EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food chain
Innovation and sustainability

Brussels, 21.02.2014

Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

This document is presenting the outcome of discussion in the working group of governmental experts on food contact materials.

This guidance was presented to and endorsed by the Member States in the Standing Committee section Toxicological Safety on the Food Chain of 20 February 2014.

The guidance is aimed at European Professional Organisations and Member States competent authorities dealing with questions concerning the interpretation and implementation of the provisions included in Regulation (EU) 10/211.

This document is made available on the DG Sanco website on food contact materials: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

Disclaimer: This document, drawn up by the services of the Directorate-General for Health and Consumers, is not binding on the European Commission as an Institution. Please note that this document cannot provide a formal interpretation of European Union law in relation to specific situations. It does also not provide legal advice on issues of national law.

For questions to this document, please contact SANCO-FCM@ec.europa.eu

TABLE OF CONTENTS

1 Introduction

1.1 Purpose of the Guidance document

This Guidance document is part of a series of documents to provide guidance on application of Regulation (EU) No 10/2011[1] on plastic materials and articles intended to come into contact with food (the "Plastics Regulation"). The series covers the present general guidance, guidance on migration testing (in preparation), guidance on migration modelling[2] and guidance on information in the supply chain[3].

This Guidance document covers general aspects of the Plastics Regulation. It is structured in the same manner as the Plastics Regulation itself. It contains in particular:

- explanations on what is covered by the Plastics Regulation and what is not,
- definitions of terms that relevant in the context of food contact materials and articles,
- function categories of additives and polymer production aids,
- explanations which substances are included in the Union list,
- explanations why substances are exempted from inclusion in the Union list and applicable provisions for these substances,
- status of biocides in plastic food contact materials and articles,
- explanations on dual use additives and an indicative list of dual use additives,
- explanations on the transitional provisions.

The Plastics Regulation is a specific measure for plastic food contact materials and articles adopted pursuant Article 5 of Regulation (EC) No 1935/2004[4] on materials and articles intended to come into contact with food (the "Framework Regulation"). It consolidates the previous Directives on plastic food contact materials and articles into one Regulation and simplifies the rules applicable to them.

2 Chapter I – General provisions

2.1 Subject matter and scope

The Plastics Regulation applies to plastic materials and articles as set out in the scope.

Plastic materials and articles include the following types of products:

- plastic intermediate materials (e.g. resins and films for further conversion) and those which already have their final composition, but still require mechanical re-shaping to reach their final article shape, without any modification of the formulation (e.g. thermo-formable sheets and bottle pre-forms);

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

[2] "*Applicability of generally recognised diffusion models for the estimation of specific migration in support of Directive 2002/72/EC*" http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m/guidance-documents.

[3] *"Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain"* http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/guidance_reg-10-2011_en.pdf.

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

- final plastic food contact material or article ready to come into contact with food (e.g. packaging material, food storage container, kitchenware or utensil, plastic part in food-processing machinery, food preparation surface, inner surface of fridge, baking trays);
- finished plastic components of the final food contact material or article which only need to be brought together or assembled, either during packing/filling or before, to make the final article (e.g. bottle and cap, tray and lid, parts of kitchenware or food processing machinery);
- plastic layers inside a finished multi-material multi-layer.

Plastic materials covered by the scope of the Plastics Regulation are based on synthetic polymers and synthetic or natural polymers that have been chemically modified. Natural polymers that have not been chemically modified are not covered by the scope of the Plastics Regulation. The Plastics Regulation also covers plastics based on polymers manufactured by microbial fermentation.

The Plastics Regulation covers bio-based and bio-degradable plastics if they are manufactured with synthetic polymers, chemically modified natural or synthetic polymers or polymers manufactured by microbial fermentation. For example, a material based on modified starch is covered by the scope of the Plastics Regulation, while a material based on natural macromolecule that is not chemically modified, such as non-modified starch, is not covered by the scope of the Plastics Regulation. Adding an additive to a natural macromolecule is not a chemical modification. The chemical modification has to occur to the macromolecule itself.

Plastics manufactured with the use of monomers or oligomers obtained by the so-called "chemical recycling" processes and manufactured with the use of production scraps are also covered by the Plastics Regulation. Plastics manufactured with recycled plastics from mechanical recycling processes are also covered by Regulation (EC) No 282/2008[5] on recycled plastic materials and articles intended to come into contact with foods, with the exception of those separated from food by a functional barrier layer.

The definition of plastics[6] in Article 3 (2) of the Plastics Regulation is quite broad. Following this definition, in principle rubber, silicones and ion exchange resins would be within the scope of the Plastics Regulation. However, as the provisions set out for plastics are not necessarily applicable to these materials and they may, in time, be covered by other specific measures, those other materials mentioned above are in Article 2 (2) explicitly excluded from the scope of the Plastics Regulation.

Plastic materials and articles are covered by the scope of the Plastics Regulation when they are coated with an organic or inorganic coating or when they are printed. Plastic materials are covered by the scope of the Plastics Regulation when they consist of several plastic layers which are bound together by adhesives. However, the rules set out in the Plastics Regulation for printing inks, adhesives and coatings used in plastics are only those with regard to their contribution to the migration from the plastic material and article. The Plastics Regulation does not set compositional requirements to printing inks, adhesives and coatings[7]. Rules for

[5] Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended t come into contact with foods and amending Regulation (EC) No 2023/2006, (OJ L 86, 28.3.2008, p.9).

[6] "Plastic" means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of the final materials and articles.

[7] Except for those coatings which form gaskets in caps and closures that are explicitly listed in Article 2 (1) (d) as falling within the scope of the Plastics Regulation.

these materials would have to be set out in separate specific Union measures. Until that date, they are covered by national measures.

The Plastics Regulation does apply to plastic layers, even if these layers are bound together with layers of other materials to form a multi-material-multilayer. It only applies to the plastic layers themselves and not to the final article made up by layers of plastic and layers of other materials.

The Plastics Regulation applies to plastic materials to which another material is added as an additive, for example, glass-fibre reinforced plastics. It applies to plastic materials consisting of co-polymers, unless the resulting co-polymer falls under the definition of rubbers.

The Plastics Regulation sets out rules concerning the following aspects:

- It sets out a Union list of authorised substances that can be used in the manufacture of plastic layers of the plastic materials and articles described in the scope.
- It sets out which types of substances are covered by the Union list and which are not.
- It sets restrictions and specifications for these substances.
- It sets out to which part of the plastic materials the Union list applies and to which not.
- It sets out specific and overall migration limits for the plastic materials and articles.
- It sets out specifications for the plastic materials and articles.
- It sets out a declaration of compliance (DoC).
- It sets out the compliance testing requirements for plastic materials and articles.

The Plastics Regulation does not apply to:

- varnished or unvarnished regenerated cellulose film, covered by Commission Directive 2007/42/EC[8];
- rubber;
- paper and paperboard, whether modified or not by the addition of plastics;
- surface coatings obtained from:
    - paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,
    - mixtures of the waxes listed in the previous indent with each other and/or with plastics,
- ion-exchange resins;
- silicones.

NOTE:
Waxes are a complex group of materials of natural, mineral, petroleum derived or synthetic origin with many different uses. Depending on their use, they may be covered by the Plastics Regulation.
Waxes are covered by the Plastics Regulation when they are used as an additive or a polymer production aid and are listed as individual substances in the Union list in Table 1 of Annex I of the Plastics Regulation.
Waxes are not covered by the Plastics Regulation when they are the sole or a major component of surface coatings. This is the case, for instance, for paraffin waxes, including

[8] Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (OJ L 172, 30.6.2007, p.71).

synthetic paraffin, and/or micro-crystalline waxes and for mixtures of these waxes with each other and/or with plastics.

NOTE:
Thermoplastic elastomers (TPE) are co-polymers made of polymers which fall under the definition of polymers set out in the Plastics Regulation. They are composed of substances identical to plastics, even though they may differ in physico-chemical properties. They are in some Member States covered by the national legislation on rubber and elastomers, while other Member States do not cover them under the scope of their national legislation or recommendation. TPE should be manufactured with monomers and additives listed in Plastics Regulation and should respect the specific migration limits (SMLs). Migration models for some of the TPE, e.g. SBS, are available in the Guidance on migration modelling. As explained in the 7th recital of the Plastics Regulation, rubbers are excluded from the scope of Plastics Regulation because they differ in composition and physico-chemical properties from plastics. As TPEs have the same composition as plastics, they are not covered by the term rubber and therefore not excluded from the scope of the Plastics Regulation.

NOTE:
All food contact materials and articles, intermediates and substances used for their manufacture which fall within the scope of the Framework Regulation are covered by and subject to the respective requirements of that Regulation. This applies to materials and articles covered by specific EU measures, such as plastics, but also to those covered by specific national measures.

