

## MATERIALS OF CONSTRUCTION FOR FOOD PROCESSING EQUIPMENT AND SERVICES: REQUIREMENTS, STRENGTHS AND WEAKNESSES

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## Abstract

Worldwide international and national legislative and standardization bodies have laid down laws, regulations, standards and guidelines with requirements that food contact materials must meet when they are used in direct contact with food. However, most of them are written from a "packaging material" rather than a "material of construction for food processing equipment and services" perspective. Materials of construction are usually selected based on their strength, elasticity, hardness, toughness, sensitivity to wear, corrosion and fatigue resistance, ease of fabrication, availability and cost price. However, in the construction of food processing equipment and services, the focus of materials of construction for food processing equipment and services also lays on the prevention of food contamination with microorganisms, dirt, chemicals and physical substances during the short period of contact between the product and equipment surfaces.

Materials of construction must be: physical durable and mechanical stable (strong, hard, tough, impact and crack resistant, resistant to wear, tear and abrasion), easy to machine (in specific sizes and shapes) and to join (continuous hygienic bonding or welding), compatible with other materials of construction (no metal-to-metal corrosion) and/or functional substances (lubricants, refrigerants, etc.), inert (no adulteration of the food with deleterious substances), chemical resistant (to the food, cleaning agents and disinfectants), heat and/or cold resistant, and last but not least hygienic (smooth, not sensitive to fouling, and easy to clean and decontaminate). To select the most appropriate materials of construction for use in either the food contact, or the non-food contact area, the equipment manufacturer must have knowledge of the physical, chemical and thermal behaviour of an as large as possible range of market available materials of construction, must be familiar with their hygiene characteristics, and must have insight in the laws, regulations, standards and guidelines applicable to the materials of

construction used in the design and manufacturing of his food processing equipment.

This text gives an overview of the regulations and hygienic requirements that materials of construction commonly applied in the manufacturing of food processing equipment and services must meet, with further emphasis on their suitability in either the food-contact or non-food contact zone, in an environment where harsh chemicals are used to clean and disinfect. For different materials of construction, specific problems with respect to their hygiene, inertness, physical characteristics, and chemical and thermal resistance will be discussed.

*Key words*: Food contact materials, Materials of construction, Legislation, Resistance.

## 1. Introduction

Materials of construction are usually selected based on their strength, elasticity, hardness, toughness, sensitivity to wear, corrosion and fatigue resistance, ease of fabrication, availability and cost price. However, in the construction of food processing equipment and services, the hygienic properties of materials of construction, such as sensitivity to fouling, cleanability and inertness in contact with the food produced, are as important. To select the most appropriate materials of construction for use in either the food contact, either the non-food contact area, the equipment manufacturer must have knowledge of the physical, chemical and thermal behaviour of an as large as possible range of market available materials of construction, must be familiar with their hygiene characteristics, and must have insight in the laws, regulations, standards and guidelines applicable to the materials of construction used in the design and manufacturing of his food processing equipment. This chapter gives an over-view of the materials of construction commonly applied in the



manufacturing of food processing equipment and services, with emphasis on their suitability to act as food contact materials in an environment where a high level of hygiene is required and harsh chemicals are used to clean and disinfect.

# 2. Legislation, General recommendations and Materials

#### 2.1 Legislation

#### 2.1.1 Legislation in Europe

In Europe, materials in contact with foodstuffs must comply with the Materials and Articles intended to come into Contact with Food Directive 89/109/EEC and Regulation (EC) No. 1935/2004, and with Regulation (EC) No. 2023/2006 on Good Manufacturing Practices for Materials and Articles intended to come into Contact with Food. Although EU member states may have their own legislation, Regulation (EC) No. 764/2008 of the European parliament and of the Council of 9 July 2008 obliges any EU member to accept the principle of Mutual Recognition.

#### Regulation (EC) No. 1935/2004

Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food, also known as the Framework Regulation, provides general principles to regulate any type of food contact material, included cutlery, dishes, food processing machines, containers, etc. Article 3 of the Framework Regulation stipulates the core requirements that any type of material intended for food contact application must meet: materials and articles (including active and intelligent materials and articles) must be suitable for food contact, and be manufactured in compliance with good manufacturing practices (GMPs) so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health, bring about an unacceptable change in the composition of the food, or bring about deterioration in the organoleptic characteristics. The Framework Regulation further indicates that specific measures (EU harmonized legislation) may be adopted for certain food contact material groups (17 in total) as defined in Annex I: active and intelligent materials, adhesives, ceramics, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, regenerated cellulose, silicones, textiles, varnishes and coatings, waxes and wood.

In addition, Regulation (EC) No. 1935/2004 establishes some specific provisions on traceability, the authorization process for new substances (authorization by EFSA), the Declaration of Compliance (DoC) for those substance groups already regulated by a specific measure as well as supporting documentation applicable to all materials covered under the Regulation [1], [2].

## EU Directives and regulations for specific groups of food contact materials

With respect to food contact materials which could be involved in the construction of food processing equipment, there is already legislation on plastics and materials in contact with food (Regulation EU N° 1183/2012, Regulation EU N° 10/2011 and Directive 2002/72/EC), recycled plastics in contact with food (Regulation (EU) No. 282/2008), elastomers and rubbers in contact with food (Resolution AP (2004) 4 and Directive 93/11/EEC), certain epoxy materials in contact with food (Regulation (EC) No 1895/2005, and Directives 2004/13/EC and 2002/16/EC), vinyl chloride monomers in food contact plastics (Directive 78/142/EEC), ceramic materials in contact with food (Directives 2005/31/EC and 84/500/EEC), active and intelligent materials in contact with food (Regulation (EC) No. 450/2009), metals and alloys used as Food Contact Materials (Council of Europe 2002 policy statement concerning metals and alloys used as Food Contact Materials), ion exchange and adsorbent resins used in the processing of foodstuffs (Resolution AP (2004) 3, superseding Resolution AP (97) 1), silicones used for food contact applications (Resolution AP (99) 3 and Resolution AP (2004) 5), coatings intended to come into contact with food (Framework Resolution AP (2004) 1, replacing Resolution AP (96) 5), and on control of Aids to Polymerization in plastic materials and articles (Resolution AP (92) 2), [1], [2].

## Commission Regulation (EC) No. 2023/2006

Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food sets out general principles to ensure the suitability of the material or article for the intended end use. It requires that business operators establish, implement and ensure adherence to an effective and documented quality control and quality assurance system within the manufacturing process and take account of the adequacy of personnel, their knowledge and skills, and the organization of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them [1], [2].

#### Regulation (EC) No. 1907/2006 (REACH regulation)

According to the EU chemicals legislation, REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), chemicals (on their own, in mixtures or in products) will need to be screened for their health and environmental impact. REACH regulation (EC) No. 1907/2006 requires the registration, with a technical dossier, of all substances manufactured or imported into the European Union in quantities above 1 tonne/ year. For quantities above 10 tonnes/year even a Chemical Safety Report (CSR) is required.



Certain food contact materials may give rise to concern because of the use of certain substances that have been placed on the REACH candidate list, for reasons that they are Persistent, Bio accumulative and Toxic, or Very Persistent and Very Bio accumulative. Substances in the candidate list may be selected to go through to the authorization process after a consultation and prioritization process. However, if such substances are present in another substance or article below the "Substances of Very High Concern" declaration limit of 0.1% w/w, then they can continue to be used, if they are cleared for use in food contact materials following a risk assessment by EU authorities. The assessment of a substance as a component of food contact materials is done under the setting of a migration limit below which the transfer is considered safe and renders the food contact material to be inert. Substances that after a risk assessment by EFSA have been approved for use in food contact materials, are no longer subject to a risk assessment for human health within a registration dossier under REACH (Article 14 of the REACH regulation). The use section of a REACH registration dossier for that substance will then reference its approval by EFSA under the regulation (EU) No 10/2011.

## <u>Regulation (EC) No. 764/2008 on the Principle of Mutual</u> <u>Recognition</u>

In intra-EU trade in goods, mutual recognition is the principle that any product not subject to Community harmonization legislation but lawfully manufactured and/or marketed in a given Member State or Turkey, must be allowed for sale on the territory of any other Member State, even when the product does not fully comply with the technical rules of the Member State of destination. However, according to Article 7 of Regulation (EC) No. 764/2008, each Member State can still pose restrictions or bans at national legislation level should any concern for health or the environment be posed for people/environment in that Member State by the use of that product/substance (e.g., Bisphenol A in France) [3].

## 2.1.2 EU member states legislations

#### National legislations

National legislations are legally binding in the specific country where they are issued and should be used to address compliance in that country. National legislations are generally structured following the concept of positive lists (e.g., list of substances authorized to be used in the manufacture of materials intended to be used in the regulated application and their restrictions and/or limitations). In some instances, listing of catalysts and/or processing aids is also included.

## 2.1.3 Legislation in the US

In the United States, legislation with respect to food contact materials is more established than in Europe. The Food and Drug Administration (FDA), which is an agency of the US Department of Health and Human Services, is among other areas responsible for protecting public health through the regulation and supervision of food safety. With respect to food contact materials, guidance is contained in the Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, parts 174-190. If a substance is not listed in any EU Regulation or reference document in the EU (as described above), Non-European Legislation (e.g., FDA regulation) might be used for further evaluation.

#### 2.2. General recommendations

Materials of construction for food processing equipment, process piping and utilities should be homogeneous, hygienic (smooth, nonporous, non-absorbent, nontoxic, easy cleanable, impervious and non-mould supporting), inert (non-reactive to oil, fat, salt, etc.; may not adulterate the food by imparting deleterious substances to it, nor affect its organoleptic characteristics), chemical resistant (corrosion proof; non-degrading and maintaining its original surface finish after sustained contact with product, process chemicals, cleaning agents and disinfectants), physically durable and mechanical stable (resistant to steam, moisture, cold, heat; resistant to impact, stress and fatigue; resistant to wear, abrasion, erosion and chipping; not prone to cracks, crevices, scratches and pits; unbreakable) and easily to maintain, in agreement with the guidance described in EHEDG guidelines N° 8 and N° 32. Additional requirements could be availability, welding ability, machinability and capability of being shaped. Notice that materials which are worked (for instance: bent, cut, sheared, extruded or drawn) during their manufacture may require additional treatment (such as surface finishing) following fabrication in order to render them corrosion-resistant. Hence, materials should be selected that are suitable for surface treatment [4], [5] & [6].

Migration of chemicals including raw materials, additives, reaction products and contaminants originating from different food contact materials into foods at various stages of processing of the products is a major concern. In general, migration of chemicals from food contact materials increases with temperature, contact time, fat content and acidity of the food, with which they come into contact. Plastic materials are particularly sensitive to the fat content and temperature of the food since many of the components in these materials are oil soluble, and plastics have relatively low heat resistance as compared to some non-plastic materials such as metals and ceramics. On the other hand, the major concern on metals and ceramics is the migration of heavy metals such as lead and cadmium.



The migration of heavy metals in metalware may increase when the article comes into contact with highly acid foods (e.g., fruit juices). Whether a chemical would pose health risks to the consumers depends on its toxicity and the amount of the chemical migrated into the foodstuff, which makes that the use of inert materials for food contact is of utmost importance.

Product contact surfaces (all surfaces exposed to direct contact with the product as well as indirectly impacted surfaces from which splashed product, condensate, liquid or solid particles may run off, drop off, or fall into the product) should be constructed of materials that meet the highest hygienic requirements. Within the food contact areas, no chemical substances are allowed to migrate from the surfaces of these materials into the product except for technically inevitable proportions which do not harm health, odour or taste. Materials of construction for components located in the non-food contact area may be of a lower grade but must be corrosion resistant, and able to withstand all cleaning solutions normally used to clean the outside of food processing equipment [4], [5].

#### 2.3 Materials

#### 2.3.1 Use of metals and alloys

#### 2.3.1.1 Definition

Metals are usually characterized on the basis of their chemical and physical properties in the solid state. Metals are the class of materials linked on an atomic scale by the metallic bond, being an array of positive metallic ions forming long-range crystal lattices in which valence electrons are shared commonly throughout the structure. As such, they are strong, ductile and have high thermal conductivity. Other characteristic properties are high reflectivity, and high electrical conductivity. Metallic alloys are composed of two or more metallic elements.

#### 2.3.1.2 Field of application

Both non-ferrous and ferrous metals and alloys are used in the construction of equipment and services for the food industry. Alloys for food contact may only contain aluminum, chromium, copper, gold, iron, magnesium, manganese, molybdenum, nickel, platinum, silicon, silver, tin, titanium, zinc, cobalt, vanadium and carbon. The machinability of these non-ferrous and ferrous materials has a large influence on the final choice for a certain construction material in a specific application.

#### 2.3.1.3 Release and migration of metal compounds

Metals and alloys are used as food contact materials, mainly in 2processing equipment, transportation bands, knives, containers and utensils but also in foils. They play a role as a safety barrier between the food and the exterior. However, unprotected with a coating some metals can give rise to migration of metal ions into the foodstuffs, as such becoming a contaminant that contributes to and influences the total oral intake. Even though some metals are essential elements, they may either endanger human health if the total content of the metals exceeds the hygienic recommended exposure limits, or may bring about an unacceptable change in the composition of the foodstuffs, or may deteriorate their organoleptic characteristics. Moreover, release and migration of metals is closely related to metal degradation, such as corrosion and leaching of metal elements. Hence, release and migration of metals should be reduced as low as reasonably.

#### 2.3.1.4 Degradation of metals and alloys

Corrosion is a phenomenon in which, in the presence of moisture and oxygen, the metal undergoes an electrochemical reaction with components of the surrounding medium. In the simple case of uniform corrosion, this reaction results in the formation of compounds of the metal (e.g. hydroxides) on the surface of the metal. The rate at which corrosion proceeds will depend in part on the composition of the aqueous medium: corrosion of iron in very pure water will be considerably slower than in water which contains, for example, acids or salts. The rate of corrosion depends also on the solubility of the formed compounds in the medium, and their rate of removal. Formed compounds may be rapidly removed in a flowing aqueous medium, increasing the corrosion rate. In a static medium, the rate of corrosion will be moderated as the ionic concentration of the surrounding medium increases. Corrosion products formed in the atmosphere are more or less adherent [7].

