastness to migration,
3. The tested toxicological properties.

The colourant manufacturers guarantee that the colourants have been toxicologically tested and that the purity criteria are met. The manufacturers of the food contact article or packaging material are responsible for the migration testing.

Consumer safety is a joint responsibility of manufacturers, processors and authorities. For the consumer, the safe use of coloured plastic food contact articles is already provided for by the current regulations in combination with a responsible approach by the pigment manufacturers and processors. Nevertheless, new knowledge must always be taken into account.

Basically, the problem of colour migration is found in vegetable oils, when they are packed into coloured polythene containers. CFTRI has developed simple methods to detect the colour migration qualitatively from plastics, within few hours, using decolourised coconut oil. However, the quantitative estimation can also be done using spectroscopic analysis.

As per US-FDA 178.3297 Colourants and Polymers, the substances may be safely used as colourants in the manufacture of articles or components of articles intended for use in producing, manufacturing, processing, preparing, treating, packaging, transporting or holding food. The term colourant means a dye pigment, or other substance that is used to impart colour to or to alter the colour of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any colour apparent to the naked eye.

As per Indian standards, colour migrated to simulant or decolourised coconut oil or food packed shall not be apparent to naked eye. If the colour migrated is clearly visible, such materials are not suitable for food contact applications, even though the extractive value is within the limit as in IS: 9833-1981.

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