2.2 Definitions

In addition to the definitions set out in the Framework Regulation and the Plastics Regulation the this guidance clarifies the use of certain terms used in the context of this Guidance document:

- "Adhesives" means non-metallic substance capable of joining materials by surface bonding (adhesion [9]), and the bond possessing adequate internal strength (cohesion[10])[11].
- "Blend" is any 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.
- "Coating" means 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.

[9] Adhesion is the force of attraction between molecules in different layers.
[10] Cohesion is the force of attraction between molecules within the same layer.
[11] Different kinds of adhesives are necessary to accommodate the specific performance requirements of the many plastic food contact articles (e.g. bags, pouches, boxes, chopping boards, kitchen furniture), and the diverse range of plastic materials employed (e.g. PE, PP, OPP, PET, PC, PVC). These different kinds of adhesives systems - primarily aqueous based or water soluble, solvent based, and 100% solid adhesive systems – are employed to produce bonded assemblies, which are fit for purpose. Each type of these adhesive systems may be reactive or non-reactive. Irrespective of the chemistry and the curing mechanism (physical or chemical), the cured adhesive films consist basically of polymeric organic substances of high molecular weight.

- "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.
- "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.

- "Dual use additives" means additives which are covered by a listing[12] in the Union list and which are also listed as food additives or flavourings in Regulations (EC) No 1333/2008[13] and (EC) No 1334/2008[14] and their implementing measures.
- "Fat consumption Reduction Factor" (FRF) is 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 SMLs.
- "Ion exchange resin" covers 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.
- "Layer" means a homogenous continuous or semi-continuous[15] 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[16].
- "Masterbatch" means 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 masterbatch is intended to be blended with a polymer and not used to make an article as such.
- "Migration modelling" means 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 recognised diffusion models. These are based on scientific

[12] Note that some food additives are the salts of acids and alcohols that are listed in the Union list, even though the acid or alcohol itself is not a food additive.

[13] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16); Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives (OJ L 295, 12.11.2011, p. 1); Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients (OJ L 295, 12.11.2011, p. 178).

[14] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

[15] For the purpose of this Guidance document, a pattern coating such as an ink, lacquer or coldseal is considered to be a layer where it is present.

[16] A layer does not necessarily need to have a flat sheet-like shape, but can have other forms in cases of moulded articles as e.g. bottles. A printing ink "layer" is often not continuous – the image may not be printed over 100% of the surface, and can be composed of coloured dots.The nature of a layer can be diverse. Examples for layers in the context of food contact materials are:plastics, printing inks, paper, metals, laminating waxes, lacquers, varnishes, organic or inorganic (e.g. metallization layer, SiOx-layer) coatings or adhesives.

evidence overestimating real migration and taking into account the Guidance document on migration modelling

- "Migration test" means the determination of the release of substances from the material or article either into food or into a food simulant.
- "Oligomer" means a substance consisting of a finite number of repeating units which has a molecular weight of less than 1000 Da.
- "Product from intermediate stages of manufacture" also referred to as "Plastic intermediate materials" means 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 or laminate requiring further processing/re-formulation steps to become a "finished" material or article. In short, this is any product which is not a basic chemical and not yet a finished plastic material or article.
- "Polymeric additive" means any 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.
- "Pre-polymer" is a polymer of relatively low molecular weight, usually an intermediate between the monomer and the final polymer or resin.
- "Printing inks" are mixtures of colorants with other substances which are applied on materials to form a print design on this material[17].
- "QM" means maximum permitted residual content of a substance in the final material or article expressed as weight per weight concentration in the final article.
- "QMA" means 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.
- "Repeated use article" means 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.
- "Rubber" means low shear modulus materials, either natural[18] or synthetic, made up of carbonaceous macromolecules, and characterised by long polymer chains arranged in a three-dimensional flexible network held by chemical covalent cross-links. They present, at service temperature and until their decomposition, elastic physical properties which allow the material to be substantially deformed under stress and recover almost its original shape when the stress is removed. The definition does not cover thermoplastic elastomers.
- "Set-off" is the 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 a contact between the outside

[17] Printing inks are preparations (mixtures) which may be manufactured from combinations of colorants (pigments, dyes), binders, plasticisers, solvents, driers and other additives. They are solvent-borne, water-borne, oleoresinous or energy-curing (UV or electron beam) systems. They are applied by a printing and/or a coating process, such as flexography, gravure, letterpress, offset, screen, non-impact printing or roller coating. Printing inks on food packaging are generally applied on the non-food contact side of primary food packaging, and – accordingly – are often referred to as "food packaging inks".

[18] For example, caoutchoucs which are naturally derived rubber from latex originating from the sap of trees.

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.

- "Single use article" means an article intended to be used once and coming into contact with not more than a single portion of foodstuffs 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. Disposable gloves should be regarded as single use articles, even if the user may be in contact with several portions of food with them).
- "Silicones" means macromolecular substances or materials based on organopolysiloxanes and which are crosslinked forming a three-dimensional network having elastomeric or rubber-like properties.
- "Substances in nanoform" refers to nanomaterials as defined in Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial[19]. 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 %.
    - 'particle' is defined as a minute piece of matter with defined physical boundaries;
    - ‘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;
    - ‘aggregate’ means a particle comprising of strongly bound or fused particles.

  Remark: Once discussions are concluded on how to implement in the food area the definition of nanomaterials 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.
- “Supply chain” means 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.
- “Surface biocide” means 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.
- "Thermoplastic elastomer" means polymer or blend of polymers that does not require vulcanisation or cross-linking during processing, yet has properties, at its service temperature, similar to those of vulcanised rubber. These properties disappear at processing temperature, so that further processing is possible, but return when the

[19] OJ L 275, 20.10.2011, p. 38.

material is returned to its service temperature. They are covered under the definition of plastics.

2.3 Placing on the market of plastic materials and articles

The definition of "Placing on the market" included in Article 2(1)(b) of the Framework Regulation applies. It covers the following actions on food contact materials which are not yet in contact with food, but also those which are already in contact with food:

- Importing food contact materials into the EU.
- Holding of food contact materials for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not.
- The sale, distribution, and other forms of transfer of food contact materials.

3 Chapter II - Compositional requirements

3.1 Union list of authorised substances

3.1.1 Union list

In principle, the Union list in Table 1 of Annex I to the Plastics Regulation contains all substances that are functional constituents of plastic.

The Union list covers the **monomers and other starting substances** to manufacture polymers. It does not list the polymers themselves, but only the monomers and other starting substances that are the building blocks of the polymer. The only polymers that need to be listed are natural macromolecules which are chemically modified to make the final plastic, and macromolecules manufactured by microbial fermentation. Monomers are the repeating unit in polymers and thus the backbone of the polymer. Other starting substances can cover substances that modify a polymer, like side-chains or end-caps that are being incorporated in the polymer chain. The term "other starting substances" also covers natural macromolecules which are being chemically modified.

The Union list covers substances **that** are added to polymers to make the final plastic. They are added to achieve either a physical or chemical effect during processing of the plastic or in the final materials or articles. They are intended to be present in the final material or article. Under the term "**additive**", the following categories and functions are covered[20]:

- Antifoaming agents, if they have a function in the final article
- Anti-skinning agents
- Antioxidants
- Antistatic agents
- Dryers
- Emulsifiers, if they have a function in the final article
- Fillers
- Flame-retardants
- Blowing agents used in the manufacture of expanded polymers like polystyrene foam
- Hardening agents

[20] Indicative list of functions covered.

- Impact modifiers (except substances that are capable of functioning as the main structural component of a finished material or article - see point 3.2.4 of this Guidance document)
- Lubricants
- Miscellaneous additives (extrusion aids)
- Optical brighteners
- Plasticizers
- Preservatives (antimicrobial substances, such as surface biocides, see point 3.4 of this Guidance document)
- Protective colloids
- Reinforcements
- Release agents
- Stabilisers
- Viscosity or rheology modifiers (except substances that are capable of functioning as the main structural component of a finished material or article - see point 3.2.4 of this Guidance document)
- UV absorbers

The Union list also covers **polymer production aids (PPA),** which are used to provide a suitable medium for polymer or plastic manufacturing. They may be present, but neither are they intended to be present in the finished materials or articles nor do they have a physical or chemical effect in the final material or article. PPAs other than those listed in the Union list may be used to manufacture plastics, subject to national legislation. Under the term PPAs, the following categories are covered[21]:

- Anti-foam reagents/degassing agents necessary during the manufacturing process
- Anti-cluster
- Anti-crusting agent
- Anti-scaling
- Buffering agents
- Build-up suppressants
- Coagulating agents
- Dispersing aids
- Emulsifiers necessary during the manufacturing process
- Flow control agents
- Nucleating agents
- pH regulators
- Preservatives necessary during the manufacturing process (antimicrobial substances used as process biocides, see point 3.4 of this Guidance document)
- Solvents
- Surfactants
- Suspension agents
- Stabilisers
- Thickening agents
- Water treatment reagents

If a substance in the Union list is used, it has to comply with the specifications and migration limits set out in the Plastics Regulation, unless it is stated explicitly that these specifications

[21] Indicative list of functions covered.

or migration limits are not applicable. If these substances are used in coatings, adhesives or printing inks that are part of the plastic materials within the scope of the Plastics Regulation (with the exception of multi-material multi-layer), then the final material has to comply with the relevant migration limits for these substances.