More complex corrosion patterns may occur, e.g. "pitting corrosion". This occurs following attack at discrete areas on the surface of the metal that are susceptible because of, for example, surface imperfections or impurities in the metal. Pitting corrosion is generally seen as small, local, areas of corrosion. However, there may be considerably larger areas of corrosion beneath the surface that can have significant effects on the strength of the affected metal. Rust is essentially hydrated ferric oxide which usually also contains some ferrous oxide and may contain iron carbonates and/or sulfates. Similarly, verdigris on copper containing surfaces consists mainly of basic copper carbonate, but may also contain copper sulfates and chlorides. However, rust is loose and easily removed, while verdigris forms a stable patina [7].

Further, in the assembly of food process equipment and services, the right combination of steels, alloys or metals must be used to avoid bimetallic corrosion (Fig. 1). Work in black steel and stainless steel must always



be kept separate. To protect them against corrosion, stainless steel equipment components should be fully wrapped with plastic film, and eventually their inlet and outlet connections should be fitted with protective caps (Fig. 2).



Figure 1. In this part of the food processing equipment, mild steel plate is combined with stainless steel bolts, giving rise to galvanic corrosion between the stainless and mild steel components



Figure 2. The stainless steel equipment components must be fully wrapped with plastic film, to protect them against corrosion during transport and storage

Immersion tests with metal coupons or specific equipment components (Fig. 3) allow to evaluate the effect of food products, detergents and disinfectants on the materials of construction used in the manufacturing of food processing equipment. Static immersion tests of the candidate materials are rapid screening test. If the plant item is to be welded, it is prudent to subject welded coupons to similar tests, as the weld metal and heat-affected zones may have different corrosion resistances from that of the unwelded material. To assess the risk of crevice corrosion, a testing procedure that involves the use of castellated washers is often used [5].



Figure 3. Bearings made from different materials of construction were subjected to immersion tests in salt brine. Bearings No. 1, 2 and 8 are thin dense chrome plated; bearing No. 3, 5 and 7are 400 stainless steel; bearing No. 4 is coated; and bearing No. 6 is black oxide coated

Table 1 gives an overview on the chemical and physical resistance of several metals and alloys in relation to the cleaning agents and disinfectants applied, the food product produced and the environmental conditions (e.g., steam 150 °C, hot water, cold, ozone) to which they are exposed.

Ma	aterials of construction	Dete	rgents	or disiı	nfectan	ts	i	Food Si	ubstan	ces	Physical factors				
		Mild alkaline	Alkaline	Strong alkaline	Alkaline + NaOCI	Alkaline + NaOCl + corrosion inhibitor	Mild acid + corrosion inhibitor	Mild alkaline disinfectant	Salt water	Acid Food	Vegetable oil & Fat	Steam 125 °C	Hot Water	Cold resistance < -25 °C	Ozone
	Zinc	3	0	0	0	0	0	3	1	0	3/2	1	2	3	0
	Nickel	3	3	3	1	1	3	3	3	3	3	3	3	3	3/2
s l	Titanium	3	3	3	3	3	3/2	3	3	3/2	3	3	3	3	3
Metals	Tin	3/2	2/1	0	2/1	2/1	2/1	2/1	3	1	3	3	3	3	3/2
_ <	Copper	3	3	0	0	0	1	3	2/1	1	3	3/2	3	3	3/2
	Aluminium	3	1	0	0	0	2/1	3	1	2/1	3	3/2	3	3	3
	Anodized aluminium	3	1	0	1	2	2	3	3	2	3	3/2	3	3	3/2

#### Table 1. Chemical and physical resistance of metals and alloys



	Carbon steel		3	3	3	0	0	1	3	1	0	3/2	3	3	2	2/1
	Cast iron		3	3	3	0	0	1	3	1	0	3/2	3/2	3/2	3	2
us Is	SS AISI 316		3	3	3	3	3	3	3	3	3	3	3	3	3	3
Ferrous steels	SS AISI 304		3	3	3	3/2	3	3	3	2	3	3	3	3	3	3
Fe S	Galvanized st	eel	2	2	1	1	2	1	3	2/1	1	3/2	3/2	3	3	1
	Nickel-plated	steel	2	2	2	2	2	2	2	1	2	3	3/2	3	3	2/1
	Painted steel		3	1	0	2/1	2/1	2	3	1	1	3/2	1	1	3/2	1
	Monel		3	3	3	1	1	2/1	3	3	3/2	3	3/2	3	3	3
Nickel alloys	Hastelloy B		3	3	3	2	2	3	3	3	3	3	3	3	3	2
Ze	Hastelloy C		3	3	3	3	3	3	3	3	3	3	3	3	3	3
	Bronze		2	2	2	2	2	1	3	3/2	1	3	3/2	3	3	3/2
Copper alloys	Brass		3	2	2	2	2	1	3	0	1	1	2	3/2	3	3/2
υø	Nickel-plated	brass	2	2	2	2	2	2	2	0	1	1	3/2	3	3	3/2
	Painted zinc		3	1	0	0	0	1	3	1	1	3	1	1	3/2	0
	Painted aluminium		3	1	0	1	2	2	3	1	1	3/2	1	1	3/2	1
Resis	tance rating	e level		Co	ntact m	edium					Defi	nition				
	3	high resis	stance	h	ighly su	ited for	consta	nt use		me	chanica	lly and	visually	not aff	ected	
	2 good resistance					, but co	ndition	al use	m	echanic	ally not	affecte	d, visua	lly sligh	ntly affec	ted
1 low resistance usable, but not continuously mechanic							ically and visually affected									
	0	no resist	ance		no	ot usabl	e at all		severe mechanically and visually damage							

#### 2.3.1.5 Metals

#### <u>Copper</u>

The best known applications of copper are vessels, traditionally used in many breweries and distilleries.

Copper is largely applied in the non-product contact area, with as main application the tubes in evaporators installed in refrigerators and freezers, electrical wiring, water pipes, etc. According to recent research, copper has shown to restrict bacterial growth.

Copper does not really constitute a food safety problem but it is recommended to avoid direct food contact with copper utensils, as it can cause unacceptable organoleptic effects. Moreover, copper can be quickly and severely affected by strong alkaline detergents, sodium hypochlorite, acid and salty food, making it not really suitable in the food contact zone. The rate of attack is slow enough that alkaline detergents can be used for the cleaning of copper vessels. As copper ions may leach from the copper metal, its surface roughness may increase. Oxidation of copper gives rise to the formation of toxic copper (II) oxide [6], [7].

## <u>Aluminium</u>

For food contact purposes, anodized aluminium should be used because uncoated aluminium is attacked by acid food and alkaline detergents. The use of silicates, however, prevents alkaline attack of aluminium. The use of uncoated aluminium utensils should be limited, even if the exposure to aluminium is usually not harmful. When coated, this coating must be resistant to alkaline detergents, chlorine containing bleach, and acid and salty food.

Anodizing is an electrolytic passivation process used to increase the thickness of the natural oxide layer on the surface of the aluminium. Aluminium anodized coatings are resistant to many inorganic chemicals in a range between pH 4 and 8.5 but are subjected to pitting in aerated chloride solutions. An optimum resistance to corrosion is obtained if the coating is in the thickness range of 18-30  $\mu$ m. The corrosion resistance of anodized coatings can be further enhanced by sealing the pores of the coating and incorporating inhibitors. However, dichromate coatings containing hexavalent Cr(VI) shall not be used for that purpose as it is toxic [6], [7].

## <u>Nickel</u>

Nickel intake via foodstuff does not cause hazards for the majority of consumers but a subgroup of the population (approximately 10%, mainly women) have contact allergy to nickel. In some patients with certain types of nickel dermatitis, a flare-up of eczema through ingestion of even small amounts of orally ingested nickel is observed. Nickel usually is evenly worn



off, although pitting and stress-corrosion cracking may occur. Intensive aeration and high temperatures may increase the corrosion rate. Nickel may be attacked by inorganic acids such as nitric, sulfuric and phosphoric acid, but has good resistance to alkaline media and at least at not too high temperatures it is hardly attacked by organic acids, such as vinegar, lemon, and formic acid. Phosphoric acid present in some acid cleaning agents and sodium hypochlorite may leach non-alloyed nickel very easy from pure nickel, causing damage to nickel surfaces during cleaning. Where brass components are nickel-plated, damage to that coating may release physiologically unacceptable amounts of nickel in the food and the product may come in direct contact with brass. In general, pure nickel, nickel-plated steel and nickel-plated brass in the food contact area should better be avoided. Notice that the use of stainless steel and nickel alloy utensils does not elicit an allergic reaction by nickel sensitized persons [7].

#### <u>Zinc</u>

Zinc is easily dissolved in diluted acids and by bases, leading to the release of zinc, but also of cadmium and lead. Zinc also reacts with steam to produce zinc oxide and hydrogen gas. Zinc in the food contact zone must be avoided, especially where wet or humid acidic foodstuffs are produced. Zinc frequently contains small amounts of the toxic metals cadmium (0.01 - 0.04%) and lead as impurities. Therefore, the use of zinc, zinc alloys or zinc galvanized consumer goods with food contact is banned in some countries [6], [7].

## <u>Titanium</u>

Titanium has been suggested to be used for corrosive or delicate liquids such as dairy products, fruit juices and in the wine industry. It is practically inert, due to the phenomenon of passivation of the titanium surface by the formation of a molecular layer of titanium dioxide. This layer, which is very adherent to the metallic substrate, is scarcely removed at high temperatures even in contact with hypo-chlorites and bleach chemicals, and highly concentrated salt and acid solutions. Titanium is resistant to crevice corrosion, and impingement and pitting attack in salt water. Titanium doesn't cause health problems, as it is generally considered to be poorly absorbed upon ingestion [7], [8].

Titanium dioxide is also used as white pigment in paints, lacquers, enamels, coatings and plastics. Further titanium compounds (e.g.,  $TiCI_4$ ) are also found in plastics, as they are used as catalysts in the manufacturing of certain plastics (Ziegler-Natta catalysts for synthesis of 1-alkene polymers). Recent research has demonstrated that the combined action of UV and titanium dioxide results in photocatalytic disinfection of food products, liquids and air.

#### <u>Silver</u>

Silver is used in the production of cutlery and tableware. Chemically, silver is the most reactive of the noble metals, but it does not oxidize readily; rather it "tarnishes" by combining at ordinary temperatures with sulfur-compounds or  $H_2S$  (e.g., in eggs). However, migration of silver is limited. Silver may be ingested via consumption, in e.g., silver salts used as drinking water disinfectants, and as a colouring agent for decorations of confectionary and in alcoholic beverages. Silver is also used as an antimicrobial in many elastomers, plastics and within coatings of stainless steel [7].

## Lead, cadmium and mercury

For health reasons, lead, cadmium and mercury in food contact materials should absolutely be avoided:

- Lead absorption may constitute a serious risk to public health. The effects of lead poisoning, which can affect nearly every bodily system, are cumulative throughout our lifetime. It is especially dangerous to infants and young children, as well as to fetuses, because it can cause slowed developments, learning or behaviour problems and lower IQ scores. Moreover, lead can increase blood pressure and cardiovascular diseases in adults. With regards to lead, the Scientific Committee for Food adopted an opinion on 19 June 1992 endorsing the provisional tolerable weekly intake of 25 µg/kg body weight proposed by the WHO in 1986.
- Cadmium absorption also constitutes a risk to humans, since it may induce kidney dysfunction, skeletal damage and reproductive disorders. As regards cadmium, the Scientific Committee for Food endorsed in its opinion of 2 June 1995 a provisional tolerable weekly intake of 7 µg/kg body weight.
- Mercury may induce alterations in the normal development of the brain of infants and at higher levels may induce neurological changes in adults. EFSA adopted on 24 February 2004 an opinion related to mercury and methyl-mercury in food and endorsed the provisional tolerable weekly intake of 1,6 µg/kg body weight. Methyl-mercury is the chemical form of most concern and can make up more than 90% of the total mercury in fish and seafood. The maximum acceptable level of mercury for fish laid down in Commission regulation EC No. 1881/2006 is 0.50 mg/kg fresh weight.

Notice, however, that these components are largely present in electrical and electronic components: batteries, fluorescent lamps, light bulbs, Black Light Blue (BLB) lamps (used in UV-light based insect killers), IT and telecommunications equipment (optical and filter glass, switches), monitoring and control instruments, semi-conductors, plasma display panels (PDP) and electron emitter displays (SED), electronic



ceramic parts (e.g., piezo-electronic devices), connector systems, electrical / mechanical solder joints to electrical conductors, etc. It is very difficult to exclude their presence in the production, packaging and storage areas within the food factory. However, electrical and electronic components should never be installed in or exposed to the food contact area. They must always be enclosed in junction boxes, casings, closed cable housings, cabinets, etc., and only installation in the non-product contact zone, or in technical corridors and rooms is allowed. In 2003, the EU adopted the Restriction of Hazardous Substances (abbreviated RoHS) Directive (2002/95/EC). This Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment bans new electrical and electronic equipment on the EU market that contains more than the permitted levels of lead, cadmium, mercury, hexavalent chromium compounds, etc. The List of RoHS Exemptions is regularly up-to-dated with new decisions, banning certain electrical/electronic equipment for industrial or consumer use, or limiting the content of lead, cadmium or mercury in these components [6], [9].

#### 2.3.1.6 Ferrous steels

#### <u>Cast iron</u>

Cast iron is an alloy of iron, silicon and carbon. Typically, the concentration of carbon in cast iron is between 3 - 4% by weight. The corrosion resistance of cast iron is comparable to that of carbon steel; and sometimes even better. However, cast iron will quickly corrode on exposure to moisture and atmospheric air. To prohibit corrosion or to reduce the corrosion rate, cast iron is often painted or even galvanized. But even a thick coating of paint or zinc will not fully prohibit corrosion due to the cracks and holes within the coating. Its corrosion resistance to neutral and alkaline liquids (high pH) is fairly good, but it has poor resistance to acids (low pH) and salt water. However, cast iron can be alloyed with 13 - 16% (by weight) silicon or 15 - 35% (by weight) nickel (Ni-resist) to improve its corrosion resistance. Due to its sensitivity to corrosion and surface roughness, cast iron cannot be used in the food contact area of food processing equipment. Its use is limited to pump casings, steam piping, equipment frames, etc., away from the food contact area [10].

