

Summary of terms and definitions relevant to food contact

Over the last couple of years, the number of expert terms used in food contact has increased. Especially in the beginning, this number might be intimidating and the exact definitions, while vital, are not necessarily clear. An additional obstacle is, that the definitions of terms are spread over several documents and it is time consuming to look them up.

This document intends to provide an overview over the most commonly used terms, their definitions and where those were derived from. The vast majority of terms are defined in either legislations or official guidance documents. Nevertheless, some terms that are commonly used have no official definition. For these, found in a separate table, a definition is provided based on the expert opinion of the members of the PlasticsEurope Food Contact Experts group.

These definitions are provided to the best of our knowledge but are not legally binding in any way.

Definitions based directly on official texts

	Definition	Reference
Business operators		
Business operator	Natural or legal person responsible for ensuring that the requirements of the Framework Regulation 1935/2004 are met within the business under their control.	Regulation 1935/2004 (Article 2)
Supply chain	All business operators, including food business operators who directly or indirectly participate in the production, converting, distribution and use of materials and articles intended to come into contact with foods, such as ingredient suppliers, raw materials manufacturers, converters, food packers and retailers.	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2) (English) other languages
Substance manufacturer	A “ substance manufacturer ” is any operator, who manufactures or produces a chemical substance.	
Manufacturer of plastic intermediate materials	A “ manufacturer of plastic intermediate materials ” is any operator who uses the chemical substances or mixtures of them and processes them into the intermediate products. In this context, processing	

	means any type of chemical reaction including polymerization, as well as physical processes e.g. blending, drying, mixing, etc. if it results into intermediate materials. Also included here is the manufacturing of films, sheets, laminate, pre-forms etc which are not the final plastic material and article, by processes such as extrusion, lamination, injection moulding.	
Manufacturer of non-plastic intermediate materials	A “ manufacturer of non-plastic intermediate materials ” is any operator who uses the chemical substances or mixtures of them and processes them into intermediate products.	
Manufacturer of final materials and articles	A “ manufacturer of final materials and articles ” is any operator who uses chemical substances and/or intermediate materials to manufacture final materials or articles. The manufacturing processes in this stage are very diverse and include chemical processes (e.g. mixing of reactive ingredients) as well as physical processes e.g. extrusion, laminating, blow-moulding, injection moulding, printing, coating, calendaring, thermoforming, and stretch blow moulding.	
User of food contact materials and articles	A “ user of food contact materials and articles ” is any operator or person who puts food or food ingredients/intermediates in contact with a final material or article. This includes the food industry and their ingredient suppliers, retailers with an additional role of user, and food vendors (catering, restaurants, canteens, baker/butcher stores and other food outlets). Included here are operators who carry out assembly operations (e.g. bottle& cap etc.) before or during putting the material or article in contact with food, as well as other processes needed for packing/filling. Examples are e.g. sealing, coding, applying a label, capping a bottle, pasteurisation or sterilisation of the packed food, etc. Users of food contact materials who sell food to consumers have an additional role as “retailers”.	Union guidance document on Regulation 10/2011 for information in the supply chain (section 3.2) (English) other languages
Distributor	A “ distributor ” is any operator who supplies products to a business operator without having manufactured the product himself. If the operator is selling to consumers, he has the role of a retailer instead. Distribution terminals of supermarkets and wholesale outlets are covered by the term “retailers”. Depending on the country of origin of the products sold, the distributor may additionally have the role of importer.	