3.1.2 Addition of new substances to the Union list

New substances can be added to the Union list following the procedure laid down in Articles 8 to 12 of the Framework Regulation. Only those substances to be used in materials covered by the scope of the Plastics Regulation and which are covered by the scope of the Union list will be added (e.g. substances to be used in coatings on paper or metal, aids to polymerisation, solvents or colorants will not be added). The procedure for authorisation requires an application which is sent to a national competent authority. The list of national contact points that may receive an application is published at:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/nat_contact_points_en.pdf

The national contact points will forward the application to the European Food Safety Authority (EFSA). EFSA will check the validity of the application according to the EFSA Guidance[22]. The EFSA guidance is published at:

http://www.efsa.europa.eu/en/efsajournal/pub/21r.htm

EFSA has then 6 months to provide an opinion on a valid application. EFSA can ask the applicant for additional information, which will stop the clock during this time period. EFSA can also extend the time period for another 6 months if it is justified. The EFSA opinion will be published at:

http://www.efsa.europa.eu/en/panels/cef.htm

Following a favourable EFSA opinion, the Commission will make a decision on the authorisation of the substance, taking into account this opinion, as well as other relevant factors. If it is concluded that a substance should be authorised, the Commission will prepare an amendment to the Plastics Regulation to include the substance in the Union list. Relevant Commission services and Member States will be consulted and the European Parliament has a right of scrutiny on the proposal. If the proposal is agreed, it will be adopted by the Commission and published in the Official Journal http://eur-lex.europa.eu/en/index.htm . This last part of the procedure may take up to 9 months.

3.2 Derogations for substances not included in the Union list

This section on derogations deals with substances:

- for which the Union list is not an exhaustive list, or
- that are not explicitly included in the Union list, but are implicitly covered through a listing of another substance and that are therefore subject to the restrictions and specifications in the Union list.

[22] Guidance document on the submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA by the Panel on additives, flavourings, processing aids and materials in contact with food (AFC), doi:10.2903/j.efsa.2008.21r .

3.2.1 Polymer production aids (PPA)

For PPAs, the Union list is not an exhaustive list. This means that PPAs others than those listed can be used in the manufacture of plastics. These other PPAs are subject to national legislation and self-assessment, in line with Article 19 of the Plastics Regulation.

3.2.2 Salts of authorised acids, alcohols and phenols

Authorised acids, alcohols and phenols can occur as free acids, alcohols or phenols or as salt of the acid, alcohol or phenol. In the Union list, only the name of the free acid, alcohol or phenol is mentioned. However, the use of certain salts of these acids, alcohols or phenols is also authorised. The salts of the following cations can be used without any restriction: aluminium, ammonium, calcium, magnesium, potassium, and sodium.

The salts of the following cations can be used subject to the restrictions for the cations in Annex II to the Plastics Regulation: barium, cobalt, copper, iron, lithium, manganese, and zinc.

The Plastics Regulation explicitly mentions double salts; however, this rule would equally apply to triple salts and other multiple salts.

3.2.3 Mixtures

Mixtures of authorised substances can be used, provided there is no chemical reaction of the components.

3.2.4 Polymeric additives

A macromolecular substance of a molecular weight of at least 1000 Da can be used as an additive without explicit listing in the Union list, but only if it can function as the main structural component of a finished material and article and if its monomers and other starting substances are included in the Union list. This does not apply to macromolecules obtained from microbial fermentation, which always have to be included in the Union list. If the substance is not capable of functioning as the main structural component of a finished material or article, it has to be included in the Union list, even if the monomers and starting substances to produce the macromolecular substance are listed. If the substance is capable of functioning as the main structural component of a finished material or article, but the monomers are not listed, then an authorisation for the monomers and other starting substances has to be sought.

3.2.5 Polymeric starting substances

The term "polymeric starting substances" covers macromolecular substances, such as oligomers, pre-polymers and polymers used as monomers or other starting substances.

A macromolecular substance can be used as a monomer or other starting substances without being included in the Union list if the monomers and other starting substances to produce it are included in the Union list. This does not apply to macromolecules obtained from microbial fermentation, which always have to be included in the Union list. If some of the monomers or other starting substances are not listed, then an authorisation has to be sought, either for these missing monomers or other starting substances, or for the macromolecular substance itself.

3.3 Substances not included in the Union list

This point deals with substances that are not subject to inclusion in the Union list because:

- They are used in minute amounts and not intended to remain in the plastic
- They are used in other layers than plastic layers which are not subject to compositional requirements of the Plastics Regulation
- They were not subject to an authorisation in the past

This covers the following groups of substances:

- aids to polymerisation;
- non-intentionally added substances;
- monomers, other starting substances, and additives only used in surface coatings;
- monomers, other starting substances, and additives only used in epoxy resins;
- monomers, other starting substances, and additives only used in adhesives and adhesion promoters;
- monomers, other starting substances, and additives only used in printing inks;
- colorants;
- solvents.

3.3.1 Aids to polymerisation

Aids to polymerisation are substances which initiate the polymerisation reaction and/or control the formation of the macromolecular structure. They are not intended to be incorporated[23] in the final polymer and do not have a function in the final plastic.

Aids to polymerisation are not covered by the Union list because they are used in minute amounts and are not intended to remain in the final polymer. Any residues should only occur in minute amounts which should be dealt with by industry, under self-responsibility. They have to comply with the general safety requirements of Article 3 of the Framework Regulation and are subject to risk assessment in line with Article 19 of the Plastics Regulation. Some "aids to polymerisation" are authorised at national level.

Under the term "aids to polymerisation", the following categories are covered:

- Accelerators
  An accelerator is a substance that activates/speeds up (accelerates) a chemical reaction. An accelerator can speed cross linking of oligomers or cause polymerization to occur at a lower temperature than normal. An accelerator and a catalyst/promoter/activator could be used in synergy to start a polymerization process, e.g. at room temperature. For example, one commonly accelerator used in the polymerization process of unsaturated polyester is cobalt naphthenate or other organic cobalt salts.
- Catalysts
  Catalyst is a substance that influences the rate of a chemical reaction or the rate in which the chemical equilibrium is reached by reducing the activation energy. Unlike other reagents that participate in the chemical reaction, a catalyst is not consumed by the reaction itself. A catalyst may participate in multiple chemical transformations. For example, a Ziegler–Natta catalyst is often used in the synthesis of polymers of polyolefines.
- Catalyst deactivators
  Catalyst deactivators cause the loss over time of catalytic activity and/or selectivity. They can be classified into several chemical types, being catalyst inhibitors, if the deactivation reaction is reversible, and catalyst poisons, if irreversible.
- Catalyst supports

[23] Incorporated in this context means reacted onto or becoming a part of the chemical structure of the polymer.

A catalyst support is the material, usually a solid, having a high surface area, on which the active centre of the catalyst is affixed to linear macromolecules or polymeric networks. Efforts are made to maximize the surface area of a catalyst by distributing it over the support that may be inert or participate in the catalytic reactions. Typical supports include, e.g. various kinds of carbon, alumina, and silica.

- Catalyst modifiers
  A catalyst modifier is a substance that is modifying the catalytic activity of a catalyst. They are often referred to as co-catalyst or promoters in cooperative catalysis.

- Chain scission reagents
  A chain scission reagent is used to generate radicals in an existing polymer chain by thermal treatment. This radical on the chain induces a scission of the polymer chains in two shorter macromolecules. A chain scission reagent induces a decrease of the molecular weight and an improvement of the melt flow properties, e.g.: organic peroxides used for visbreaking of polypropylene.

- Chain transfer or extending agents or molecular weight regulators
  Chain transfer is a polymerization mechanism by which the activity of a growing polymer chain is transferred to another molecule. Chain transfer agents are often used to control and reduce the average molecular weight of the final polymer. The chain transfer reactions can be either controlled deliberately during the polymerization by using a chain transfer agent or it may be an unavoidable side-reaction with various components of the polymerization. Chain transfer agents are sometimes called "chain modifiers" or "chain regulators", e.g. thiols, especially n-dodecylmercaptane, and halocarbons, such as carbon tetrachloride.

- Chain stop reagents
  A chain stop reagent is a substance used for ending polymer chain propagation at a specific point in time, so as to obtain desirable molecular weight distribution and the linked polymer properties.