## <u>Mild steel</u>

Mild steel (also called carbon steel) is made from iron and carbon (< 1%) without addition of other "alloying elements". Carbon steel will quickly corrode on exposure to moisture and atmospheric air. It is also sensitive to acids, salt water and chlorine containing bleach, but fairly good resistant to neutral and alkaline liquids (high pH). Due to its corrosion sensitivity it cannot be used in the food contact area, but it is often used in the construction of valves for non-food applications [6], [10].

## Galvanized, nickel plated and painted mild steel

To retard its corrosion, mild steel is often galvanized (zinc plated), nickel plated or painted but, with time, these coatings get damaged and peels off (Fig. 4). Galvanized steel should be avoided in the product contact area (the splash area included), because any alkaline or acid product will rapidly attack and remove the galvanizing, so although it would prevent corrosion by water, it does nothing to protect metal against the detergents. The only permitted applications of galvanized steel are in contact with dry and non-acidic foodstuffs. Painted steel never shall be used in the neighbourhood of food because paints often contain zinc, lead, cadmium and phenolics. Moreover, paint can crack or flake, and steam and some cleaning agents rupture the physical integrity of paints. Paint that peels off can fall onto the product, creating a health risk. Paint surfaces used in non-product contact areas may crack or flake and should be repainted immediately [6], [10].



Figure 4. To retard its corrosion, this hinge is painted but the paint could not fully prohibit corrosion due to the cracks and holes within the coating. Moreover, part of the paint coating is peeled off

#### Stainless steels

The main elements in all stainless steels are iron, chromium, molybdenum and nickel, with none of them being harmful to consumer health. Especially the austenitic chrome-nickel or chrome-nickel-molybdenum steels are used for the construction of equipment and services in the food industry. Stainless steel AISI SS 304(L) can be used for the construction of food processing equipment and service systems in applications with low chloride levels (up to 50 mg/L [ppm]), near neutral pH (between 6.5 and 8) and low temperatures (up to 25 °C). Due to its sensitivity to sodium hypochlorite and salt that is usually present in food in high contents, the use of stainless steel AISI SS 304(L) should be limited to exterior equipment surfaces, motor and electrical cabinets, etc. Susceptibility to chloride attack is especially high if the water has an acidic pH, and can be further accelerated in the presence of oxidiz-



ing agents. The small additional cost of using AISI SS 316(L) rather than AISI SS 304(L) makes that stainless steel AISI SS 316(L) is commonly used as construction material for food processing equipment. If the stainless steel is provided with a coating, that coating must be inert, chemical resistant, physically durable and easy to clean.

However, as temperatures approach 150 °C, even AISI SS 316 stainless steels may suffer from stress-corrosion cracking in regions of high stress and exposed to high levels of chloride. Therefore, other stainless steel types were developed to overcome that problem (e.g., duplex steel). Duplex stainless steel has higher strength and toughness, higher corrosion resistance (it remains intact in contact with aggressive foodstuffs and saline solutions at high temperatures), and excellent resistance to stress corrosion cracking and corrosion fatigue. Other stainless steel types are the super-austenitic grades, which are used in similar applications and also for steam heating systems and boilers. An alternative to the stainless steels are nickel alloys [6], [7], [8], [10].

#### 2.3.1.7 Nickel alloys

These alloys have a much higher nickel content showing higher corrosion resistance than the ferrous steels. The high nickel alloys are suitable in high salty and acidic environments at very high temperatures and in high stress applications. With regards to the corrosion resistance of these nickel alloys, the following inventory can be made: Hastelloy B < Monel < Incoloy < Hastelloy C. In alloys, nickel is strongly and micro-structurally bond, because the "alloying elements" react with and dissolve into each other to form a material with new crystalline structures. Strong atomic and chemical binding forces between the constituting alloying elements reduce their migration out alloys [7], [8].

#### 2.3.1.8 Copper alloys

The copper alloys brass (60 - 70% copper, 30 - 40% zinc) and bronze (80 - 95% copper, 5 - 20% tin) are more prone to corrosion by alkaline and acidic detergents, salty and acid food than the ferrous steels. Brass is susceptible to de-zincification (in e.g., steam), and because cadmium and lead are co-elements to zinc, brass shall never be used in the food contact area. Although bronze was used in the production of cookware and utensils in prehistory and ancient times, its use in the food contact zone should be avoided because it quickly becomes porous in contact with acid foodstuffs, cleaning agents and steam. Notice however that bronze is widely accepted as material of construction for control valves in food gas cylinders, allowing to control gas pressure and flow without compromising the quality of the food gas. Copper alloys, such as brass and bronze, also exhibit antimicrobial activity, albeit of smaller magnitude. Electrical components in bronze or brass should be contained in enclosures [6], [7] & [10].

#### 2.3.1.9 Titanium alloys

Titanium alloys are stronger and more resistant to corrosion than the metal itself. Titanium is also used in certain so-called "stabilized" forms of stainless steels, which in general contain less than 1%. In medicine, titanium alloys are used in implants, and they have never indicated any local effects on tissues. However, the use in food contact materials is unknown. Studies on titanium alloys used in implants do not indicate any local effects on tissues [7].

#### 2.3.2 Use of Plastics

#### 2.3.2.1 Definition

Plastics are defined as shaped and hardened synthetic materials composed of long chain organic molecules called polymers, plus various additives. Additives are used to facilitate handling and processing (lubricants, mould-release agents, blowing agents, etc.), to change or improve various properties of the base polymer (heat stabilizers to cope with higher temperatures; fillers, reinforcing agents, fibers, impact modifiers to improve the durability; plasticizers to improve the flexibility; anti-statics to prevent electrical uploading; colouring agents for pigmenting; antimicrobials to prevent or retard microbiological corrosion) and to protect plastics from the effects of time and environmental conditions (flame retardants; antioxidants; UV stabilizers to absorb ultraviolet) [12].

#### 2.3.2.2 Release and migration of plastic compounds

As substances with a molecular weight above 1000 Da usually cannot be absorbed in the body the potential health risk from the polymer itself is minimal (Quotation: Reg. (EU) No 10/2011, whereas (8)). Unreacted residual monomers can be found in the polymeric material, several of which are hazardous for human health and/or the environment. Besides the residual monomers other polymerization impurities, such as oligomers and low molecular weight polymer fragments can be present in plastics.

There are several ways to produce a polymer and the chosen method determines the use of solvents, suspension aids, surfactants, initiators, catalysts and other polymerization additives. The bulk process is carried out without solvents and gives the purest polymers, with only trace amounts of catalysts or initiators. In solution and dispersion polymerization techniques, organic solvents are used which may be toxic (e.g., carcinogenic) and flammable. The last traces may be very difficult to remove. Most polymerization additives, e.g. initiators, catalysts, chain transfer agents and suspension aids, are added only in small amounts (< 2 wt.%). In most cases, they do not have very hazardous properties; but they can migrate from the polymer, contributing to the overall leaching of chemical substances

from the polymer material. Initiators become a part of the polymer, but catalysts do not and may therefore be found as residual catalysts. Initiators such as benzoyl peroxide, potassium and ammo-nium persulfate are hazardous, as well as tributyltin (for polyurethane), zinc oxide (for polybutylene terephthalate, polycarbonate and PET), copper chloride (for polyphenylene ether) and antimony trioxide (for polycarbonate and PET) catalysts. Some of the raw material substances from which the monomers are produced, intermediate substances or by-products in the synthesis of monomers are sometimes more toxic than the monomer itself. Heat stabilizers of the lead- and cadmium-type are toxic, requiring their replacement with less hazardous heat stabilizers. It is also recommended to delay any exposure of food to recently produced or processed plastics, so as to allow these plastics to release most of their volatile toxic substances. Additional amounts of these volatile substances can be released with increasing temperatures and on exposure to the food and/ or the cleaning and disinfecting agents. The first food batch should be sent to disposal [13].

As they may leach out, additions (pigments, anti-static agents, etc.) should be avoided in food contact applications. However, also metals, carbon fibres or glass fibres which are added for strength may leach out or go into solution. When carbon or glass fibres in PTFE are poorly consolidated, PTFE is particularly susceptible to porosity. Components of glass-reinforced plastic also can react with certain wetting agents in detergents. This can be observed by the fact that the material turns black. Of more concern is the risk of small pieces of material becoming dislodged and finding their way into the product.

## 2.3.2.3 Degradation processes in plastics

Similar to metals, plastics may be prone to fatigue, erosion, spherical void expansion, creep and corrosion. These phenomena cause changes in the chemical and physical properties of a certain plastic material, while metal corrosion rather manifests as a process of surface disintegration. Degradation of plastic materials rather proceeds at the inside and is usually invisible from the outside.

## Water absorption as a cause of plastic failure

Due to their structure, some plastics may absorb water from the surrounding liquid or atmosphere and slowly diffuse into the molecular structure where it can affect chemical and intermolecular bonds. With increasing moisture content, the stiffness of the plastic decreases and the plastic becomes soft. Where swelling of a given plastic component is prohibited, internal stress may lead to premature failure of that plastic component. On the other hand, plastics with a too low water content may become prone to embrittlement [11].

### Microbiological corrosion

Some plastic material can be used by microorganisms as a source of carbon and energy, especially lower molecular weight additives such as fillers, lubricants, antioxidants, stabilizers, emulsifiers, plasticizers, colourants, etc., that are released from the plastic materials. Microbial corrosion of plastics may induce changes in the properties of plastics. They may undergo discolouration, may lose their strength, and may suffer from weight reduction because of the fact that they lose their constituents. Some unfilled plastics such as PE, PS, PVC, PTFE or PC showed increased resistance to microorganisms [11].

## Stress corrosion cracking

Already at relatively low strains, triggered by stresses within plastic components, plastics may become prone to stress corrosion cracking, which may become visible as hairline cracks. Highly stressed zones within plastics may arise during the exertion of loads, and as the consequence of water retention and chemical attack. Due to these stresses, polymer chains within the plastic may become overstretched and may be torn from their entangled configuration, resulting in the rupture of chemical bonds. The damage induced cannot be reversed, and remains permanent even after stress relief. In filled and fibre reinforced plastics micro cracks mainly originate and grow at the interface of the polymer matrix and fillers, which in fibre-reinforced semi-crystalline plastics occurs at the boundary of crystallites and reinforcing fibres [11].

## 2.3.2.4 Legislation applicable to plastics

## EU legislation

Plastics used in food contact in the EU must meet Regulation EU N° 1183/2012, Regulation EU N° 10/2011 and Directive 2002/72/EC. The Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food consolidates and replaces previous Directive 2002/72/EC with its six amendments and also integrates some former Directives to migration testing (Directive 82/711/EEC and amendments), simulants (Directive 85/572/EEC and amendments) and to Vinyl chloride (Directive 78/142/ EEC, 80/766/EEC and amendments).

The Plastics Regulation defines several compositional requirements for substances in plastics [2]:

 The Union-list set in Table 1 of Annex I provides a list of authorized monomers, other starting substances and additives, including information on identity and the use of the substance (additive, monomer, polymer production aids, etc.). In agreement with Regulation (EU) No. 10/2011, specific restrictions (e.g., purity requirements, Specific Migration Limits (SML)



and the Overall Migration Limit (OML)) or specifications are set.

- Components of the raw material with a molecular weight below 1000 Dalton which are not authorized are not automatically rejected. Regulation (EU) No 10/2011 permits their use provided the substances are not carcinogenic, mutagenic or reproductive toxic.
- Substances not subject to the Union-list (some polymer production aids not yet covered by the Union-list, aids to polymerization, non-intentionally added substances like impurities, reaction by-products, degradation products, oligomers having a molecular weight of less than 1000 Da, etc.) shall be assessed in accordance with internationally recognized scientific principles on risk assessment (article 19).
- Specific restrictions on some metals and on primary aromatic amines.

The Regulation also defines provisions on Declaration of Compliance and supporting documents (Articles 15 and 16).

#### Legislation in the United States

Apart from the European legislation, it is often commercially desirable for plastic manufacturers to meet the requirements of the US Food and Drug Administration. FDA regulations consider elastomers and plastics as indirect food additives, and the Food and Drug Administration (FDA) requires pre-market approval for all food additives since 1958. The regulations for indirect food additives laid down positive lists of permitted substances, which were published in Title 21 of the US Code of Federal Regulations.

## 2.3.2.5 Hygienic requirements to be met by plastics in contact with food

Apart from their different resistance to several media and their divergent behaviour to extreme physical conditions (very high and low temperatures, UV), thermoplastics and thermosets (resins) show also differences in tensile, compression and impact strength; differences in hardness, resilience and flexibility; and divergent electrical properties. For use in the food contact area, it is important that these plastics should be odourless, nonporous, smooth and free from cracks, crevices, scratches and pits which can harbour and retain soil and/or microorganisms after cleaning. Additionally, they may not absorb product constituents and microorganisms, must have high mechanical strength (withstand the mechanical shocks that are likely to occur during normal operation; be resistant to ageing, creep, brittleness, fatigue, etc.) and good wear/abrasion resistance, shall be resistant to heat, cold flow, hydrolysis, electrostatic charging, etc. Abrasion which can occur due to the transfer of solids, slurries or pastes (e.g., tomato concentrate) can damage the surface of the material and have a significant effect on the accumulation of soils, biofilm formation and cleanability [11].

When using a plastic material (conveyor belts, gaskets, electric cables, etc.), it is of utmost importance to secure that the material is able to withstand all temperatures from -50 °C (freezer applications) to temperatures as high 121 °C (steam sterilization) without cracking or breaking. Moreover, the plastic material must be chemical resistant to solvents, acid, alkaline, reducing and oxidising agents, cleaning and disinfection agents, and corrosive food gases at these temperatures. The equipment manufacture should test the chemical and temperature resistance of the plastic material [11].

Plastics also may not impart any odours and taste to the food. When food components diffuse into the plastic, they subsequently may leak back out into 'later' food, causing a loss of the perceived quality of the food, such as changes in visual appearance or organoleptic qualities (sometimes called 'tainting' of the flavour).

Coolants and lubricants used for the machining of plastics may not be absorbed in the plastic material. After machining (e.g., cutting) they must be sufficiently removed, although degreasing and final cleaning of plastic components is not as easy as for metal parts. Solvents used in degreasing (halogenated organic solvents in particular) may harm plastic components or get absorbed leaving residues.