Importer	An “importer” is any business operator who releases or intends to release into free circulation in the EU goods from countries or territories not forming part of the customs territory of the EU. Purchasing from a representative of the third-country seller located within the customs territory of the EU, is not importing; instead the representative would be the importer. Purchasing from a seller located in another country within the customs territory of the EU is not importing; instead the purchaser may have the role of a distributor or any other role, depending on his activities.	
Retailer	A “retailer” is a business operator selling final plastic materials and articles (with or without food) only to the final consumer. It includes distribution terminals of supermarkets and wholesale outlets. If the operator is selling to a business operator, then he has the role of a distributor instead.	
final consumer	A “final consumer” is not a business operator, but a private person buying food or food contact materials and articles, or the two combined as packaged foods, from a retailer or “user”. The consumer should follow the instructions of use.	
Food contact materials & articles		
Food contact material and article	Materials and articles, which, in their finished state <ul style="list-style-type: none"> • are intended to be brought into contact with food; or • are already in contact with food and were intended for that purpose; or • can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use. 	Regulation 1935/2004 (Art 1.2)
Active food contact materials and articles	Materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.	Regulation 1935/2004 (Art 2.2)
Intelligent food contact materials and articles	Materials and articles which monitor the condition of packaged food or the environment surrounding the food.	Regulation 450/2009 (Art 3)

Rev 18/08/2020

Single use articles and materials	An article intended to be used once and coming into contact with not more than a single portion of food stuffs during its lifetime. (Food packaging should be regarded as single use article, even if the consumer may re-use it. This includes, for example, lids for jars).	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2) (English) other languages
Repeated use articles and materials	An article intended to be used several times that comes into contact with different portions of foods during its lifetime. For example, kitchenware, reusable containers or components of packaging machinery.	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2) (English) other languages
Plastic	A polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles.	Regulation 10/2011 (Art 3(2))
Intermediate plastic material	A product from intermediate stages of manufacture” e.g. a plastic powder, granules or flakes (including “masterbatch”), pre-polymer excluding Article 6(3)(d) of the Plastics Regulation, any semi-finished material and article such as a film, sheet, laminate, etc. requiring further processing/re-formulation steps to become a “finished” material or article	Union guidance document in Regulation 10/2011 for information in the supply chain (Section 3.1b-d) (English)
Intermediate non-plastic material	An ink, a coating or an adhesive formulation applied in the printing or coating of plastic articles or in combining of plastic layers. They still require application on the plastics and may require drying or curing. The composition may change due to reaction and degradation.	
Final plastic material or article	A plastic material or article ready to go into contact with food, but not yet in contact with food	other languages
Blend	A mixture of plastics in the same physical state, each of which is capable of functioning as a main structural component of finished materials and articles	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2) (English)
Masterbatch	A preparation of one or more polymers which encapsulate a high concentration of ingredients like colorants, fillers, fibres or stabilizers that influence the physical properties of the final preparation. A master batch is intended to be blended with a polymer and not used to make an article as such.	

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Rev 18/08/2020

Layer	A homogenous continuous or semi-continuous material of defined composition that is extended in two dimensions separated by an interface from another homogenous continuous or semi-continuous material of a defined but different composition.	other languages
Functional barrier	A barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation.	Regulation 10/2011 (Art 3(15))
Food-contact-side	The surface of a material or article that is directly in contact with food	COMMISSION REGULATION (EC) No 2023/2006
Non-food-contact-side	The surface of a material or article that is not directly in contact with food	COMMISSION REGULATION (EC) No 2023/2006
Plastic multi-layer	A material or article composed of two or more layers of plastic.	Regulation 10/2011 (Art 3(4))
Multi-material multi layers	A material or article composed of two or more layers of different types of materials, at least one of them a plastic layer.	Regulation 10/2011 (Art 3(5))
Coating	<p>A non-self-supporting layer composed of substances applied on an already existing substrate in order to impart special properties or improve technical performances of the finished article.</p> <p>o "Inorganic surface coating" means a non-self-supporting layer composed of inorganic substances applied on an already existing substrate, e.g. a silicon dioxide coating.</p> <p>o "Organic surface coating" means any resinous or polymerised preparation which is converted to a thin, solid polymer layer used to provide a functional effect on a surface and which is not capable of acting by itself as a main structural component of a final material and article.</p>	<p>Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2)(English)</p> <p>other languages</p>
Adhesive	A non-metallic substance capable of joining materials by surface bonding (adhesion), and the bond possessing adequate internal strength (cohesion).	Union Guidelines on Regulation (EU) No 10/2011