- Cross-linking agents (that are not incorporated in the polymer)
  A cross linking agent is a substance linking with a chemical bond one polymer chain to another. The chemical bonds can be covalent bonds or ionic bonds. Cross linking agents are used to modify the mechanical properties of a polymer and the resulting modifications of mechanical properties are strongly depending of the cross-link density. Cross-linking agents (e.g. organic peroxides) used here does not include polyfunctional monomers or starting substances that are incorporated in the polymer and covered by the Union list.

- Cross-linking catalysts or Cross-linking accelerators
  They are substances that improve the efficiency of a cross linking agent.

- Desensitizing agent
  Desensitizing agents are added to initiators to improve their thermal, chemical and mechanical stability during transport[24] and storage to prevent auto-decomposition, e.g. organic/inorganic solids, organic liquids with high boiling point, or under certain circumstances water.

- Initiators and promoters

[24] Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p.13).

They are substances used to start a chemical (chain) reaction (initiation). Initiators are consumed during the initiation step and the fragments are incorporated in the built compound, e.g. organic peroxides used as initiators to initiate a radical polymerization of unsaturated monomers or substances capable to generate carbanion active species in anionic polymerization.

- Polymerisation inhibitors
  Polymerisation inhibitors, also referred to as polymerisation killers or short stoppers, are substances that slow down or block a polymerization reaction of unsaturated monomers. Generally, they are substances which react with free radicals and so prevent free radical polymerization, e.g. hydroquinone or BHT.

- Redox agents
  A redox agent is a chemical that has the ability to generate an oxydo-reduction reaction. Redox agents are substances that have the ability to oxidize or reduce other substances. Substances able to oxidize other substances are also called "oxidizing agents", "oxidants", or "oxidizers". Substances that have the ability to reduce other substances are known as "reducing agents", "reductants" or "reducers". If the redox-reaction is used to initiate radical polymerization, this type of initiation is referred to as "redox initiation", "redox catalyst", or "redox activation". For example, iron salts or Cr2+, V2+, Ti3+, Co2+, and Cu+ salts can be used for the reduction of hydrogen peroxide or organic peroxide.

3.3.2 Non-intentionally added substances (NIAS)

Non-intentionally added substances are either impurities in the substances used or reaction intermediates formed during the polymerisation process or decomposition or reaction products which can occur in the final product. They are exempted from the authorisation and inclusion in the Union list. However, in certain cases, Annex I and Annex II (restrictions on materials and articles) to the Plastics Regulation may include restrictions on non-intentionally added substances. In principle, non-intentionally added substances will have to comply with the general safety requirements of Article 3 of the Framework Regulation and are subject to risk assessment in line with Article 19 of the Plastics Regulation.

3.3.3 Stabilisers in monomers, starting substances and additives

Certain monomers, starting substances and additives need to be stabilised to prevent reaction or oxidation of the pure substance during storage. These stabilisers are not necessarily listed in the Union list. If they are listed, they have to respect the migration limits set out therein. If they are transferred into the plastic in concentrations that exhibit an additive function in the plastic itself, they should be included in the Union list. In applications for authorisation of monomers, starting substances and additives, the necessary stabilisers should be mentioned.

3.3.4 Coatings, printing inks and adhesives

Coated and printed plastic materials and articles are covered by the scope of the Plastics Regulation. Plastics held together by adhesives are also covered by its scope. However, substances used only in printing inks, adhesives and coatings are not included in the Union list because these layers are not subject to the compositional requirements of the Plastics Regulation. The only exceptions are substances used in coatings which form gaskets in closures and in caps. The requirements for printing inks, adhesives and coatings are intended to be set out in separate specific Union measures. Until such measures are adopted, they are

covered by national law. If a substance used in a coating, a printing ink or an adhesive is listed in the Union list, the final material or article has to comply with the migration limit of this substance, even if the substance is used in the coating, printing ink or adhesive only.

Example:

A food container is composed of 3 plastic layers, an adhesive layer and is printed on the non-food contact side. Substances A, B and C are used in the production of the plastic container and are listed in the Union list with an SML. Substance A is used in one of the plastic layers, substance B is used in a plastic layer and the adhesive, and substance C is used in the printing ink. The final container has to respect the SML for all three substances.

3.3.5 Colorants

Even though colorants fall under the definition of additives, they are not covered by the Union list of substances. Colorants used in plastics are covered by national measures. Certain colorants, in particular, cadmium pigments, are regulated by EU legislation on chemicals and listed in Annex XVII of Regulation (EC) 1907/2006 (REACH)[25]. They have to comply with the general safety requirements of Article 3 of the Framework Regulation and are subject to risk assessment in line with Article 19 of the Plastics Regulation.

3.3.6 Solvents

Even though solvents fall under the definition of polymer production aids, they are not included in the Union list of authorised substances. Although volatile solvents are expected to be removed in the manufacturing process, solvents used in plastics are covered by national measures. They have to comply with the general safety requirements of Article 3 of the Framework Regulation and are subject to risk assessment in line with Article 19 of the Plastics Regulation.

3.4 The status of antimicrobial substances

The purpose of use of antimicrobial substances in a plastic food contact material defines whether the antimicrobial substance is considered as an additive, a polymer production aid or an active substance covered under Regulation (EC) No 450/2009 on active and intelligent materials intended to come into contact with food [26] (the "Regulation on active and intelligent materials"). Depending on the function of the antimicrobial substance in the plastic food contact materials, we distinguish the following categories:

[25] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1); see also Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (OJ L 134, 21.5.2011, p. 2).

[26] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food (OJ L 135, 30.5.2009, p. 3).

(1) Process biocides, that keep the material or preparations which are to be processed into final food contact materials (e.g. pre-polymer solutions) free from microbial contamination during the production, storage or handling process;

- they are used as components in the manufacture of food contact materials, but not intended to be present in the food contact material itself;
- as no antimicrobial function is exerted on the final food contact material, the substance would be regarded as polymer production aid;
- their incorporation into the food contact material could be regarded as an unintentional but unavoidable carry-over.

Note that process biocides are subject to Regulation (EU) No 528/2012[27] (the "Biocides Regulation"), which applies as from 1 September 2013. They are usually covered by Product-type 6, 7 or 12 in Annex V to the Biocides Regulation.

(2) Surface biocides, that keep the surface of the food contact material free from microbial contamination (e.g. used on inner surface of fridges, cutting boards, gaskets, conveyer belts, storage containers);

- they are used in the manufacture of food contact materials and are intended to be present in the food contact material itself;
- as an antimicrobial function is exerted on the final food contact material, the substance would be regarded as an additive;
- currently, no surface biocides are included in the Union list of the Plastics Regulation. The provisional list of additives covered by Article 7 of the Plastics Regulation contains 10 surface biocides which can be used in accordance with national law. (For the status of the provisional list see also point 3.5. of this Guidance document)

Note that materials and articles containing surface biocides are subject to Article 58 of the Biocides Regulation. They are usually covered by Product type 4 in Annex V to that Regulation.

(3) Preservatives to be released into or onto food to preserve the food

- they are used in the manufacture of food contact materials and intended to be released into the food itself or have a preservative effect on the food;
- as an antimicrobial function is exerted on the food, the substance would be regarded as an active substance covered by the Regulation on active and intelligent materials;
- in accordance with the Regulation on active and intelligent materials, only those preservatives that are authorised as food preservatives in the food additives legislation can legally be used for this function.

Note that materials and articles containing substances to be released as food preservatives are not subject to Biocides Regulation, as food additives are excluded from its scope.

3.5 Establishment and management of the provisional list of additives

To establish the exhaustive list on additives that can be used in plastic food contact materials, any person was invited to apply for an EU authorisation of the additive by 31 December

[27] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

2006[28]. Additives which were legally marketed in, at least, one Member State by 31 December 2006, and for which a valid application was received by 31 December 2006, were included in the "provisional list of additives" under EFSA evaluation made publicly available as from 2008 at:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/080410_provisional_list_7_211009.pdf

Given the fact that these additives were legally marketed in Member States, these substances can continue to be used according to national law, even after 1 January 2010, the date when the non-exhaustive list of additives became an exhaustive list, until a decision on their inclusion or not into the Union list is taken by the Commission[29].

Substances will be removed from the provisional list: (i) when they are included in the Union list; (ii) when a decision is taken not to include them in the Union list, or (iii) when the applicant fails to provide additional information requested by EFSA, within the time frame set-out by EFSA.