## 2.3.2.6 Thermoplastics

Thermoplastic polymers soften when heated and can be reshaped, the new shape being retained on cooling. The process can be repeated many times by alternate heating and cooling with minimal degradation of the polymer structure. Thermoplastics are largely used in the construction of food processing equipment and utilities. The physical and thermal properties as well as the chemical resistance characteristics of the most commonly used thermoplastics are given in Table 2.

Commonly used thermoplastics; applications, strong and weak points:

 Polytetrafluorethylene (PTFE) or Teflon, is inert (to all known chemicals), nontoxic, nonflammable, and has a working temperature range of -270 to 260 °C. It has an extremely low coefficient of friction, and is applied as "non-stick" coating. It is used for machine packings, seals, gaskets, insulators, tubing, vessels for aggressive chemicals, coating in cookware, conveyor belt coating, mechanical and electrical bearings, insulation for coaxial cable, fixture and motor lead wire, industrial signal and control cable, etc.

Polytetrafluoroethylene (PTFE) is often considered to be a potentially attractive material, because of its high chemical resistance. However, care must be taken, because it can be porous and thus difficult to clean.



In addition it may be insufficiently resilient to provide a permanently tight seal, and it is therefore considered unsuitable for aseptic processing [14].

#### Table 2. Chemical and physical resistance of thermoplastics

	Materials of construction		D	eterge	nts or d	lisinfec	tants		5	Food Substar		Physical factors				
		Mild alkaline	Alkaline	Strong alkaline	Alkaline + NaOCl	Alkaline + NaOCl + corrosion inhibitor	Mild acid + corrosion inhibitor	Mild alkaline disinfectant	Salt water	Acid Food	Vegetable oil & Fat	Steam 125 <sup>0</sup> C	Hot Water	Cold resistance < -25 <sup>0</sup> C	Ozone	
	Acetal Plastic (POM)	3	0	0	0	0	0	3	3	0	3	0	1	3	0	
	Polyamide plastic (PA)	3	1	1	1	1	1	3	3	1	3/2	3	2/1	3	0	
	Polyvinylchloride (PVC)	3	3	3	3	3	3	3	3	3	3	1	2	0	3/2	
	Polyurethane (PU)	3	2	0	0	0	2	3	3	1	3	1	3	3	3	
	Polycarbonate (PC)	0	0	0	0	0	1	3	3	2/1	3	1	2/1	1	2/1	
Thermoplastics	Teflon (PTFE)	3	3	3	3	3	3	3	3	3	3	3/2	3	3	3	
lqor	Polyethylene (PE)	3/2	3/2	2	3	3	3	3	3	3	3	0	3/2	1	2/1	
hern	Polypropylene (PP)	3	3	3	3	3/2	3	3	3	3	3/2	2	3/2	1	0	
	PVDF	3	2	2	3/2	3/2	3	3	3	3	3	3	3	3	3	
	Tefzel <sup>®</sup>	2	2	2	3	0	2	2	3	2	3	3	3	2	3	
	Polyetheretherketon (PEEK)	3	3	3	3/2	3/2	3	3	3	3/2	3	3	3	3	3	
	Polystyrene (PS)	3	3	3/2	3	3	3	3	3	3	0	0	1	3	1	
	Acrylonitrile butadiene styrene	3	3	3	0	0	3	3	3	3/2	1	2/1	3	3	1	

Resistance rating	Resistance level	Contact medium	Definition
3	high resistance	highly suited for constant use	mechanically and visually not affected
2	good resistance	constant, but conditional use	mechanically not affected, visually slightly affected
1	low resistance	usable, but not continuously	mechanically and visually affected
0	no resistance	not usable at all	severe mechanically and visually damage

Polyvinyl chloride (PVC) is the most widely used plastic in industry. It appears in transparent, opaque and coloured forms. It is applied as material for drains and gutters (max. 80 °C), chilled and deionised water piping, rainwater pipes, tanks, guards, conveyor belt coating, electrical conduit and trunking, electrical cable sheathing, junction boxes, etc. PVC is tough, strong, with good resistance to chemicals, good low-temperature characteristics, but does not retain good mechanical perfor-mance above 80 °C. In a food processing plant, where there is a significant amount of splashdown and where harsh cleaning agents are used daily to achieve sanitation standards, PVC is a better choice than PUR because it is

more resistant to water and harsh cleaning chemicals. PVC is also cheaper than PUR and minimizes the risk of downtime due to cable failure.

Serious drawbacks are the presence of low residual quantities of the cancerogeneous vinylchloride monomer and the extensive use of plasticizers such as di(2-ethylhexyl) phthalate (DEHP) which are believed to be pseudo-oestrogenic. Directive 78/142/EEC establishes a specific migration limit for unreacted vinyl chloride monomer in food of 0.01 mg/kg, and a maximum permitted quantity of unreacted vinyl chloride monomer of 1 mg/kg PVC [12].





· Polyethylene (PE) is a non-polar, semi-crystalline, translucent to opaque thermoplastic with very low density, that absorbs very little water. It provides a smooth, soft and very tough surface and waxy-like feeling, but its low strength and hardness limits its use as engineering material. Polyethylene is very chemically resistant but sensitive to halogen and oxidizing acids, as well as to oxygen in the presence of heat and UV light. Polyethylene allows maximum continuous services temperatures of about 60 - 90 °C, depending on the load. The lower temperature limit of use is about -50°C. A distinction is made between LDPE (low-density) and HDPE (high-density). LDPE is sensitive to grease and oil causing swelling and softening, or even stress cracking. The chemical resistance of HDPE is superior to that of LDPE, in particular towards oil and greases. Low-density polyethylene (LDPE) is applied as packaging material, plastic film, coating, pipes and fittings for drinking water and gases, domestic mouldings, electrical cable sheathing and insulation. High-density polyethylene (HDPE) is used to fabricate larger mouldings (transport and storage tanks), modular conveyor belts, sheet, tube, bearings, gears, etc. [11].

The use of starting materials and production aids for polyethylene is subject to the Commission Regulation (EU) No. 10/2011. Benzoyl peroxide, potassium and ammonium persulfate are not recommended as initiators for the radical chain polymerization. The finished products must not test positively for peroxides [1], [13].

 Polypropylene is a semi-crystalline thermoplastic with high water resistance that absorbs no moisture. Polypropylene has considerably high hardness, stiffness and good creep, wear and heat resistance. The maximum temperature operation limit amounts 110 °C without exertion of load. The resistance to aqueous saline, acid and alkaline solutions, alcohol and solvent is good to very good. At higher temperatures, PP swells in contact with oils, greases and waxes. Polypropylene is used for packaging films, plastic containers, pipes and fittings for drinking water, drains, conveyor belt coating, modular conveyor belts, electrical cable sheet, etc. [11].

For use in the food sector, starting materials and production aids are subjected to the Commission Regulation (EU) No. 10/2011. Benzoyl peroxide, potassium and ammonium persulfate are not recommended as initiators for the radical chain polymerization. The finished products must not test positively for peroxides [13].

 Polystyrene (PS) is an amorphous, clear transparent thermoplastic with low moisture absorption (approximately 0.05%), and available on the market in several opaque colours. In its unmodified form, polystyrene is a tough, dimensionally stable and highly resistant material but with rather poor elasticity. Polystyrene is not very useful as an engineering material because of its brittleness in unmodified forms. High-impact forms are obtained by compounding with butadiene or resins with a certain degree of elasticity, and heat-resistant forms are obtained by the use of fillers. Polystyrene also can be stabilized against ultraviolet radiation and also can be made in expanded form for thermal insulation and filler products. Polystyrene is suitable for operations at temperatures between -70 and 70 °C. Polystyrene is resistant to alkalis, lyes, diluted mineral acids, alcohols, water and aqueous salt solutions, but is prone to attack by steam, many solvents and strong oxidizing materials. Polystyrene is sensitive to stress cracking, so that any residual stress within the finished product must be avoided. Applications include food packaging material, refrigerator lining, holding tank and freezing containers, thermal and electrical insulation, etc. Applications include food packaging material, refrigerator lining, holding tank and freezing containers, thermal and electrical insulation, etc. [11].

Polystyrene produced by the polymerization of styrene in the presence of approved process aids (within the acceptable limits of use) is suitable for direct food contact if the requirements of commission Regulation (EU) No. 10/2011 are met. Finished products must not test positively for peroxides.

• Polyamide is a semi-crystalline thermoplastic with relatively high water absorption that only decreases slowly. Dry polyamide components are stiff and brittle, necessitating pre-conditioning by immersion in water to set the final mechanical properties. Polyamide shows high creep and fatigue resistance, and good resistance to abrasion and friction. Its elasticity and strength can be increased by the addition of short glass fibres to the melt, which concomitantly reduces its sensitivity to volume shrinkage and increases its heat resistance. Maximum temperatures of use are in the range of 80 - 120 0C, and -40 0C at the lower end of the temperature scale. The lower the temperature, the more brittle polyamide becomes. Highly crystalline polyamide exhibits good resistance to oils, fats, organic and inorganic alkalis at medium strength concentrations, while resistance to strong bases, mineral acids and solutions with oxidizing agents is poor. Polyamide is mainly used for gears, bearings, rollers, conveyor belts, tissues, pipes and hoses [11].

Polyamide is approved for food contact purposes in the normal conditions of use, with as additional requirements that starting materials and production aids used in the polymerization process are subjected to the Commission Regulation (EU) No. 10/2011, and that its organoleptic properties such as taste and odour (especially during high temperature treatment) are not changed. The finished products must not test positively for peroxides [13].



· Polycarbonate (PC) is a light weight amorphous thermoplastic material commonly formed by the reaction of Bisphenol A with phosgene or diphenyl carbonate, and as such falls into the polyester family of plastics. Polycarbonate (PC) is an optical transparent or translucent high-performance plastic, also available in several grades (many colours), that remains clear over a wide temperature range (-90 up to about 130 °C). It is a hard and stiff plastic with high dimensional stability that maintains its strength, rigidity and toughness up to 140 ° and down to -20 °C. Moisture absorption is low, being less than 0.5% after immersion in water during a long time, but gradual chemical degradation in hot water can occur, and it is also sensitive to steam. Polycarbonate has only fair resistance to chemicals, and is sensitive to mineral and organic acids, alkalines and oxidizing agents (ozone, sodium hypochlorite, peracetic acid, etc.). It is resistant to alcohols (except for methyl alcohol), various oils and fats as well as neutral and light acidic saline solutions. Some modified polycarbonates are more resistant against oxidizing and reducing agents, mineral acids and organic acids. By the use of proper additives, the weathering resistance can be increased. Stabilization of polycarbonate provides resistance against ultraviolet radiation. The durability, shatter resistance, high heat resistance and glasslike appearance of PC make it an ideal replacement for glass, and it is used in the assembly of containers, valves, housings, moulded parts, gears, glazing panels, light shields (UV stabilized), safety glass, etc. [11].

Polycarbonate may be used for materials and articles in direct contact with food, if the starting materials and process aids as stipulated in commission Regulation (EU) No. 10/2011 are approved and within the acceptable limits of use. Polycarbonates must be evaluated on the presence of residual amounts of catalysts, which could be hazardous (e.g., zinc oxide, and antimony trioxide which is suspected of causing cancer) [13].

· As non-polar semi-crystalline thermoplastic, polyoxymethylene (POM, also called acetal plastic) has good creep resistance, and high strength, hardness and toughness even at low temperatures. Further polyoxymethylene has considerably high yield strength at room temperature and good resilience in the elastic region. The friction coefficient is low, and the wear and abrasion resistance is high. Also the water absorption is very low, but polyoxymethylene is sensitive to steam. Normal operation temperatures in the 80 - 100 0C range can be extended up to 140 0C under momentary loads. Polyoxymethylene has good temperature resistance and a low coefficient of thermal expansion. Polyoxymethylene has excellent resistance to alcohols, weak acids and alkalis but is not resistant against oxidizing agents, strong bases and strong acids (pH < 4) [11].

For use in the food sector, starting materials and production aids are subjected to the Commission Regulation (EU) No. 10/2011. Acetal plastics are unsuitable for storing acidic contents with a pH value of less than 2.5. Polyoxymethylene co- and homopolymer may be safely used for moulded articles intended for use in contact with food, if they meet the requirements in the FDA Code of Federal Regulations (CFR), Title 21, section 177.2470 & 177.2480. The FDA also requires that the use temperature of acetal plastic does not exceed 121°C, because of its thermal degradation and concomitant release of formaldehyde. However, at 116°C, formaldehyde may still leach into food, just more slowly. UV radiation cause POM to break down but UV resistant grades are available. Polyoxymethylene (acetal plastic) is used for bushings, bearings, gears, pipe fittings, valve bodies, pumps parts, filter and instrument housings, apron and modular conveyor belts, etc.

· Polyvinylidene fluoride (PVDF) is a partially crystalline high molecular weight thermoplastic, free from stabilizers, pigments and other additives. It has higher stiffness than PTFE, and combines high strength, high toughness, high abrasion and creep resistance with excellent chemical resistance similar to PTFE. It is resistant to acids and bases, and only swells at higher temperatures in the presence of ketones and esters. The temperature range for continuous use is at the lower end of the temperature scale -40 down to -100 °C and at the higher end 150 ° up to 200 °C. Due to its low conductivity of heat, liquids in PVDF recipients loose little heat. The dimensional stability of PVDF at high temperatures can be considerably increased by the addition of glass fibres. Water absorption is very low (around 0.04%). Polyvinylidene fluoride is a hydrophobic material which can be produced with a surface finish of about Ra  $\leq$  0.2  $\mu$ m, reducing the tendency of microorganisms to adhere to surfaces. As polyvinylidene fluoride is physiologically harmless, it can be used both in the food and pharmaceutical industry (e.g., polyvinylidene fluoride is used for pure water systems) [11].

Polyvinylidene fluoride is applied for the construction of tank equipment and pipes operating with corrosive media at high temperatures, pumps, valves, lining of equipment, electrical and electronic components, wire and cable insulation, etc.

Tefzel<sup>\*</sup> is a modified ETFE (ethylene-tetrafluoroethylene) fluoroplastic that combines superior mechanical toughness with an outstanding chemical inertness that approaches that of Teflon<sup>\*</sup> (PTFE). Tefzel<sup>\*</sup> combines high purity with low water absorption, high mechanical strength, good permeability and excellent abrasion resistance over a temperature range of -185 °C to 150 °C. However, the temperature stability and mechanical properties are worse than with PTFE. However, its hardness is much higher.