Rev 18/08/2020

		(Section 2.2)(English) other languages
Printing ink	Mixtures of colorants with other substances which are applied on materials to form a print design on this material.	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2)(English) other languages
Ion exchange	Ion exchange and adsorbent resins, made of synthetic organic macromolecular components, which can be used in the processing of foodstuffs to bring about exchange of ions or adsorption of foodstuffs constituents. They do not include, however, cellulosic ion exchangers.	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2)(English) other languages
Silicones	Silicones constitute a group of polymeric chemical substances and preparation, all containing polysiloxanes. Polysiloxanes are characterized by Si-O-Si bonds.	AP(2004)5 BfR XV
Silicone rubbers/elastomers	Silicone rubbers or elastomers means macromolecular substances or materials based on organopolysiloxanes and which are crosslinked forming a three-dimensional network having elastomeric or rubber-like properties	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2)(English) other languages
Substances		
(Chemical) substance	Any basic chemical ingredient to be used in the further manufacturing of materials which are further used in the manufacturing of plastic materials and articles intended for use in contact with food.	Union guidance document in Regulation 10/2011 for

Rev 18/08/2020

		information in the supply chain (Section 3.1a)(English) other languages
Monomer or other starting substance	<ul style="list-style-type: none"> a substance undergoing any type of polymerisation process to manufacture polymers; or a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or a substance used to modify existing natural or synthetic macromolecules 	Regulation 10/2011 (Art 3(6)+(7))
Additive	A substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article.	
Dual-use additives	Additives which are covered by a listing in the Union list and which are also listed as food additives or flavourings in Regulations (EC) No 1333/2008 and (EC) No 1334/2008 and their implementing measures	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2)(English)
Polymeric additive	A polymer which is used as an additive having a physical or chemical effect in the plastic and which cannot be used in the absence of other polymers as a main structural component of finished materials and articles.	other languages
Aid to polymerization (AP)	A substance which initiates polymerization and/or controls the formation of the macromolecular Structure	Regulation 10/2011 (Art 3(10))
Polymer production aid (PPA)	Any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article.	Regulation 10/2011 (Art 3(8))
Non-intentionally added substances (NIAS)	An impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product.	Regulation 10/2011 (Art 3(9))
Nano substances	Substances in nanoform" refers to nanomaterials as defined in Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of	

Rev 18/08/2020

	<p>nanomaterial. This Recommendation defines a nanomaterial as a natural, incidental or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and, where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.</p> <ul style="list-style-type: none"> o 'particle' is defined as a minute piece of matter with defined physical boundaries; o 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components; o 'aggregate' means a particle comprising of strongly bound or fused particles. <p>Remark: Once discussions are concluded on how to implement in the food area the definition of nano materials included in the Recommendation, an amendment to the Plastics Regulation will be proposed, taking into account the definition in the food area and the specific requirements of the food contact materials sector.</p>	<p>Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2)(English)</p> <p>other languages</p>
Surface biocide	a substance intended to keep the surface of a material or article free from microbial contamination, but which is not intended to have a preservative effect on the food itself.	
Oligomer	A substance consisting of a finite number of repeating units which has a molecular weight of less than 1000 Da.	<p>Union Guidelines on Regulation (EU) No 10/2011 (section 2.2)(English)</p> <p>other languages</p>
MOH MOSH MOAH POSH	Mineral oil hydrocarbons Mineral Oil Saturated Hydrocarbons Mineral Oil Aromatic Hydrocarbons Poly Olefin Saturated Hydrocarbons	EFSA- CONTAM opinion on mineral oil hydrocarbons in food (2012)
Pre-polymer	A polymer of relatively low molecular weight, usually an intermediate between the monomer and the final polymer or resin	Union Guidelines on Regulation (EU) No 10/2011