The provisional list contains mainly surface biocides. At this moment, no EU rules are established for the use of surface biocides in plastic food contact materials and articles. Until EU rules are established and implemented, the surface biocides listed can be used in accordance with national law and subject to the provisions of the Biocides Regulation. (see also point 3.4)

3.6 General requirements on substances

3.6.1 Specifications and restrictions for substances, materials and articles

If a substance in the Union list is used in the manufacture of plastic materials or articles, it has to comply with the specifications and restrictions set out in the Plastics Regulation, unless it is stated explicitly that these specifications are not applicable. Specifications and restrictions which are established following the risk assessment of the substance are set out in column 10 of the Union list in Table 1 of Annex I to the Plastics Regulation. If these substances are used in coatings, adhesives or printing inks that are part of the plastic material within the scope of the Plastics Regulation, then the final material has to comply with migration limits and the relevant specifications for these substances. If the substances are used in other functions than additive or monomer, then the final material has to comply with the relevant migration limits and the relevant specifications of the substances.

Relevant specifications for the use of substances that are also applicable when used in coatings, adhesive or printing inks or in other functions than additive or monomer could be:

- the restriction in relation to the food that may come in contact, e.g. "not to be used for articles in contact with fatty foods";

[28] Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs, (OJ L71, 10.3.2004, p.8).

[29] Commission Directive 2008/39/EC of 6 March 2008 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food, (OJ L63, 7.3.2008, p.6).

- the way to express the SML, e.g. "SML expressed as the sum of the substance and its hydrolysation product";
- the restriction in relation to contact conditions, e.g. "only in repeated use articles".

It has to be decided on a case by case basis which specification or restriction is relevant for a substance when used in coatings, adhesives or printing inks.

The general requirements on substances set out in Article 8 of the Plastics Regulation have to be respected in every case. This means that the substances used in the manufacture of plastic layers in plastic materials and articles have to be of a technical quality and a purity suitable for the intended and foreseeable use of the materials and articles. If no specifications are listed in column 10 of the Union list in Table 1 of Annex I to the Plastics Regulation, it does not necessarily mean that all purities of a substance are suitable. Impurities are regarded as non-intentionally added substances in accordance with Article 3(9) of the Plastics Regulation. They have to be assessed by the business operator in accordance with internationally recognised scientific principles on risk assessment (Article 19).

General restrictions on plastic materials and articles are laid down in Annex II to the Plastics Regulation. These restrictions cover migration limits for certain metal ions and the specification on primary aromatic amines.

Specifications related to certain substances are laid down in Tables 1 and 2 of Annex I to the Plastics Regulation. Restrictions on the use of substances and simple compositional specifications are usually inserted in column 10 of Table 1 in Annex I, dealing with restrictions and specifications. When necessary, more detailed compositional specifications of the substances are included in Table 4 of Annex I.

The authorisation usually does not specify the particle size of the substance authorised. However, unless clearly specified in column 10 of Table 1 in Annex I, the authorisation does not cover substances in nanoparticulate form. The reason for this is that the safety evaluation of the substances at the time of the evaluation did not cover substances in nanoparticulate form. The EFSA opinion on "*The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety*" published at:

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en.pdf?ssbinary=true

states that the risk assessment of engineered nanomaterials has to be performed on a case-by-case basis. Based on this opinion, any authorisation of substances in nanoparticulate form will be granted only on a case-by-case basis, based on a case-by-case evaluation of the substance in nanoparticulate form.

For silicon dioxide (FCM No 504) and carbon black (FCM No 411), particle sizes in nanoparticulate form are mentioned in column 10 of Table 1 in Annex I to the Plastics Regulation. These particle sizes are authorised in addition to the bulk form (non-nanoparticulate form). These particle sizes characterize the silicon dioxide and carbon black nanoparticulate forms on the market for use in plastic food contact materials at the time of the authorisation of these two substances. For titanium nitride nanoparticles (FCM No 807) the name indicates that the authorisation only covers the nanoparticulate form that is mentioned in column 10 of Table 1 in Annex I to the Plastics Regulation.

A database characterising commercially available authorised substances including specifications has been established at the website of the EU Reference Laboratory for food contact materials (EURL FCM):
http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m/resource-centre-legislative-docs/reference_substances

For the majority of substances, the data are based on the substance provided by the applicant for the authorisation. The substances were subsequently characterised by the EURL FCM.

3.6.2 Specific migration limits (SMLs)

The SML is set out in the Union list in Table 1 of Annex I to the Plastics Regulation. If it applies to a single substance, then it is listed in column 8 of Table 1. If it applies to a group of substances, then the Group Restriction Number is listed in column 9 of Table 1. Table 2 in Annex I gives the total specific migration limit, SML(T), for each Group Restriction Number.

If a substance that is listed in the Union list is used in the final plastic material, it has to comply with the SML for this substance listed in column 8 in Table 1 and the group restriction listed in column 9 of the same table, unless it is explicitly stated that this SML is not applicable in that particular case. This applies also to the use of these substances in coatings, adhesives or printing inks that are part of the plastic materials within the scope of the Plastics Regulation.

The SML is based on the safety evaluation of the substances by EFSA (or, in the past, by the Scientific Committee on Food), taking into account information on the toxicity and the migration behaviour of the substance provided by the applicant. For setting the SML, it is conventionally assumed that 1kg of food containing the substance is consumed daily by a person with 60 kg bodyweight. It is assumed that the 1kg of food is in contact with a plastic food contact material releasing the substance at the SML. It is further assumed that the food contact surface area is 6 dm^2 per kg food.

For substances for which no SML is established, it is set out in Article 11(2) of the Plastics Regulation that the specific migration of these substances shall not exceed a generic SML of 60 mg/kg.

If the toxicological evaluation results in a specific migration limit of 60 mg/kg or below, then this is listed as SML in Table 1 or 2 of Annex I to the Plastics Regulation. If the toxicological evaluation would result in a SML above 60 mg/kg, this is not listed in Table 1 or 2, as it would be above the generic SML.

3.6.3 Dual-use additives

Certain substances used in food contact plastics are, at the same time, authorised food additives or authorised flavourings respectively by Regulation (EC) No 1333/2008 or Regulation (EC) No1334/2008 or their implementing measures. These substances are called dual-use additives. To avoid the unauthorised presence of food additives or flavourings in food, specific requirements are set out for the migration of these substances from food contact materials. The substances shall not be released into foods in quantities which have a technological function in the food.

If substances are added to the plastics to be released into food to have a technological function in the food, they are covered by the Regulation on active and intelligent materials and should comply with the relevant Union and national provisions applicable to food.

If the substances are added to the plastics with no intention to be released into food to have a technological function in the food, but they are authorised as a food additive or flavouring, the additional unintentional migration from food contact materials shall not lead to an exceeding of the authorised limit set out by the specific legislation on food additives or flavourings, even if this limit is lower than the SML set out in the Plastics Regulation. If the substance is not authorised as a food additive or flavouring in a certain food, then the migration from food contact materials into this food should not achieve a technological function in the food, and neither impart odour or taste (flavouring), nor should the SML be exceeded. In cases where the substance does not exhibit a technological function in food, migration up to the SML should be allowed, even if the substance is not authorised as food additive or flavouring in that type of food.

To decide if a substance can be considered as a dual-use additive, it is sufficient that the chemical identity of the plastic additive matches that of an authorised food additive or flavouring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic.

In the case of salts, it is the salt that matters, not the authorised acid, phenol or alcohol. Example: sodium acetate is a dual-use additive (E262), but zinc acetate is not. The substance included in Union list of the Plastics Regulation is acetic acid. Note that sodium acetate is identified as E262, even if the purity doesn't match that of its use in food.

The main intention of the legislation is that the user of food contact materials is informed on the presence of a dual-use additive in the plastic, so that these can be considered in relation to the relevant food legislation or interactions between food and packaging.

A non-exhaustive list of dual-use additives is reported in Tables 1 and 2 below. Table 1 covers additives used in plastic food contact materials that are listed in food additives legislation. Table 2 covers additives used in plastic food contact materials and are listed in the food flavourings legislation.