Tefzel<sup>\*</sup> ETFE is used in tank construction and linings, wire and cable insulation/jacketing, super-cold refrigeration components, valves (linings, seats, seals, etc.), compressors and pumps (linings and components), films, electrical components (insulators, cable clamps), gaskets, bearings, etc. [11].

- Polyurethanes are compounds formed by reacting the polyol component with an diisocyanate compound, typically toluene diisocyanate (TDI), methylene diisocyanate (MDI) or hexamethylene diisocyanate. Polyols are relatively nontoxic (i.e., polyether type polyols are found to be safe, because they are low in oral toxicity with almost no irritation effect to the eyes and skin), however, isocyanates are highly toxic and the product can have a significant toxicity if remnants of isocyanate are in it, which manifests itself mainly as a respiratory (as well as a dermal) hazard. Fully reacted polyurethane polymers may be considered as chemically inert. In the EU, for food applications, polyurethanes should be food grade according to the EU Regulation 10/2011. When extended with 1,4-butanediol, polyurethane must comply with FDA regulation 21 CFR 177.2600 (rubber articles intended for wet and dry repeated-use food-contact applications). When extended with hydroquinone bis-(2-hydroxy-ethyl)ether (HQEE), polyurethane must comply with 21 CFR 177.1680 (polyurethane resins which may be safely used as food-contact surface of articles intended for use in contact with bulk quantities of dry food that do not have free surface fats or oils). Polyurethane coatings may be safely used as the food-contact surface of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food if it meets the criteria laid down in 21CFR175:300, including a wear test, and the amount of extractives in respectively distilled water, 8% ethanol and N-heptane must be  $\leq$  2.8 mg/ cm<sup>2</sup>. Processing equipment used in USDA-inspected facilities no longer requires specific approval by USDA. In the absence of this approval process, meat and poultry product manufacturers may request a letter of assurance from their polyurethane suppliers to ensure that only safe and suitable compounds are used. Polyurethane resists weathering and can be safely used in temperatures ranging from -65°C to 110°C. It has excellent resistance to abrasion, ozone and ageing, and very good chemical and oil resistance. Polyurethanes may also be used as the surface layer in conveyor belts and in hoses and tubings for conveying certain liquids [11], [13].
- Polyether ether ketone (PEEK) is a non-polar, tough, semi-crystalline thermoplastic with high bending, impact and tensile strength. Polyether ether ketone is suitable for applications with high bending and tensile stresses at high temperatures up to 250 °C.

Moreover, it can be reinforced with glass, graphite or carbon fibres. Non-reinforced polyether ether ketone has a softening temperature of 160 °C, but provided with 30% glass fibres this temperature limit increases up to 315 °C. Polyether ether ketone and glass fibre reinforced polyether ether ketone have excellent wear and abrasion resistance, and a low friction coefficient. Because of its crystallinity, polyether ether ketone is resistant against a wide range of organic and inorganic chemicals, and it is also insoluble in all common solvents. Its superior chemical resistance makes it an excellent substitute for metals in aggressive environments. Polyether ether ketone also has an excellent resistance to hydrolysis in boiling water and superheated steam (sterilization/ autoclaving) at temperatures up to 250 °C.

PEEK is largely used in the food - and pharmaceutical industry, such as for linings for tubes, measurement devices. As polyether ether ketone shows sufficient elasticity without cold flow, polyether ether ketone can be successfully used as a sealing material. Polyether ether ketone is often reinforced with carbon fibre and fillers such as graphite and PTFE material, making it easy to machine and providing it extremely low friction and wear, which is excellent for bearings [11].

Hydrolysis, chemical attack and the application of mechanical stress can accelerate the process of ageing and lead to environmental stress cracking after an extended period in contact with the product at service temperature. Most plastics (especially PA and ABS) can absorb moisture and other matter from their environment. In extreme cases, and in addition to simple porosity effects, swelling becomes visibly noticeable and the mechanical performance will degrade. Many plastics also suffer from hydrolytic attack at elevated temperatures over extended periods of time, which can lead to cracking, spalling, embrittlement or mechanical failure. The resistance of many thermoplastics to steam is rather poor, and restricts their use both in the food and non-food contact area where cleaning or sterilization with steam is regularly performed. Sensitive for hydrolytic attack by steam are POM, PE, PC and PVC. Good performance can be obtained from a range of materials including PP, PTFE, PVDF and PEEK. Many plastics are also sensitive to pH and/or certain ions, and may suffer corrosion or loss of properties in certain environments. Some detergents and disinfectants have shown to attack plastics resulting in, for example, absorption, dissolution, corrosion, material shedding or embrittlement, with the attendant risks of flavour taints and poor hygiene. For strongly acid environments, good performers may include PP, PTFE and PVDF. For strongly alkali environments, good performers may include PP, PTFE and PEEK. Thermoplastics such as PS, ABS, PP, PA, PE, PC and POM that are sensitive to ozone should not be applied in applications like

water treatment installations using ozone as disinfectant. Also food fats and oils can be remarkably aggressive (e.g., chocolate, meat fats or butter), with many plastics suffering considerably from such attack. It may exhibit physical degradation of their properties and, in some cases (e.g., PES), material shedding and cracking. Good performers, however, include PEEK, PTFE, PVDF and some polyamides [5], [11].

Unmodified types of thermoplastics that are degraded by UV are POM, PVC, PC, ABS and PA6/6. PP and PE have low resistance to UV light, whereas other plastics such as PS and certain polyamides show fair resistance to UV light. Polymers with good resistance to UV are PU, PTFE, PVDF, PES and PEEK. Covers (lenses, refractors and diffusers) installed at the bottom of light armatures to protect the process area below against shattering glass are often made of polycarbonate that only will yellow and brown less quickly if UV-stabilized.

Plastic components which shatter under adverse tensile or bending loads, or under impact, can cause food product contamination with sharp particles that are not detected by common in-line metal detectors. Such materials therefore represent a similar hazard to glass. Plastics which give good performance against brittleness are PP, PTFE and PEEK. Hydrolysis can cause brittleness in some plastics such as Polyethyleneimines (PEI), at higher temperatures, while other plastics become brittle at low temperatures. Polyvinyl chloride

Table 3. Chemical and physical r	resistance of thermoharders
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(PVC), polypropylene (PP), polyethylene (PE) and poly-carbonate (PC) have poor cold resistance and may crack at very low temperature. In areas at very low temperatures (e.g., cold-storage warehouse) cold resistant jacket materials that may be used, are PA, PUR, PTFE, etc. [5].

## 2.3.2.7 Thermosets

Thermosets are cured plastics, which means that polymer chains within thermosets are intensively crosslinked, so that they no longer can be softened at higher temperatures and re-shaped by heating. In their final state, they set to a rigid, hard, heat and solvent resistant solid. Thermosets are generally stronger and stiffer than thermoplastics, and have a high modulus of elasticity which is even maintained at high temperatures. With the addition of fillers, the properties of the thermoset resins can be further improved. Inorganic additives such as grinded rock powder, long glass fibres or lamellar mica may give thermosets a higher density, increased strength and thermal resistance, and reduced sensitivity to volume shrinkage. Thermosets are largely used in the construction of food processing equipment and utilities [11]. The physical and thermal properties as well as the chemical resistance characteristics of the most commonly used thermosets are given in Table 3.

	Materials of construction			Detergents or disinfectants							es	Physical factors			
		Mild alkaline	Alkaline	Strong alkaline	Alkaline + NaOCl	Alkaline + NaOCl + corrosion inhibitor	Mild acid + corrosion inhibitor	Mild alkaline disinfectant	Salt water	Acid Food	Vegetable oil & Fat	Steam 125°C	Hot Water	Cold resistance < -25°C	Ozone
	Polyester	3	3/2	2/1	2/1	2/1	3/2	3	3/2	3	3	0	0	3	3
	Poly(methy Imethacrylate) (PMMA)	3	3	3	3	3	3	3	3	3	3	0	0	1	3/2
Resins	Ероху	3	3	1	3	3	3/2	3	3	3	3	3	3	3	0
Res	Phenolics (PF)	1	1	0	0	0	3/2	1	3	2	3	3/2	3	3	3/2
	Ureum-formaldehyde (UF)	3/2	1	0	0	0	1	1	1	2/1	3	0	1	1	3/2
	Melamine-formaldhyde (MF)	3/2	1	0	0	0	3/2	1	3	2	3	0	3	3	3/2

Resistance rating	Resistance level	Contact medium	Definition
3	high resistance	highly suited for constant use	mechanically and visually not affected
2	good resistance	constant, but conditional use	mechanically not affected, visually slightly affected
1	low resistance	usable, but not continuously	mechanically and visually affected
0	no resistance	not usable at all	severe mechanically and visually damage



Commonly used thermoharders; applications, strong and weak points:

- Phenolic resins have proven to be resistant to heat, fire and mechanical abrasion. Under these conditions, it maintains its form and mat or glossy surface structure very easily. Phenolic resins are used for the construction of electrical circuit boards, electrical components (plugs, switches, knobs, fittings, lighting fixtures), wiring devices, thermal insulation, mechanical parts (gears, cams), heat resistant handles, etc. The FDA Code of Federal Regulations (CFR), Title 21, section 177.2410 states that phenolic resins may be safely used for moulded articles intended for use in contact with food at the condition that migration studies have revealed that pre-set threshold values are not exceeded. Regulation EU N° 10/2011 allows the use of phenol as monomer but forbids the use of phenol as additive or polymer production aid in the production of plastics. Applications in the food contact area of food processing equipment is not at all recommended due to the free phenolic compounds (phenol, cresol and/or tertiary-butyl phenol) and formaldehyde that may be released or migrate into the food products produced [11].
- Urea-formaldehyde (UF) resin is used in plywood, electrical applications, and as foam for thermal insulation. Urea-formaldehyde resins are very hard, scratch-resistant, odourless and tasteless with reasonable chemical resistance, and they have superior electrical properties. They show good resistance to all types of oils and greases but are affected by alkalis and strong acids. Urea-formaldehyde resins are less stable than melamine-formaldehyde resins. UF resins are also sensi-tive to light [11].

The FDA Code of Federal Regulations (CFR), Title 21, section 177.1900 states that urea-formaldehyde resins may be safely used for moulded articles intended for use in contact with food at the condition that migration studies have revealed that pre-set threshold values are not exceeded. However, the potential release of formaldehyde makes it not the most appropriate material for food contact applications. According to EU regulations No.10/2011 and 1282/2011, urea is authorized only as a monomer with an implicit specific migration limit of 60 mg/kg.

 Melamine-formaldehyde (MF) resin is a durable, hard and rigid thermoset, with a non-scratch, smooth and even glossy surface. It may show good chemical and acceptable heat and cold resistance. Most MF-manufacturers specify a temperature of -30 °C to 120 °C, while some even claim a temperature of up to 140 °C.
For many years, melamine-formaldehyde resins are used for the production of low cost tableware. They are used for insulators (especially in wet and dirty conditions), for industrial laminates, for structural electrical parts, circuit breakers and switch board panels [11]. The FDA Code of Federal Regulations (CFR), Title 21, section 177.1460 states that melamine-formaldehyde resins may be safely used for moulded articles intended for use in contact with food at the condition that migration studies have revealed that pre-set threshold values are not exceeded. However, melamine-formaldehyde resins are not recommended in the food contact area of food processing equipment. If they are exposed to high temperatures above 70 °C (e.g., cooking, frying), melamine-formaldehyde resins chemically degrade and release concentrations of melamine and formaldehyde that are likely to be dangerous to human health. This is especially the case for acid foods including many fruit and vegetable preparations. According to EU regulations No. 10/2011 and 1282/2011, melamine and formaldehyde are authorized as both monomers and additives, with a specific migration limit of 2.5 and 15 mg/kg, respectively [11].

• The properties of a given unsaturated polyester resin are dependent on the structure of the polyester and the type and degree of reinforcement (mainly glass fibre is used). In general, the strength, stiffness and creep resistance of the unsaturated polyester resin are high. Unsaturated polyester resin is resistant to temperatures as high as 200 0C and even more. If the surface layer of the resin is hermetically closed, unsaturated polyester resins have very good chemical resistance to diluted acids and lyes, aqueous saline solutions and oils. However, it is prone to attack by concentrated acids and alkalis, organic solvents, alcohol, hot water and steam [11].

The use of starting materials and production aids for unsaturated polyester resins is subject to the Commission Regulation (EU) No. 10/2011. In finished products made from a combination of resin and fibres, which are subject to mechanical wear, the fibres must not be in direct contact with the surface. Before finished products enter the market, they must be sufficiently tempered and subsequently thoroughly washed for 1 - 2 hours in hot water at 80 °C, or steam treated. The finished products must not test positively for peroxides.

Unsaturated polyester resin is used in the fabrication of storage tanks and pressure vessels, conveyor belt coating, linings, castings, piping and electrical parts, for industrial mouldings, as reinforcing fibre in composites, for components where high resistance to corrosive agents and mechanical stress is required, etc. Due to its transparency, it is also applied for window frames and skylight domes.

 Epoxy resins are networked by a polyaddition reaction and quite often reinforced with materials such as quartz, chalk, talk, glass beads and glass, coal and textile fibres. Epoxy resins are characterized by low moisture absorption, which leads to low shrinkage and high dimensional stability. Epoxy resins have high strength which decreases only slightly up to



150 °C. Reinforcement of the epoxy resin with fibres allows strengths in the vicinity of steel. Also the hardness and abrasion resistance are high. Epoxy resin varieties that are cold cured at room temperature, are resistant to alkalis, diluted acids and aliphatic alcohols. Epoxy resins warm-hardened at temperatures of 80 - 200 °C with phtalic acid are resistant to aromatic hydrocarbons, oils and fats. Epoxy resin is not resistant to strong oxidizing substances, and further is odourless, tasteless and nontoxic. Epoxy resin can also be used as glue/adhesive to wood, metal and glass, as wall/floor coating, as insulation material, and in the construction of electrical parts and circuit boards [11].