Rev 18/08/2020

		(section 2.2)(English) other languages
Polymer	Any macromolecular substance obtained by: <ul style="list-style-type: none"> • a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or • chemical modification of natural or synthetic macromolecules; or • microbial fermentation 	Regulation 10/2011 (Art 3(3))
Direct food additive	any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods The following are not considered to be food additives: ... (iii)substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods;	Regulation (EC) No 1333/2008
Indirect food additive	ingredients of food, through migration from their immediate wrapper, container, or other food-contact surface any food additive substance that may be added to food as a result of use in articles that contact food	FDA 21 CFR § 186.1 FDA 21 CFR § 174.5
Restrictions, specifications		
Specification	A composition of a substance, purity criteria for a substance, physico-chemical characteristics of a substance, details concerning the manufacturing process of a substance or further information concerning the expression of migration limits	Regulation 10/2011 (Art 3(18))
Restriction	A limitation of use of a substance or migration limit or limit of content of the substance in the material or article	Regulation 10/2011 (Art 3(17))

Rev 18/08/2020

Specific migration limit (SML)	The maximum permitted amount of a given substance released from a material or article into food or food simulants	Regulation 10/2011 (Art 3(13))
Total specific migration limit (SML(T))	The maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated	Regulation 10/2011 (Art 3(14))
QM	The maximum permitted residual content of a substance in the final material or article expressed as weight per weight concentration in the final article.	Union Guidelines on Regulation (EU) No 10/2011 (Section 2.2)(English) other languages
QMA	The maximum permitted residual quantity of a substance in the final material or article expressed as weight per surface area of the article in contact with food.	
Overall migration limit (OML)	The maximum permitted amount of non-volatile substances released from a material or article into food simulants	Regulation 10/2011 Art 3(11)
Migration testing		
Migration modelling	A calculation of the specific migration level of a substance based on the residual content of the substance in the material or article applying generally recognized diffusion model. These are based on scientific evidence overestimating real migration and taking into account the Guidance document on migration modelling.	Union Guidelines on Regulation (EU) No 10/2011 (section 2.2)(English) other languages
Migration test	The determination of the release of substances from the material or article either into food or into a food simulant.	
Hot fill	'Hot-fill' means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.	Regulation 10/2011 (Art 3(19))
Set-off	Phenomenon of the transfer of substances from outer layer of materials and articles to the inner food contact layer through direct contact and not via diffusion through the material. Set-off may occur, where there is	Union Guidelines on Regulation (EU) No 10/2011

Rev 18/08/2020

	a contact between the outside and inside of the material or article during, for example, storage or transport. Such direct contact may occur when materials are wound in reels or stacked in sheets or when articles such as trays and pots are nested inside each other. Unlike migration under these conditions, set-off may occur in both materials and articles with or without a functional barrier.	(section 2.2)(English) other languages
Food simulant	A test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials	Regulation 10/2011 (Art 3(12))
Fatty food	A food for which in migration testing food simulants D1 or D2 are laid down in Table 2 of Annex III to this Regulation	
Non-fatty food	A food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table 2 of Annex III to this Regulation	Regulation 10/2011 (Art 3(16))
Fat (consumption) Reduction factor (FRF)	A factor between 1 and 5 by which measured migration of lipophilic substances, as indicated in Annex I of the Plastics Regulation, into a fatty food or simulant D1 or D2 and its substitutes shall be divided before comparison with the SML's.	Union Guidelines on Regulation (EU) No 10/2011 (section 2.2)(English) other languages
Good Manufacturing Practice		
Good manufacturing practice (GMP)	Those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof.	
Quality assurance system	Means the total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.	Commission regulation (EC) No 2023/2006 (Art 3)

Rev 18/08/2020

Quality control system	The systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system.	
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Definitions derived using expert interpretation