Table 1: Food Additives

FCM number	PM REF	CAS	FCM name	E-number	Food additive name
9	30610		acids, C_2-C_{24}, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	E471 E 470a E 470b	Mono- and diglycerides of fatty acids Magnesium salts of fatty acids Potassium salts of fatty acids
10	30612		acids, C_2-C_{24}, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	E471 E 470a E 470b	Mono- and diglycerides of fatty acids

					Magnesium salts of fatty acids Potassium salts of fatty acids
21	42500		carbonic acid, salts	E 170 E 501i E 500i E 503i	Calcium carbonate Potassium carbonate Sodium carbonate Ammonium carbonate
67	67840		montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol	E912	Montan acid esters
99	19460 62960	0000050-21-5	lactic acid	E 270 Na: E 325 K: E 326 Ca: E 327	
100	24490 88320	0000050-70-4	sorbitol	E 420	
101	36000	0000050-81-7	ascorbic acid	E 300 - E 302	
103	18100 55920	0000056-81-5	glycerol	E 422	
106	24550 89040	0000057-11-4	stearic acid	E 570 E 572	Stearic acid Calcium stearate
109	23740 81840	0000057-55-6	1,2-propanediol	E 1520	
110	93520	0000059-02-9 0010191-41-0	α-tocopherol	E 307	
111	53600	0000060-00-4	ethylenediaminetetraacetic acid	E 385	Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA)
115	10090 30000	0000064-19-7	acetic acid	E 260 E 262	Acetic acid Sodium acetate
116	13090 37600	0000065-85-0	benzoic acid	E 210 - E 213	
139	14680 44160	0000077-92-9	citric acid	E 330 - E 333	
161	92160	0000087-69-4	tartaric acid	E 334 -E 337	Tartaric acid (L(+)-)
162	65520	0000087-78-5	mannitol	E 965	
196	18670	0000100-97-0	hexamethylenetetramine	E 239	

	59280				
221	40570	0000106-97-8	butane	E943a	
252	87200	0000110-44-1	sorbic acid	E 200-203	
290	55360	0000121-79-9	gallic acid, propyl ester	E 310	Propyl gallate
303	12130 31730	0000124-04-9	adipic acid	E 355	
315	46640	0000128-37-0	2,6-di-tert-butyl-p-cresol	E 321	Butylated hydroxytoluene (BHT)
321	36080	0000137-66-6	ascorbyl palmitate	E 304	Fatty acid esters of ascorbic acid
386	55280	0001034-01-1	gallic acid, octyl ester	E 311	Octyl gallate
390	55200	0001166-52-5	gallic acid, dodecyl ester	E 312	Dodecyl gallate
394	41280	0001305-62-0	calcium hydroxide	E526	
395	41520	0001305-78-8	calcium oxide	E 529	
397	64720	0001309-48-4	magnesium oxide	E 530	
399	81600	0001310-58-3	potassium hydroxide	E 525	
400	86720	0001310-73-2	sodium hydroxide	E 524	
407	87040	0001330-43-4	sodium tetraborate	E 285	
409	62240	0001332-37-2	iron oxide	E 172	Iron oxides and peroxidiesac
413	35600	0001336-21-6	ammonium hydroxide	E 527	
414	87600	0001338-39-2	sorbitan monolaurate	E 493	
415	87840	0001338-41-6	sorbitan monostearate	E 491	
416	87680	0001338-43-8	sorbitan monooleate	E 494	
499	19965 65020	0006915-15-7	malic acid	E 296, E 350-352	Malic acid Sodium malate Potassium malate Calcium malate
504	86240	0007631-86-9	silicon dioxide	E 551	
505	86480	0007631-90-5	sodium bisulphite	E 223	Sodium metabisulphite
506	86920	0007632-00-0	sodium nitrite	E 250	
507	59990	0007647-01-0	hydrochloric acid	E 507	Chloridic acid
509	23170 72640	0007664-38-2	phosphoric acid	E 338 E 339 E 341iii	Phosphoric acid Sodium phosphate Calcium phosphate (tri-)
511	91920	0007664-93-9	sulphuric acid	E 513	
516	86960	0007757-83-7	sodium sulphite	E 221	
528	63760	0008002-43-5	lecithin	E 322	

530	41760	0008006-44-8	candelilla wax	E 902	
531	36880	0008012-89-3	beeswax	E 901	
533	42720	0008015-86-9	carnauba wax	E 903	
534	80720	0008017-16-1	polyphosphoric acids	E 452	
541	58480	0009000-01-5	gum arabic	E 414	Arabic gum
542	42640	0009000-11-7	carboxymethylcellulose	E 466	
544	58400	0009000-30-0	guar gum	E 412	
545	93680	0009000-65-1	tragacanth gum	E 413	Tragacanth
546	71440	0009000-69-5	pectin	E 440	Pectins
552	81500	0009003-39-8	polyvinylpyrrolidone	E 1201	
555	53280	0009004-57-3	ethylcellulose	E 462	
557	66640	0009004-59-5	methylethylcellulose	E 465	Ethyl methyl cellulose
559	61680	0009004-64-2	hydroxypropylcellulose	E 463	Hydroxypropyl cellulose
561	66240	0009004-67-5	methylcellulose	E 461	
566	33350	0009005-32-7	alginic acid	E 400-404	Alginic acid Alginates
567	82080	0009005-37-2	1,2-propyleneglycol alginate	E 405	
568	79040	0009005-64-5	polyethyleneglycol sorbitan monolaurate	E 432	Potassium polyoxiethylene sorbitane monolaurate
569	79120	0009005-65-6	polyethyleneglycol sorbitan monooleate	E 433	
570	79200	0009005-66-7	polyethyleneglycol sorbitan monopalmitate	E 434	
571	79280	0009005-67-8	polyethyleneglycol sorbitan monostearate	E435	
573	79440	0009005-71-4	polyethyleneglycol sorbitan tristearate	E 436	
575	76721	0063148-62-9	polydimethylsiloxane (Mw > 6 800 Da)	E 900	Dimethyl polysiloxane
579	61800	0009049-76-7	hydroxypropyl starch	E1440	
585	41120	0010043-52-4	calcium chloride	E 509	
596	95935	0011138-66-2	xanthan gum	E 415	
610	93440	0013463-67-7	titanium dioxide	E 171	
615	92080	0014807-96-6	talc	E 553 b	
635	40720	0025013-16-5	tert-butyl-4-hydroxyanisole	E 320	Butylated hydroxyanisole (BHA)
643	87760	0026266-57-9	sorbitan monopalmitate	E 495	Monopalmitate

					sorbitane
651	88240	0026658-19-5	sorbitan tristearate	E492	
713	43480	0064365-11-3	charcoal, activated	E 153	Vegetable Carbon
811	80077	0068441-17-8	polyethylene waxes, oxidised	E914	Oxidized polyethylene wax
902		0000128-44-9	1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	E954	Saccharin

Table 2: Food Flavourings

FCM number	PM REF	CAS	FCM name	Flavouring No	Flavouring name
195	37360	0000100-52-7	benzaldehyde	05.013	
247	24820 90960	0000110-15-6	succinic acid	08.024	
249	17290 55120	0000110-17-8	fumaric acid	08.025	
286	38240	0000119-61-9	benzophenone	07.032	

3.6.4 Overall migration limit (OML)

The overall migration limit is linked to the inertness of a material. The Framework Regulation on food contact materials sets out, in Article 3, that food contact materials shall not release their constituents into food in concentrations that could change the composition of the food. A release of 10 mg of constituents per 1 dm^2 surface area of plastic food contact material is established as the limit above which the migration is regarded as an unacceptable change of the food.

As the measurement of the overall migration in food is not feasible, the overall migration is measured into food simulants, which represent the hydrophilic, amphiphilic, and lipophilic properties of food and therefore, the chemical characteristics that lead to a transfer of substances from the food contact material into the food. Migration in any of the 5 simulants A, B, C, D1 and D2 shall not exceed 10 mg/dm^2 under the standardised testing conditions set out in Annex V of the Plastics Regulation.

The OML covers non-volatile substances. Therefore, testing in simulant E, which is established for volatile substances and dry foods, is not necessary.

As infants and young children (0-3 years) are a vulnerable consumer group, the OML is restricted to 60 mg/kg food (independent of the packaging size) for plastic materials and articles specifically dedicated for this age group. Through this rule the alteration of the food packaged in small plastic containers with a high food contact surface area to food volume is limited in the same restrictive way as food packaged in larger containers.

4 Chapter III - Specific provisions for certain materials and articles

Multi-layer materials and articles are those articles which are composed of two or more layers. The layers can be held together by adhesives or by other means; for example, they can be generated through co-extrusion. Two different cases can be differentiated: those that are composed only of plastics (point 4.1) or of plastics together with layers of other materials, such as paper or aluminium (point 4.2).

4.1 Plastic multi-layer materials or articles

Plastic multi-layer materials or articles are solely made of plastic layers, which are held together by adhesives or by other means, printed or not, covered or not by a coating. A material made of different plastics, including a metallised plastic layer, should be regarded as a plastic multi-layer material. The metallization of the plastic layer does not make it a multi-material, as the metallisation itself cannot be regarded as a separate layer.

The final plastic multi-layer material or article has to comply with the SMLs set out for the authorised substances in the Union list. In this context it is irrelevant whether the substance subject to an SML was used in the manufacture of the plastic layer or in a coating, in the printing or the adhesive. It is irrelevant to which extent each of the components (plastic layer, adhesive, coating, printing ink) of the plastic material or article contributes to the migration of the substance. Decisive is that the migration of the final plastic multi-layer material or article is below the SML for the given substance. The final plastic multi-layer material or article also has to comply with the OML, regardless of the layer from which the constituents derive.