- Poly(methyl methacrylate) (PMMA), often "Acrylic glass", is a crystal-clear amorphous thermo-plastic with very good optical properties and quite resistant to discolouration. Besides high stiffness and strength, PMMA is also hard, brittle and scratch-resistant. Further, it has good light, ageing and weathering resistance. It is suitable for applications up to 70°C. PMMA is resistant to weak acids and alkalis, salt solutions, fats, oils and non-polar solvents, but is not resistant to concentrated acids. Further, PMMA is odourless and tasteless, and physiologically safe. The use of starting materials and production aids for PMMA is subject to the Commission Regulation (EU) No. 10/2011. Benzoyl peroxide, potassium and ammonium persulfate are not recommended as initiators in radical chain polymerization. The finished products must not test positively for peroxides. Typical areas of application are moulded parts for optical devices such as glasses, sight glasses, control knobs, light housings, transparent coverings, wash basins, etc. [11].
- In contrary to all other plastics that largely consist of carbon, silicone resin consists of a lattice of silicon and oxygen. As compared to other thermosets, its strength and elasticity is rather low but its hardness is high, and it provides low compression set and long-term resiliency. Silicone resin has excellent electrical, UV and ozone resistance. Other properties are almost constant in a wide temperature range from 80 up to 200 °C. Silicone resin is chemically very resistant, especially to dilute and concentrated mineral acids. It is totally water repellent (hydrophobic) and has anti-adhesive properties. For use as food contact material in the food industry, resolution AP (99) 3 and Resolution AP (2004) 5 of the Council of Europe must be met, stating that silicone resin should be manufactured in accordance to ISO9002 and under the conditions specified in "Technical document No. 1 - List of substances applied in the manufacture of silicones used for food contact applications" (only certain starting materials and production aids may be used). They may further not transfer constituents to foodstuffs in quantities which could endanger

human health, bring about an unacceptable change in the composition of the foodstuffs or deteriorate the organoleptic characteristics thereof. Silicone resins must be odourless and tasteless, and the release of any substances from silicone resin to foodstuffs should be as low as technologically possible. Silicone resin is mainly used for surface and corrosion protection, heat resistance coatings, release coatings in food production such as in bakery, high-temperature laminates, as well as for impregnating motor windings, etc. [11].

#### 2.3.3 Use of Elastomers

#### 2.3.3.1 Definition

Rubber can be defined as a polymeric material which can be substantially deformed under stress, but rapidly recovers almost to its original stage when the stress is removed. It can be stretched repeatedly to at least twice its original length, but returns to its original length on release of the stress. The elastic properties of rubber are brought about by a combination of the chemical structure of the polymer backbone and the vulcanization (cure) process which brings about the formation of a lightly cross- linked three dimensional structure.

Thermoplastic rubber is a polymer or blend of polymers that with respect to resilience and rapid recovery behaves similar to vulcanized rubber. However, to obtain these elastic properties, it does not require vulcanization or cross-linking during processing. Thermoplastic rubber can thus repeatedly be softened by heating to enable processing, and then regains its elastomeric character on cooling to room temperature.

## 2.3.3.2 Field of application

Rubber products are largely used in food processing equipment, such as for seals, gaskets, plate heat exchanger gaskets, hoses, conveyor belting, skirting, milk liners, butterfly valves, diaphragm pumps, feather pluckers, etc.

#### 2.3.3.3 Release and migration of rubber components

During the processing of food, the contact of the food with the rubber present in conveyor belts, hoses, seals, gaskets, etc. becomes quite significant. The impact of a given rubber on the food with which it is in contact, is largely determined by the type of food, its temperature, the contact time and the contact area. Rubbers are chemically very complex, as they contain polymers, oligomers, residual unreacted monomers (left after the polymerization reaction) and additives. Some typical monomer remnants are styrene (left after the production of styrenic rubbers), butadiene (left after the production of poly-butadiene rubbers), toluene diisocyanate, methylene diisocyanate or hex-



amethylene diisocyanate (left after the production of polyurethane rubber) and acrylonitrile (left after the production of nitrile rubbers), all of which are toxic. Their concentrations can be critical to know, because their molecular weights are small, letting them migrate to the surface easily. Permissible limits of such species must be defined and followed carefully for food contact applications (in natural rubber, the concentration of free monomer is set at 1 mg/kg as a maximum). Oligomers that can exist in the system after completion of the polymerization process can pose similar problems. Typical additives found in rubbers are plasticizers, process aids, emulsifiers, retarders, antidegradants (antioxidants, antiozonants), curing agents, cure accelerators, antistatic agents, fillers, pigments (mostly in the form of blends), reinforcing agents, resins, biocides, etc. Hence, there are a number of potential migrating agents in the system, especially because the rubber matrix is flexible with high permeabilities. Plasticizers in rubbers are usually at high concentrations, and although concentrations of antidegradants (antioxidants and antiozonants) are much lower, they are all very critical in food contact rubber products. These intentional and unintentional compounds (which are called indirect food additives by the FDA) have the potential to migrate into the food, in the case of rubber contact with the food [12], [13].

There is not much of published data available on the migration of chemicals from rubber into food (or food simulants) but prepared rubber samples of natural rubber, EPDM, fluorocarbon and silicone rubber cured with sulfur (and all accelerators contain sulfur) showed characteristically high levels of extracted N-nitrosamines (suspected as carcinogens), aromatic amines (e.g., phenyl-naphthylamine) and aldehydes (mainly formaldehyde). So migratory components produced during the curing of rubber can be released subsequently. Other studies also have shown the migration of metal ions (arsenic, barium and lead). Levels of nitrosamines in rubber products are restricted < 10 µg/kg, or as extractable nitrosamines < 1 µg/kg.

Vulcanization (cure) of rubbers is usually complex, and a number of different reaction products (nitrosamines and nitrosatable substances) can be produced. Besides these new (unwanted) products, certain rubber cure accelerators can be left completely unreacted in the system, such as thiurams (tetramethyl thiuram disulfide and tetramethyl thiuram monosulfides), thioazoles, sulfenamides, diphenyl guanidine and dithiocarbamates. As such, both reaction products and vulcanization remnants are potential dangers for migration in food contact applications. Especially for rubbers contacting aqueous media, breakdown product migration is more common [12]. Migration from a food contact rubber material into food (or into food simulants) is usually expressed in two ways, either as:

- a) Overall migration (total extractables: mass of overall migration without considering composition of the migrant), which is FDA recommended.
- b) Specific migration (where the composition and quantity of migrant are of interest).

Only compounds on a permitted list of additives (positive list) for food-contacting rubbers should be used.

#### 2.3.3.4 Legislation applicable to rubber

In Europe, rubber in contact with food must comply with Food Directive 89/109/EEC and Regulation (EC) No. 1935/2004, so that in normal use they will not transfer their constituents to food in quantities that could endanger health, cause unacceptable changes in the composition of food, or deteriorate its organoleptic properties. Rubber also should be manufactured in accordance to Regulation (EC) No. 2023/2006 on Good Manufacturing Practices for Materials and Articles intended to come into Contact with Food.

Resolution AP (2004) 4 on rubber products intended to come into contact with foodstuffs was adopted in 2004 by the Council of Europe's Committee of Experts on Materials and Articles coming into Contact with Food. This document has an inventory list of additives within it and a small section that deals with breakdown products – N-nitrosamines and amines. This inventory list is described as Technical document No. 1 - List of substances to be used in the manufacture of rubber products intended to come in contact with foodstuffs. Rubber products must be manufactured from substances mentioned in that list and according to the conditions therein specified for each of the existing categories as set out in Article 5 of the Resolution. Rubber products also may contain other decomposition and reaction products as well as impurities originating from these authorized substances, provided that they don't endanger health, don't cause any unacceptable changes in the composition of food or deteriorate its organoleptic properties. The following requirements apply for each of the categories mentioned in article 5 of the Resolution [15]:

 Rubber products belonging to Categories I and II should comply with the restrictions laid down in "Technical document No. 1 and should not transfer their constituents to foodstuffs or food simulants in total quantities > 60mg/kg of food or food simulant (overall migration limit). They also should not contain detectable N-nitrosamines, N-nitrosatable substances and aromatic amines at the requested detection limits of respectively 0.01 mg/kg food or food stimulant (for N-nitrosamines) and 0.1 mg/kg food or food simulant (for N-nitrosatable substances) (Directive 93/11/EEC).



Rubber products belonging to Category III don't require any migration testing, except for those rubber products containing N-nitrosamines, N-nitrosatable substances and aromatic amines, and/or Category III substances with an SML in *"Technical document No. 1 – List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs".*

In addition, substances should be used only in amounts strictly needed for the manufacturing and performance of the rubber product. Moreover, if rubber is blended with plastics and/or other materials, the composition of these materials used in the blends should comply with relevant Council of Europe resolutions or European Union directives, or, in their absence, with relevant national regulations. Further, the rubber products should comply with the overall migration limit as well as with the relevant specific migration limits (SML). Notice that rubber products intended for repeated use should be subjected to tests according to Directive 2002/72/EC.

Besides Technical document No. 1, there exist 4 other documents applicable to rubber materials:

- "Technical document No. 2 Guidelines concerning the manufacture of rubber products intended to come into contact with foodstuffs", which lays down the requirements for verification of compliance with the quantitative restrictions.
- "Technical document No. 3 Good manufacturing practices of rubber products intended to come into contact with foodstuffs".

- "Technical document No. 4 Test conditions and methods of analysis for rubber products intended to come into contact with foodstuffs".
- "Technical document No. 5 Practical guide for users of Resolution AP (2004) on rubber products intended to come into contact with foodstuffs".

### **2.3.3.5 Hygienic requirements to be met by elastomers in contact with food**

Elastomers must be chemically resistant to fat, cleaning agents and disinfectants; they may not show expansion and shrinking under the influence of temperature changes or chemical fluids; they must be abrasion resistant (e.g., rotary shaft seals, or seals in static applications that are subjected to abrasion from dry material product); and they must retain their surface and conformational characteristics (no loss of elasticity, no embrittlement, no rubbed-off parts, no crevices, etc.). However, elastomers can be degraded by product, cleaning agents, disinfectants, thermal and mechanical stress, much earlier than metal components, with as results: leakage of lubricants, loss of bacteria tightness, increased adherence and retention of dirt and bacteria in crevices, insufficient cleaning and problematic disinfection. Partly destroyed sealings allow ingress of liquids containing chlorides under gaskets and seals, so that a high chloride concentration may subsist between damaged sealings and adjacent metal, which favours crevice corrosion even in stainless steel. Therefore, gaskets and seals preferably should be of a removable type. The resistant characteristics of several elastomers can be found in table 4 [5], [6].

	Materials of construction		De	tergei	nts or o	disinfec	tants		Foo	d Substa	nces	Physical factors			
		Mild alkaline	Alkaline	Strong alkaline	Alkaline + NaOCl	Alkaline + NaOCl + corrosion inhibitor	Mild acid + corrosion inhibitor	Mild alkaline disinfectant	Salt water	Acidic Food	Vegetable oil & Fat	Steam 125 <sup>0</sup> C	Hot Water	Cold resistance < -25 <sup>0</sup> C	Ozone
	Neoprene	3	3	3	1	1	1	3	3	3	1	3	3	3	1
s	Nitrile rubber (NBR)	2	2	2	2	2	2	3	3	2/1	3	0	3	3	1
me	Silicone rubber	3	3	3/2	3	3	3	3	3	2	2	1	3	3	3
Elastomers	EPDM	3	3	3	3	3	2	3	3	2	1	3/2	3	3	3
	Perfluor-elastomer (PFE)	3	3	3	3	3	3	3	3	3/2	3	3	3	1	3
	Styrene butadiene rubber	3	3	2	3	3	3	3	3	3/2	0	1	3	3	0

Table 4. Chemical and physical resistance of elastomers

Resistance rating	Resistance level	Contact medium	Definition
3	high resistance	highly suited for constant use	mechanically and visually not affected
2	good resistance	constant, but conditional use	mechanically not affected, visually slightly affected
1	low resistance	usable, but not continuously	mechanically and visually affected
0	no resistance	not usable at all	severe mechanically and visually damage



Typical rubbers used in the assembly of food processing equipment and services are:

- Natural rubber latex is obtained from rubber trees as a milky latex fluid (with small particles of rubber dispersed in an aqueous matrix). The mechanical properties of natural rubber, such as hardness and strength, can be influenced during the vulcanization with sulfur, as well as by addition of fillers and plasticizers. The tensile strength of the basic material obtained from rubber plants is already quite excellent, and the resilience of natural rubber is only surpassed by polybutadiene rubber. Natural rubber also shows very good damping behaviour and properties that makes it very suitable for dynamic applications. However, the long term service temperature only amounts 60 - 70°C. Natural rubber resists only slightly swelling in non-polar solvents, and even less in mineral oils. Also, its ozone resistance is guite poor. Natural rubber has about 1% of allergenic fraction of proteins (e.g., a-glubulins, hevein), that can cause allergic skin reactions. It is also possible to have hypersensitivity due to the chemicals added during its processing. Natural rubber found on the market is usually of the soft type, and is commonly used for car tires, gloves, spring elements, etc. [11], [12].
- · Silicone rubber elastomers (VMQ) combine excellent heat resistance with good resistance to hot air, ozone, UV radiation, engine and transmission oils, animal and vegetable fats. However, silicone rubber is not resistant to high-pressure steam. Silicone elastomers are suitable for operations at temperatures between -20 and 200°C (low- and high-temperature seals). Continuous short-term use at temperatures up to 230 °C is possible. However, due to its poor abrasion resistance, silicone rubber is not applicable in dynamic applications. Silicone compounds are very clean (no odour, no taste and no discolouration), making them suitable in many food applications. Silicone rubber is mainly used for seals, O-rings, gaskets, suction cups (pneumatics), conveyor belt coating and sheathing of cables. For use as food contact material in the food industry, resolution AP (99) 3 and Resolution AP (2004) 5 of the Council of Europe must be met [11].
- Thermoplastic polyurethane (TPU) elastomer has high tensile strength, high tear and abrasion resistance (the best of all rubbers) and high modulus of elasticity. The flexibility of thermoplastic polyurethane elastomer remains intact over a wide temperature range from 40 up to about 80 °C under continuous use, and also the low-temperature flexibility is excellent. In the presence of water, its properties remain unchanged up to the temperature of about 60 °C. At room temperature, thermoplastic polyurethane elastomer resists attack by diluted acids and alkalis, but it is affected by these chemicals at high

temperatures. Its resistance to hot water, steam and ethylene glycol is rather poor. The weathering resistance (e.g., ozone resistance) is good [11].