	Definition	Reference
Substances		
Non-listed substances (NLS)	Substances that are intentionally used but which are not listed/exempted from listing in Annex I of Regulation No 10/2011	Regulation 10/2011 (Art 6)
Non-listed substances (NLS) subject to Art 19	Substances that are subject to Art 6(1), 6(2), 6(4), 6(5) and 14(2) of Regulation 10/2011	
Production or Processing aids	<u>Paper:</u> Substances and polymers used in the manufacturing of paper and board <u>Rubbers:</u> Substances that might be added to starting materials in the manufacturing of finished products <u>Plastics:</u> Polymerisation aids used in the manufacturing and processing of polymers	Bfr XXXVI Bfr XXI BfR III
Polymerisation aids	Aids to polymerization (AP) and Polymer production aids (PPA)	UBA KTW guideline (section 2.1)
Food contact materials & articles		

Rev 18/08/2020

Direct food contact material	A subset of Food Contact Materials. A direct food contact materials is defined as a material that is intended to be, or can foreseeably be, in direct physical contact with food.	Term most frequently used in the area of printing inks. For additional information see for instance the EUPIA “Manufacturing Practices (GMP) : Printing Inks for Food Contact Materials”
Indirect food contact material	A subset of Food Contact Materials where the material is used on the non-food-contact surfaces of food packaging and articles intended to come into contact with food. There is a potential for migration of components from this material.	Term most frequently used in the area of printing inks. For additional information see for instance the EUPIA “Manufacturing Practices (GMP) : Printing Inks for Food Contact Materials”
Direct food contact layer	The layer of a material that is directly in contact with food	
Indirect food contact layer	The layer of a material that is not directly in contact with food	
Compliance testing		
Maximum migration calculation /worst case migration calculation	Calculated theoretical maximum possible migration. 100% migration, refinements are possible if the parameters are known.	Regulation 10/2011 (Annex V section 3.4.1)
Substitute overall migration tests	When simulant D2 can technically not be used as simulant, an overall migration test can be carried out with a food simulant substitute, e.g. ethanol 95 % and isooctane and/or simulant E depending on the testing conditions needed.	Regulation 10/2011 (Annex V 3.2 +3.4.2)

Rev 18/08/2020

<p>food simulant substitute</p>	<p>a simulant which is not defined in table 1 of Annex I of Regulation (EU) No. 10/2011 and that either can be used in migration tests in case it is not technically feasible to perform one or more of the tests according to OM1 to OM6 in food simulant D2 or are allowed to screen for specific migration, provided it is based on scientific evidence that the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2. Ethanol 95 % ((v/v) and isooctane are regarded as substitute food simulants”</p>	<p>Regulation 10/2011 (Annex V 2.2.4 +3.4.2)</p>
<p>Food simulant D2 Reduction Factor (D2RF)</p>	<p>A correction factor for dividing migration test results, before comparing the results with the migration limit, for types of food indicated in sub-column D2 of Table 2 of Annex III with a cross followed by an oblique stroke and a figure.</p>	
<p>Total reduction factor (TRF)</p>	<p>Combination of correction factors D2RF and FRF $TRF = DRF \times FRF \leq 5$ A combined correction factor for dividing specific migration test results, before comparing the results with the migration limit, which may be performed when testing is performed in food simulant D2 and when the test results are corrected with the D2RF in Table 2 of Annex III. The combined TRF factor shall not exceed 5</p>	<p>Regulation 10/2011 (Annex V section 4.1 or 4.2) JRC Guidance document on fat reduction factor (2011) Draft JRC technical guidelines for compliance testing (2016) – Chapter 7.2 +7.4</p>
<p>Union cube / Euro cube / EU food packaging cube</p>	<p>Theoretical food package, consisting of a surface of 6 dm² per 1kg of food used as conventional surface area /volume ratio. Can be used for worst case calculations if no further parameters are known.</p>	<p>Regulation 10/2011 (Annex V section 4.2)</p>

Rev 18/08/2020

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