The plastic layer in direct contact with food always has to comply with the compositional requirements of the Plastics Regulation. A plastic layer behind the plastic layer in contact with food can be manufactured with additives or monomers not included in the Union list or does not need to comply with all restrictions or specifications set out in the Union list if one of the layers separating it from the food works as a functional barrier. This means that a monomer or additive not listed in the Union list can be used in the manufacture of the layer behind the functional barrier if the migration of this substance is not detectable in food with a detection limit of 0.01 mg/kg (10ppb). This also means that a listed substance can be used in a layer at a higher residual concentration than allowed in the Union list if the final article respects the SML. Only for vinylchloride monomer the restrictions and specifications set out in the Union list always have to be respected in all plastic layers of the plastic multi-layer material or article.

In principle, substances used behind a functional barrier will have to comply with the general safety requirements of Article 3 of the Framework Regulation and are subject to risk assessment in line with Article 19 of the Plastics Regulation.

The functional barrier concept cannot be applied to substances which are mutagenic, carcinogenic or toxic to reproduction or to substances in nanoparticulate form. For the use of substances that fall in any of the above mentioned categories, an independent case-by-case evaluation of the toxicological properties and the migration behaviour is necessary. Therefore, a case-by-case risk assessment by EFSA, followed by an authorisation and inclusion in the Union list, is obligatory before such a substance can be used in the manufacture of plastics.

The printing inks, adhesives and coatings do not have to comply with the compositional requirements of the Plastics Regulation. This means they can be manufactured with substances not listed in the Union list for plastics. Rules for printing inks, adhesives and coatings can be set in separate specific Union measures. Until a specific Union measure is adopted, they are covered by national law. If, however, a substance used in the manufacture of a coating, a printing ink or an adhesive is included in the Union list, the final material has to comply with the migration limits and relevant specifications of this substance, even if the substance is used in the coating, printing ink or adhesive only.

4.2 Multi-material multi-layer materials or articles

Multi-material multi-layer materials or articles are composed of two or more layers of different types of materials, at least one of them being a plastic layer. One example are beverage cartons composed of a paper layer, an aluminium layer and a plastic layer. The plastic layer does not necessarily need to be the food contact layer.

The final material and article does not need to comply with the SMLs and OML set out in the Plastics Regulation, as it is composed of different materials for which no harmonised specific measures exist yet at EU level.

The plastic layers may only be composed of substances listed in the Union list. The plastic layers on their own do not have to comply with the SMLs and OML set out in the Plastics Regulation, as this migration may not be representative of the migration into food of the final material. The plastic layers have to comply with the restrictions set out for vinyl chloride monomer as regards residual content and non-detectable migration.

Plastic layers not in direct contact with food can be manufactured with monomers and additives other than those included in the Union list, if they are separated from the food by a functional barrier which ensures that the final material or article complies with the requirements of Article 3 of the Framework Regulation. The functional barrier concept cannot be applied to substances which are mutagenic, carcinogenic or toxic to reproduction or substances in nanoparticulate form. For the use of substances that fall in any of the above mentioned categories, a case-by-case evaluation of the toxicological properties and the migration behaviour is necessary. Therefore, a case-by-case risk assessment, followed by an authorisation and inclusion in the Union list is obligatory before such a substance can be used in the manufacture of plastics.

4.3 Set-off in the case of multi-layer materials or articles

The functional barrier concept in line with Article 13(2) of Plastics Regulation can only be applied when substances are not being transferred into food in detectable amounts, including contributions from possible set-off transfer.

Set-off is the phenomenon of the transfer of substances from outer layers of materials and articles to the food contact side. Set-off may occur in stacks or reels where contact between the outside of the material or article with the food contact side during storage or transport, for example, is possible. Unlike migration under these conditions, set-off may occur in both materials and articles with or without a functional barrier.

This transfer is not exclusively restricted to substances from plastic layers behind a functional barrier or to printing inks, but includes all substances from outer layers which have a certain migration potential.

As layers consisting of materials without specific measures at EU level (e.g. printing inks, lacquers or coatings) may contain substances not listed in the Union list or in the provisional list additives, particular attention has to be paid to the transfer of substances from these layers by set-off to the food contact side. The transfer of these substances shall be in line with the requirements of Article 3 of the Framework Regulation.

Point 1(b) of Section A of the Annex to Regulation (EC) No 2023/2006 [30] on good manufacturing practice for materials and articles intended to come into contact with food sets out that substances from printing inks shall not be transferred to the food-contact side of materials and articles by set-off in the stack or in the reel in concentrations leading to levels of the substance in the food not compliant with the requirements of Article 3 of the Framework Regulation.

5 Chapter IV - Declaration of compliance and Documentation

Detailed information on the declaration of compliance and supporting documentation is, available in the separate "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain".

5.1 Declaration of compliance (DoC)

The manufacturer of a food contact material should reassure the customer that the food contact material complies with the applicable EU and national legislation. The final article can only be compliant if the requirements arising from the Plastics Regulation have been adhered to throughout the production chain. Therefore, a DoC is necessary to provide this assurance, in a standardised format, from the moment a substance, mixture or plastic is intended for food contact. Each manufacturer has to declare compliance for the manufacturing steps under his responsibility. For example, a producer of a monomer has to ensure that the monomer is authorised and complies with the specifications relevant to it. The producer of a plastic intermediate has to ensure that monomers and additives are authorised and, as far as under his responsibility, indicate the conditions of use under which migration limits can be complied with. The manufacturer of the final article has to indicate the conditions of use under which restrictions and migration limits can be complied with. The information is, in particular, relevant for the so-called dual use additives.

The manufacturers of adhesives, printing inks and coatings should provide their customers, using their products in plastic materials or articles or plastic intermediates, with adequate information that allows the manufacturer of the plastic article to issue his DoC.

National legislation may provide for a DoC for all materials and articles which are not subject to specific measures at Union level. Therefore, national legislation should be checked for the

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

necessity to issue a DoC for adhesives, printing inks, coatings and non-plastic materials used in multi-material multilayers.

5.2 Supporting documentation

The business operator needs to have available appropriate documentation that substantiates the DoC. This documentation has to contain the relevant information for the manufacturing step under his responsibility, as well as documents he received from his suppliers and documents he provides to his customers. This documentation may contain specifications on the substances used in the manufacture, production recipes, analytical results of residual content, analytical results of migration tests, results of migration modelling and any justification why the results are applicable to the material for which the DoC is issued, if the material is not the tested material itself. This documentation can be in electronic or in paper format and has to be made available, without delay, to control authorities on demand.

NOTE
Business operators also have to keep documentation on the application of the quality assurance and quality control systems, as set out in Regulation (EC) No 2023/2006 on good manufacturing practice.

6 Chapter V - Compliance

6.1 Expression of migration test results

This chapter includes information on how to express the migration results obtained by migration testing or migration modelling. The migration results should be normalised before being compared with the migration limits set out in the Plastics Regulation.

Migration results can be obtained in food itself, or in food simulants, or can originate from migration modelling. They can be obtained by testing the final article itself or an article made from the material specifically designed for the migration test. In principle, these results should be normalised per kg of food in contact with the material, based on the real surface-to-volume ratio of the final article in the actual use. Several exceptions to this rule have been established to simplify migration testing. However, none of these exceptions (in particular those in Article 17(2)(a) and (d) of the Plastics Regulation) apply to plastic materials and articles specifically dedicated for infants and young children. Through this rule the alteration of the food packaged in small plastic containers with a high food contact surface area to food volume is limited in the same restrictive way as food packaged in larger containers and to avoid underestimation of real migration.

For large containers with a volume of more than 10 litres, the surface-to-volume ratio is standardised to 6, meaning 6 dm^2 assumed to be in contact with 1 kg of food. For small containers with a volume less than 500 ml, the surface to volume ratio is also standardised to 6. For large containers, this may lead to an overestimation of real migration while, for small containers, this may lead to an underestimation of real migration.

For films and other articles for which it is impractical to establish the contact surface when the article is not yet in contact with food, the surface-to-volume ratio is also standardised to 6.

For sealing articles like gaskets and stoppers which are not yet in contact with food and which can be used for sealing containers with different volumes, specific provisions for expression of migration results have been established. The following cases can be distinguished:

- Case 1: The volume of the container for which the stopper or gasket is used is known. In this case the migration result is expressed using the actual surface to volume ratio of the sealing article plus the container in the final use, taking into account the rules for small and large containers.
- Case 2: The volume of the container for which the stopper is used is unknown. In this case, the migration result can be expressed as mg per article. Final compliance can then only be established in the final use.

6.2 Testing of migration

Food contact materials must be in compliance with applicable legislation. In case of compliance testing in food, it should be considered that non-compliant test results may also be due to other sources than the food contact material. This may be for example the case for dual-use additives, mentioned in point 3.5.2 of this Guidance document. In such cases, other relevant EU legislation, e.g. EU Food Law, should also be considered.