Thermoplastic polyurethane elastomer is approved for food contact purposes in the normal conditions of use, as laid down in Commission Regulation (EU) No. 10/2011. No peroxide residues must be detectable. Thermoplastic polyurethane elastomer is used for flat seals and gaskets (for example, in hydraulic applications and water disinfection installations that make use of ozone), gears, films, hoses, as conveyor belt coating, coating of grain silos, moulded wire and cable harness assemblies (because of its excellent electrical insulating properties).

 Styrene butadiene rubber (SBR) has rather low strength, but the addition of fillers to the base material may increase that strength. Its thermal resistance is rather low, about 70 0C. The chemical resistance of styrene butadiene rubber against many non-polar solvents, diluted acids and alkalis is excellent, but it swells in contact with oils and fats, although to a lesser extent than natural rubber. Further, styrene butadiene rubber has moderate ozone resistance [11].

Styrene butadiene rubber must be produced of approved starting materials and production aids within the acceptable limits of use, as laid down in Commission Regulation (EU) No. 10/2011. Finished products must not test positively for peroxides. Areas of application are tubes, hoses, gaskets, technical and anti-vibration mouldings, conveyor belt coating, as well as hygienic articles.

• Ethylene propylene diene monomer (EPDM) rubber is a ter-polymer with amorphous structure, made from ethylene, propylene and a diene-component (dicyclopentadiene (DCPD), ethyldiene norbornene (ENB) and vinyl norbornene). The diene-component allows vulcanization by sulfur or peroxide cures. Ethylene propylene diene monomer has good abrasion and tears resistance. EPDM elastomers are suitable for operations at temperatures between -45 and 150 <sup>o</sup>C. EPDM is sensitive to most organic oils and fats, or is only conditionally suitable. EPDM is resistant to diluted acids and alkalis, but not against concentrated acids. Ethylene propylene diene monomer (EPDM) rubbers may resist hot water and steam. Of all rubbers available on the market, EPDM has the best moisture and ozone resistance, and it also has excellent weather ageing resistance. Main applications are hoses, gaskets, O-rings, conveyor belts, silicone fluid systems, and electrical insulation [11].

For use in the food sector, starting materials and production aids (Ziegler-Natta or metallocene catalysts) are subjected to the Commission Regulation (EU) No. 10/2011. The migration limit of 1.0 µg/dm<sup>2</sup> for N-nitrosamines must not be exceeded. Further, independ-



ent of the contact time with food, the finished EPDM rubber products must not test positively for peroxides. EPDM rubber is approved by the FDA according to Code of Federal Regulations (CFR), Title 21, section 177.2600. For contact with dry food, as requirement, the EPDM rubber must be formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use. EPDM components intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

 Fluoro-elastomers (FKM), such as Viton<sup>\*</sup>, are a class of elastomers containing carbon-fluorine bonds besides carbon-hydrogen bonds. Their fluorine content varies between 66 and 70%. They are far more stable and about 30% stronger than elastomers of the hydrocarbon type (e.g., EPDM), for reasons that fluorine-carbon bonds are less vulnerable than hydrogen-carbon bonds. To cure fluoro-elastomers, commonly used cross-linkers are of the di-amine, peroxide or bisphenolic type. Fluoro-elastomers cured by means of peroxide don't meet the hygienic requirements imposed by the food and pharmaceutical industry [11].

On the exception of the perfluoro-elastomers, fluoro-elastomers allow maximum continuous service es temperatures of up to 210°C and short-term service temperatures of up to 280 0C. At the lower end of the temperature scale, they are suitable down to -20 0C. Fluoro-elastomers exhibit excellent chemical resistance in harsh environments, which spans considerable concentration and temperature ranges. They are chemical compatible with corrosive media such as mineral acids, solvents, hydrocarbons (e.g., petroleum oils), salt solutions, chlorinated hydrocarbons, etc., but are not suited for steam service. Fluoro-elastomers are used for tough sealing applications requiring extreme chemical resistance: O-rings, hydraulic seals, pneumatic seals, butterfly valve O-rings and seats, etc.

 Perfluoro-elastomers (FFKM), such as Kalrez<sup>®</sup>, which consist of polymer chains with only carbon and fluorine atoms and without any hydrogen-carbon bonds, have greater chemical and temperature resistance (range -25 up to 260 °C) than fluoro-elastomers. Perfluor-elastomers are resistant to most oxidizing agents, acids and alkalis, making them an excellent alternative in applications (e.g., sealing) where other rubber-types fail. They are more resistant to swelling and some types are not prone to oxidation up to 300 °C. Perfluoro-elastomers maintain their elastic properties over long periods and temperatures up to 315 °C. Perfluoro-elastomers are typically used for O-rings, pipes, plates, V-ring packing systems, flange gaskets and T seals for equipment and pumps in the area of aggressive media, etc. Some perfluoro-elastomers are particularly suitable for hot water, steam and vacuum applications [11].

Perfluoro-elastomers not only should meet the requirements of the FDA Code of Federal Regulations, Title 21, section 177.2600, but also those of FDA Code of Federal Regulations (CFR), Title 21, section 177.2400. The latter states that cured perfluoro-elastomers are suitable for repeated use in contact with nonacid food (pH above 5.0), if the monomers and substances used to produce cured perfluoro-elastomers are generally recognized as safe (GRAS) in food. Finished food contact articles containing cured perfluoro-elastomers shall be thoroughly cleaned prior to their first use in contact with food.

- · Polybutadiene rubber is a polymer formed in the polymerization process of 1,3-butadiene. Polybutadiene rubber is highly elastic, and has a very high degree of resistance to dynamic stress, retaining these properties even at extremely low temperatures. Polybutadiene rubber is suitable within a temperature range of -110 up to 95 °C. The low tensile strength can be improved by blending with natural rubber (NR) and styrene-butadiene rubber (SBR), while elasticity, abrasion and crack resistance can be improved at the same time. Polybutadiene rubber is used as substitute for natural rubber but in generally it has inferior properties. It is used for hoses and is the first choice for conveyor belts. The polymer contains no substances that may become a source of N-nitrosamines [11].
- Butyl rubber (BR) is a copolymer of isobutylene with a small amount of isoprene. Due to its low resilience, butyl rubber has excellent shock absorption and vibration damping capabilities. Butyl rubber also has a high coefficient of friction, and its elasticity is increased by long-term heating in the air up to 100 °C. These elastic properties are maintained down to -55 °C, which means that butyl rubber behaves well in cold environments down to -40 °C. Butyl rubber's low gas permeability makes it ideal for vacuum applications. Butyl rubber is also highly resistant to salt solutions, diluted acids and alkalis; and it is also not affected by oxidizing agents such as ozone, sodium hypochlorite, potassium permanganate and potassium dichromate. Its resistance to hot water and steam is also excellent, as well as its UV resistance. Butyl rubber is used for diaphragms, gaskets, hoses (transport of liquids, food gases, compressed air), liners, O-rings, water-proof and anticorrosion coatings, high pressure/vacuum sealing applications, cable insulation and glues [11]
- Polychloroprene rubber (CR), widely known as Neoprene<sup>\*</sup>, is a homopolymer of chlorobutadiene, that has relatively low compression set, good resilience, good fatigue, good tear, good abrasion and excellent flexural cracking resistance. It has excellent adhesion qualities to metals, for rubber-to-metal bonding applications. Polychloroprene rubber tends to slowly

absorb water, and its gas permeability is fairly low. Polychloroprene rubber is moderately resistant to weather (ozone, UV and oxygen), water and steam. It is resistant to diluted acids, alkalis and oxidizing agents. Polychloroprene rubber is also extensively used for sealing refrigeration fluids, due to its excellent resistance to Freon<sup>\*</sup> and ammonia. It also has better heat resistance (optimal service temperature is between -40 up to 121 °C) than natural rubber. Polychloroprene rubber is applied in belting, conveyor belts, coated fabrics, wraps, gloves, adhesives, hoses, seals, O-rings, gaskets, cable jackets, installations where ozone disinfection of water takes place, weather stripping, corrosion-resistant coatings, etc. [11].

Polychloroprene rubber, if pure (free of residual monomer and additives), is not classified as carcinogenic, but care must be taken for residual chloroprene monomer, as it is a highly reactive carcinogenic toxicant. Potassium persulfate which is often used as initiator is guite hazardous. Finished polychloroprene products must not test positively for peroxides. Metal oxides (e.g., zinc oxide, lead oxide) and thioureas that are used to crosslink individual polymer strands may cause toxic effects. The use of starting materials and production aids for polychloroprene rubber is subject to the Commission Regulation (EU) No. 10/2011. The limit of 1.0  $\mu$ g/dm<sup>2</sup> for N-nitrosamines must not be exceeded. Polychloroprene rubber is approved by the FDA according to Code of Federal Regulations (CFR), Title 21, section 177.2600. It must be thoroughly cleaned prior to its first use in contact with food [13].

 Acrylonitrile butadiene rubber, usually abbreviated as nitrile rubber (NBR), is a complex family of unsaturated polar copolymers of acrylonitrile and butadiene. Nitrile rubber has good mechanical properties and high tear, wear and abrasion resistance, but it is not resistant to weathering (e.g., UV light and ozone). Nitrile rubber shows excellent cold flexibility at -35 °C down to -60 °C, and heat resistance up to 121 °C. Resistance to dilute acids and alkalis is good, but strong acids may affect nitrile rubbers. Water resistance is excellent, but its sensitivity to steam is higher [11].

Acrylonitrile butadiene rubber is used for conveyor belts, coatings of conveyor belts, hoses, liners, O-rings, gaskets, bushings, diaphragms, adhesives, coatings for various rolls and chemical devices, cable jacketing, membranes, bellows, valves, shock and vibration absorbers, seals for all kinds of plumbing, hydraulic and pneumatic applications (due to its good abrasion resistance).

 Hydrogenated Nitrile Butadiene Rubber (HNBR) is obtained by partial or total hydrogenation of acrylonitrile butadiene rubber, providing it with superior tensile and tear strength, improved elongation, better abrasion resistance and compression set at elevated temperatures up to 165 °C (with peaks up to 190 °C). HNBR has excellent resistance to hot water, steam and many refrigerants. HNBR also has better resistance against oxygen and ozone and improved low temperature characteristics (still suitable for applications at -40 °C). Like EPDM, HNBR can either be cured with sulphur or peroxide, with the latter providing it with a better heat stability. It can be compounded for both low and high temperature use. Typical applications include diaphragms, O-rings, gaskets, rod and piston seals, refrigeration applications, etc. [11].

Fluoro-silicone, common name for fluorovinylmethyl silicone rubber (FVMQ), is an inorganic "hybrid" elastomer which combines the wide temperature range spectrum of silicone with some of the chemical resistance of fluorocarbon rubber. Fluoro-silicone rubber has low to fair tensile strength, high friction sensitivity, and poor abrasion and tear resistance, making it not suitable for dynamic applications (e.g., dynamic seals) and limiting its use to static seals. Fluoro-silicone rubbers are resilient, retain excellent flexibility at low temperature, and have excellent compression set resistance. They also have good resistance to diluted and concentrated acids and alkalis, oxidizing chemicals, ozone, ammonia, alcohol and water, but show some sensitivity to steam. Fluoro-silicone rubbers further have high and low temperature stability, allowing operations over a very wide range of temperatures from -60 °C up to 230 °C. Their resistance to weathering (e.g., sun light) is excellent, and their permeability to gases is poor. As they are clean and have low odour and taste, they are approved by FDA for food applications, such as diaphragms, gaskets, hose linings, O-rings, extreme low temperature static seals, etc. [11].

#### 2.3.4 Use of Composites

Composite materials generally comprise a matrix (e.g., thermoplastic or metal) carrying added fillers to improve lubricity, strength, thermal properties, impact resistance, etc. Strength will be improved by the addition of reinforcing materials (e.g., glass or carbon fibre) which commonly will be fibrous. They may be chopped short fibres or long fibres which may be woven. Lubricity may be modified by adding, for instance, PTFE granules, laminar minerals or metal oxides. Impact resistance may be modified by adding silicones.

The compatibility of any addition with the process environment must be assured. Components can react with certain wetting agents in detergents or food substances, which can be observed as porosity, increased surface roughness, absorption of flavours and taints, or by the fact that the material turns black. It has been suggested that, if the added fibres are sufficiently



small, porosity is not an issue as the pore dimensions should generally be smaller than virus sizes.

Woven composites could give rise to delamination problems, making that they are not used extensively at present owing to their susceptibility to break-up. However, special cases do exist, e.g. lined composite pipes. The use of carbon fibre could also help solve the problem [5], [14].

## 2.3.5. Use of Coatings

#### 2.3.5.1 Coatings for specific purposes

Originally, coatings were developed to allow components to function reliably for long periods under extreme operating conditions without maintenance. But coatings are also used for many other reasons:

- Protection of equipment and structures from the aggressive environment (e.g., harsh cleaning chemicals and disinfectants).
- To reduce friction between two contacting surfaces.
- Control of fouling by using microorganism repellent surfaces or coatings that leach biocides.
- Hydrophilic coatings are used to increase the surface wettability, allowing condensed moisture to be quickly shed from the equipment surfaces. Such coatings may delay frost formation on the fins of evaporators within still air and blast freezers.
- To improve the visibility, by accentuating certain equipment components or services.
- To provide a pleasant appearance, or to facilitate easy detection of dirt.
- To change the light intensity.
- To contain broken glass fragments within the protective lamp envelope of a coated lamp.
- To modify the chemical, mechanical, thermal, electronic and optical properties of materials.

## 2.3.5.2 Legislation

#### EU legislation

The Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food compromises only plastic food contact materials but no coatings. With respect to coatings, at EU level, the general principles of the framework regulation EC No. 1935/2004 need to be respected. Coatings may contain other substances than those authorized at EU level for plastics, provided they allow the final article to comply with article 3 of the Framework Regulation: no transfer of constituents to food in quantities which could endanger human health and change the composition and/or organoleptic characteristics of the food. Framework regulation (EC) No. 1935/2004 also re-quires GMP provision (see also GMP Regulation (EU)

No 2023/2006, section 2.1), traceability and control of release of migrants.

Framework Resolution AP (2004)1, which has replaced Resolution AP (96) 5, provides a list of approved starting materials and additives that may be used in coatings. The resolution also limits the sum of migrating substances (global, overall or total migration) to 10 mg/dm<sup>2</sup> (or 60 mg/kg). Whilst this Resolution has no legal status within the EU member states, it can be used to demonstrate 'due diligence' [15].

Also for coatings, Regulation (EC) No. 764/2008 on the Principle of Mutual Recognition is applicable. A substance that is listed in a national regulation can be marketed also in any other EU member state, provided the country of destination has not posed any bans or restrictions to this substance.

#### Legislation in the United States

In the United States, the FDA allows the use of a particular coating as a component of articles intended for food contact, if one or more of the optional substances are mentioned in Subpart B of the FDA Code of Federal Regulations (CFR), Title 21, parts 175.105 (Indirect Food Additives: Adhesives and Components of Coatings) and are used at the prescribed limitations. Another FDA Code of Federal Regulations (CFR) which may be relevant to coatings is Title 21, section 175.300, being Resinous and Polymeric Coatings, where direct food contact compliance allows direct contact with the coating.

## 2.3.5.3 Hygienic requirements

Coatings, if used, shall be free from surface delamination, pitting, flaking, spalling, blistering and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning, bactericidal treatment or sterilization. If the use of a coating is absolutely unavoidable, it should be of a contrasting colour that can easily be seen should a piece of it break off into the food, but the colourant used must also be food-compatible and must not adversely affect the properties of the coating material.

## 2.3.6 Use of Adhesives

#### 2.3.6.1 Definition of an adhesive

The "Association of the European Adhesive & Sealant Industry" (FEICA) defines an adhesive as a non-metallic substance capable of joining materials by surface bonding (adhesion by gluing) in a way that the final bond possesses adequate internal strength (cohesion).

Organic adhesives consist basically of organic polymeric binders of high molecular weight, which determine their adhesiveness (adhesion) and internal strength (cohesion). These organic binders are either of



natural (proteins, carbohydrates or resins) or synthetic origin (substances of the hydrogen-carbon type, and/ or compounds containing oxygen, nitrogen, chlorine, silicon and/or sulfur). Besides binders, an adhesive formulation also consists of one or more of the following additives: water or organic solvent carrier, plasticizers, biocides and fungicides for natural product adhesives, catalysts, emulsifiers, antioxidants, etc. These additives determine in particular the end use and processing characteristics. Inorganic adhesives are based on silicates, borates, phosphates or metal oxides [2], [11].

Either similar materials must be connected; either completely different materials must be connected, in e.g. glass with plastic or metal with ceramic material. Adhesives are in particular used for the bonding of plastics. Materials with a high surface energy (metals, glasses, ceramics and certain plastics such as PC or PVC) allow better adhesion than those with a low surface energy (rubber, silicone, PTFE, etc.). Materials with a high surface energy are held together by means of strong chemical bonds of the covalent, ionic or metallic type. Solids (rubber, silicone, PTFE, etc.) with low surface energy are held together essentially by physical forces (e.g., van der Waals and hydrogen bonds).

#### 2.3.6.2 Legislation applicable to adhesives

#### EU legislation

Chemicals (ingredients or reaction products) migrating from adhesives could cross the different layers of a plastic laminate and reach the food. With respect to adhesives, at EU level, the general principles of the framework regulation EC No. 1935/2004 need to be respected. Framework regulation EC No. 1935/2004 allows that adhesives may contain substances that are not listed in the Union-list, provided they allow the final article to comply with article 3 of the Framework Regulation and do not endanger human health. Besides article 3, the most important legal requirements from the Framework regulation (EC) No. 1935/2004 relevant to adhesives manufacturers are: GMP provision (see also GMP Regulation (EU) No 2023/2006, section 2.1), traceability and control of release of migrants.

Also for adhesives, Regulation (EC) No. 764/2008 on the Principle of Mutual Recognition is applicable. A substance that is not mentioned in the Union-list, but that is listed in for example the German Bedarfsgegenstände-verordnung only, can be marketed also in any other EU member state, provided the country of destination has not posed any bans or restrictions to this substance.

## EU resolutions and EU member state legislations and non-legally binding texts

Currently very little national legislation regulates adhesives specifically, and also positive lists relating to

other food contact material might be used to assess compliance. The relevant national legislation and restrictions should be referenced in the Food Contact Status Declaration. For substances in the adhesive that are neither listed in EU regulations nor in national legislation, reference can be made to non-legally binding texts such as: EFSA Opinions, German BfR Recommendations, Resolutions of the Council of Europe.

#### Legislation in the United States

In the United States, the FDA Code of Federal Regulations (CFR), Title 21, section 175.105 allows the use of a particular adhesive as a component of articles intended for use in packaging, transporting or holding food, if that adhesive is prepared from one or more of the optional substances mentioned in the list of "Approved Substances for Use Only as Components of Adhesives" (Subpart B of the FDA Code of Federal Regulations (CFR), Title 21, parts 175.105, Indirect Food Additives: Adhesives and Components of Coatings) at the prescribed limitations. Where Indirect Food Contact Compliance implies, the material is separated from food by another material (functional barrier).

#### 2.3.6.3 Hygienic requirements

An appropriate selection of the adhesive and the layers in between the food and the adhesive is needed. Adhesives must be nontoxic, and produced from substances that are generally recognized as safe for use in food. The constituents must be permitted for use in adhesives in contact with food by prior sanction or approval, and employed under the specific conditions of use prescribed by such sanction or approval. The recommended conditions of use should be communicated to the user within the Food Contact Status Declaration and/or via the technical documentation. To assure food safe usage of an adhesive, the container with finished adhesive must be provided with a label bearing the statement "food-safe adhesive".

The adhesives must be resistant to products and process conditions such as temperature. The user also must keep in mind that adhesives used for keeping gaskets in place can cause localized corrosion of stainless steel if not used according to the supplier's specification. All bonds must be continuous and mechanically sound, which means that glued layers must be firmly bonded without any visible defects such as microscopic crevices that can form a niche for microorganisms and/or product residues and can hamper proper cleaning. Under normal conditions of use, the adhesive will remain firmly bonded to the base materials without visible separation [11], [14].



#### 2.3.6.4 Application of adhesives

In certain cases, the structure or microstructure of the materials to be joined must be changed in the area of contact (e.g., to join plastics they usually must be partially dissolved), while in other cases the surface structure may remain unchanged (e.g., to join ceramics and metals). In a first stage, to activate the surfaces that must be joined; the surface wetting must be improved by degreasing and cleaning with solvents, cleaning solution or steam. Quite often, also the roughness must be increased, which can be done either mechanically (e.g., by blasting or grinding), either chemically (e.g., by pickling or dissolving) or physically (e.g., heat treatment). Also ionization procedures such as coronary discharge between electrodes positioned in the air flow and pre-treatment with adhesion promoters have proven to be effective in the roughening of plastic surfaces.

## 2.3.7 Use of Other Materials

## 2.3.7.1 Glass

Glass is transparent, and may occasionally be used as a food contact surface (e.g., light and sight glasses into vessels, and in very limited extent glass piping). For such applications, glass should be nontoxic (glasses containing lead are not allowed in the food contact area), integral (homogeneous and continuous), impervious, inert (nonabsorbent, resistant to degradation, and insoluble by process or cleaning fluids), smooth (free of cracks, crevices and pits), durable (robust, heat resistant, resistant to scratching, scoring and distortion when exposed to bioprocessing fluids). Glass shall be rated for the applicable pressure and temperature range, as well as for thermal shock. Bubbles at the glass surface are not accepted. Notice however, that the surface of glass is not completely smooth. It rather has a rough surface made of peaks and pit holes that can be filled with organic and inorganic contaminants. When these impurities react chemically with the glass, the glass easily may become stained and discoloured. Glass also may become prone to hydrolytic and chemical attack by certain alkali and acid solutions, which even can make the glass surface much rougher. Resistance to water and/or acid/alkaline solutions varies from excellent to poor depending on the composition of the glass. It is important to choose the right type of glass.

In most cases, the use of glass is not recommended because it is also brittle, may break and cannot endure thermal cycling. Replacement of glass by transparent alternatives like Perspex (poly methyl methacrylate) or polycarbonate is recommended [8], [11].

## 2.3.7.2 Ceramics

#### Properties

Ceramics are produced by the fusion and hardening of mineral substances. Fired at high temperatures, they become pressure, temperature, abrasion, high-temperature corrosion and erosion-corrosion resistant. They may reduce friction and wear; but are brittle (they rather break than bend) and weaker in tension. However, by adding small amounts of long organic polymers, less brittle and less prone to fracture, more flexible organo-ceramics can be obtained. In general, ceramic materials are also very resistant to acids and sufficiently resistant against lye.

## Application

Ceramics are more and more employed in the food industries due to their resistance to extreme operating and cleaning conditions. They are used in the coating of other stable materials, in the production of ceramic membranes and in the construction of processing equipment for very sensitive products.

#### Hygienic requirements

To meet all applicable hygiene criteria, ceramic materials must be/have [11]:

- Inert.
- Nonporous and non-absorbent. To prohibit any porosity, ceramic pieces should be fired to their full maturity so that ceramic particles melt together enough to form a waterproof surface. When not correctly fired, ceramic pieces may remain porous, enough to let fluids penetrate the surface and soak into the ceramic material.
- Smooth, unbroken surfaces, entirely free of crazing (small hairline cracks) and blemishes, including the lip of recipients. Crazing may compromise the strength of the ceramic body, and may allow bacteria to hide in the hairline cracks. Even low doses of bacteria can become a large culture in the food. Moreover, ceramic bodies that absorb liquids via the cracks become less durable and will retain heat more if subjected to heating. Cracks also incline to release toxic materials from the ceramic body much easier.
- Resistant to scratching, scoring and distortion when exposed to the conditions encountered in the environment of intended use (harsh cleaning chemicals and disinfectants, sterilization).
- Nontoxic, free of leachable lead, cadmium and other potentially toxic heavy metals. Compounds of nickel, chrome, cobalt, antimony and manganese (most often their metal oxides) are often used, and they are known to cause health problems, especially when used in large quantities. Other metals that could be problematic are barium and lithium, which



commonly are found in their carbonate form and may leach into (especially acid) foods or liquids. Any barium ingested can lead to severe abdominal pain, nausea, diarrhea, vomiting, muscle weakness, muscle cramps and heart problems, and in a worse case difficult breathing, high blood pressure, tachycardia and possible death. Lithium carbonate is fairly safe but some people take lithium carbonate for mental problems.

- Good thermal shock resistance must allow the ceramic piece to withstand sudden temperature changes without cracking.
- The ceramic material shall have good acid and alkali resistance.

#### 2.3.7.3 Wood

As it is inexpensive and durable, wood (hard marple, ash, basswood, beech, birch, butternut, cherry, oak and American black walnut) has been a traditional material for many applications in the food industry: ice cream sticks, cutting boards, vegetable and fruit boxes, pallets, etc. In the American regulations, hard maple or an equivalently hard, close-grained wood may be used for cutting boards, cutting blocks, butcher's blocs, bakers tables and utensils such as rolling pins, chopsticks, etc. Because of the high acidity and salt content of brines in some products, which can cause severe corrosion problems even for expensive metallic construction materials such as stainless steel, fermentation tanks and storage containers in wood are still accepted in the food industry for wine, pickles and olives.

However today, the usage of wood in the food industry remains under debate. The reason for the negative attitude towards wood seems to be caused by the food legislation and the interpretation thereof in Europe and elsewhere. Wood is out of grace because of hygienic and mechanical strength problems: risk of splinters, porosity of wood (promotes the absorption of blood, fat and moisture), difficulties to keep it smooth and free of cracks, difficulties to keep it clean and hygienic due to the lack of cleaning and/or sanitation methods, etc. Moreover, strong and oxidizing acids and diluted alkalis may attack wood. To avoid pest infestations and the growth of moulds with concomitant production of mycotoxins, wood in contact with food is also often treated with pesticides and fungicides. Control for the presence of residual levels of these fungicides and pesticides in the food in contact with the wood should be performed [16], [17].

In conclusion, the use of wood is not really recommended. On some exceptions, wood is certainly not allowed within the product contact area, and should not be exposed to the outside. It must be permanently and tightly sealed off from the product zone.

#### 2.3.7.4 Insulation

Thermal insulation must be adequate to maintain the heat or cold within given equipment. Non-chloride-releasing insulation material should be used, that does not absorb and retain water. Styrofoam, foam glass or another rigid foam are better choices over fibrous materials. The problem with fibreglass batting is that it has already proven to be an excellent harbourage of dust, insects and rodents. The insulation should not be exposed to the outside but must be permanently and tightly sealed off from the product zone. It is highly recommended to install fully welded, vapour tight, plastic, aluminium or stainless steel cladding of appropriate thickness that resists tear and abrasion. The exterior of the insulation protection should be smooth, and installed in a correct way to avoid dust traps, for example, joints should face downwards. It should be impossible to walk on the insulation during maintenance. Pipe cladding should be applied in both dry and wet areas. Asbestos shall never be used as insulation material as it may cause lung and peritoneum mesothelioma [6].

#### 2.3.7.5 Nanomaterials

The use of nanomaterials in the food industry may present potential risks, requiring the need for risk assessments to identify and quantify these risks. Some nanoparticles have been found to exhibit negative effects on tissues such as inflammation, oxidative stress and signs of early tumour formation [18].

#### 2.3.7.6 Antimicrobial compounds

The European Hygienic Engineering & Design Group clearly states that materials which have been modified with antimicrobial chemicals may not be considered as a substitute for hygienic design or cleaning/disinfection practices. Microorganisms may build up resistance against such chemicals over a period of time, and antimicrobial chemicals may gradually leach out of the surface material with time. Antimicrobial nanoparticles may create adverse health effects as shown in several scientific papers.

## 3. Conclusions

- This text gives an overview of the regulations and hygienic requirements that materials of construction commonly applied in the manufacturing of food processing equipment and services must meet, with further emphasis on their suitability in either the food-contact or non-food contact zone, in an environment where harsh chemicals are used to clean and disinfect.

- In this paper can be found different materials of construction, specific problems with respect to their



hygiene, inertness, physical characteristics, and chemical and thermal resistance which can be used by all individuals working with food contact materials and with materials of construction.

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