Testing of migration is described in detail in Annex V to the Plastics Regulation. The transitional provisions applicable to migration testing and the sequence of phasing in new migration testing requirements are set out in Chapter VI of the Plastics Regulation, on final provisions. Detailed guidance on migration testing is provided in a separate Guidance document.

6.3 Assessment of substances not included in the Union list

Certain substances are not subject to authorisation and listing in the Union list. These substances include the following substance classes:

- non-intentionally added substances
    - impurities present in authorised substances
    - reaction products generated during the production of plastic materials and articles and resulting from the contact with food
    - degradation products generated during the production or storage of the plastic materials and articles
- aids to polymerisation
- polymer production aids including solvents that are not included in the Union list
- colorants
- substances used behind a functional barrier

For these substances, it is within the responsibility of the business operators to ensure compliance with the general rules of the Framework Regulation. Therefore, business operators have to be able to demonstrate the absence of risk for human health by performing a risk assessment based on internationally recognized scientific principles on risk assessment. These principles include hazard characterisation and exposure. Information on this risk assessment should be part of the DoC and supporting documentation.

7 Chapter VI - Final provisions

7.1 Amendments of EU acts

Until 31 December 2012, the food simulants (Table 3) set out in Council Directive 85/572/EEC[31] laying down lists of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs have been used by official control laboratories when performing migration testing.

Table 3: Food Simulants used until 31.12. 2012

Food Simulant	Abbreviation
Distilled water or water of equivalent quality	Food Simulant A
Acetic acid 3 % (w/v)	Food Simulant B
Ethanol 15 % (v/v)	Food Simulant C
Ethanol 50 % (v/v)	Food Simulant D1
Rectified olive oil: if for technical reasons connected with the method of analysis, it is necessary to use different simulants, olive oil must be replaced by a mixture of synthetic triglycerides, or by sunflower oil	Food Simulant D2

For testing migration with screening tests referred to in Article 18(3) and Article 18(5) of the Plastics Regulation, the food simulants set out in the table included in point 3 of Annex III of the Plastics Regulation (Table 4) may already have been used in line with the rules on screening tests set out in Annex V, Chapters 2 and 3 of the Plastics Regulation.

As from 31 December 2012, the Annex to Directive 85/572/EEC has been replaced by the reference to the food simulants set out in point 3 of Annex III to the Plastics Regulation (EU) No 10/2011 (Table 4).

Table 4: Food Simulants used as from 31.12.2012

Food Simulant	Abbreviation
Ethanol 10 % (v/v)	Food Simulant A
Acetic acid 3 % (w/v)	Food Simulant B
Ethanol 20 % (v/v)	Food Simulant C
Ethanol 50 % (v/v)	Food Simulant D1
Vegetable Oil	Food Simulant D2
Poly(2,6-diphenyl-p-phenylene oxide)[32], particle size 60-80 mesh, pore size 200 nm	Food Simulant E

7.2 Repeal of EU acts

As from 1 May 2011, the following Commission Directives are repealed:

[31] Council Directive 85/572/EEC of 19 December 1985 laying down lists of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs, (OJ L 372, 31.12.1985, p.14).

[32] Also known as MPPO or TENAX®.

- Commission Directive 80/766/EEC of 8 July 1980 laying down the Union method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs[33]
- Commission Directive 81/432/EEC of 29 April 1981 laying down the Union method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs[34]
- Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs[35]

The repeal of a Directive includes the repeal of all its amendments.

Analytical methods for testing migration and residual content of vinyl chloride monomer, as described in Commission Directives 80/766/EEC and 81/432/EEC are outdated. Analytical methods should comply with the criteria set out in Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[36].

Council acts cannot be repealed by a Commission act, but have to be repealed by an act adopted by the Council and Parliament. Once all the requirements of the Plastics Regulation are applicable and transitional provisions are completed, the following Council Directives become obsolete and can be repealed by the Council and Parliament.

- Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs[37]
- Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs[38]
- Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs[39]

7.3 Application and transitional provisions

The Plastics Regulation is applicable as from 1 May 2011.

Certain requirements set out in specific articles, however, only apply as from a later date, to ensure a transition period. The important dates for the transitional provisions are 31 December 2012 (Art. 22(5) and Art. 23 fifth subparagraph) and 31 December 2015 (Art. 23 3rd and 4th subparagraph). The following timetable describes the applicability of the requirements of the Plastics Regulation. Examples are given in the following section.

Applicable as from 1 May 2011 (Article 23 2nd subparagraph)

33 OJ L 213, 16.8.1980, p. 42.
34 OJ L 167, 24.6.1981, p. 6.
35 OJ L 220, 15.8.2002, p. 18.
36 OJ L 165, 30.4.2004, p. 1.
37 OJ L 44, 15.2.1978, p. 15.
38 OJ L 297, 23.10.1982, p. 26.
39 OJ L 372, 31.12.1985, p. 14.

- Union list of authorised substances: all substances on the list or covered by the Union list (combinations of metals and acids, salts, alcohols) may be used in accordance with the specifications and restrictions. For substances for which the restrictions and specifications have been changed a transitional period until 31. December 2012 has been introduced (Article 22(5)). For articles for which the rules have been changed, a transitional period until 31. December 2012 has been introduced (Article 22(5)).
- The overall migration limit of 10 mg/dm^2: with the exemption of those intended for infant food, for which 60 mg/kg food applies. For those materials with a volume between 500 ml and 10 l for which the overall migration limit was expressed before in 60 mg/kg a transitional period until 31. December 2012 has been introduced (Article 22(5)).
- The general restriction for certain metal ions in Annex II to the Plastics Regulation.
- Substances in nanoform can only be used if explicitly authorised and mentioned in the specifications in the Union list.
- Plastic layers in multi-material multilayers, which are not separated from the food by a functional barrier, have to be manufactured with monomers, starting substances and additives listed in the Union list.
- The rules for expressing the results of migration testing. For articles for which the rules have been changed, a transitional period until 31. December 2012 has been introduced (Article 22(5)).
- The screening methods for assessing compliance with migration limits.
- Obligation for risk assessment of substances not subject to inclusion in the Union list. For materials containing these substances which comply with Article 3 of the Framework Regulation for which, however, no formal risk assessment is available, a transitional period until 31. December 2012 has been introduced (Article 22(5)).
- The DoC and the supporting documentation.
- Repeal of vinyl chloride testing methods.
- The application of the migration testing regime set out in Directives 82/711/EEC and 85/572/EEC is obligatory for enforcement authorities to come to a decision whether a material is not compliant with the Plastics Regulation.
- A DoC can be issued if the supporting documentation is based on testing in accordance with the screening methods of the Plastics Regulation or with methods in accordance with Council Directive 82/711/EEC (including simulants referred to in the directive). (Article 22(1) of the Plastics Regulation)

- A **transitional period** has been introduced **until 31. December 2012** meaning that materials and **articles which have been lawfully placed on the market** complying with the requirements set out in former Directive 2002/72/EC[40] as regards
    - the compositional requirements
    - the OMLs,
    - the SMLs,
    - the restrictions and specifications, and

  which are accompanied by a DoC referring to Directive 2002/72/EC and for which supporting documentation in line with Directive 2002/72/EC is available, can

[40] Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs, (OJ L220, 15.8.2002, p. 18).

continue to be placed on the market until 31. December 2012. (Article 22(5) of the Plastics Regulation)

- A **transitional period** has been introduced **until 31. December 2015** for the application of the Union list for additives
    - other than plasticizers used in plastic layers or coatings in caps and closures
    - used in glass fibre sizing for glass fibre reinforced plastics.

  In these applications other additives than those listed in the Union list may be used. (Article 23 3rd and 4th subparagraph)
- Ban on use of Bisphenol A for the manufacture of polycarbonate infant feeding bottles (no transitional period applicable) (Regulation (EU) No 321/2011[41] Article 2 2nd subparagraph)

Applicable as from 1 June 2011 (1st amendment Regulation (EU) No 321/2011)

- Ban on placing on the market of polycarbonate infant feeding bottles manufactured with Bisphenol A (no transitional period applicable) (placing on the market refers to the holding for purpose of sale, offering for sale or any form of transfer, sale, distribution or any other form of transfer)

Applicable as from 31 December 2012 (Art. 23 5th subparagraph)

- The verification method for compliance with specific migration limits set out in Article 18(2) of the Plastics Regulation. When using the verification method the food simulants described in Annex III of the Plastics Regulation have to be used and the testing rules described in Annex V, Chapter 2 Section 2.1 of the Plastics Regulation have to be applied. The application of the verification method is obligatory for enforcement authorities to come to a decision whether a material is non-compliant with the Plastics Regulation.
- The verification method for compliance with the OML (Article 18(4) of the Plastics Regulation). When using the verification method the food simulants A, B, C, D1 and D2 as described in Annex III to the Plastics Regulation have to be used and the testing rules in Chapter 3 of Annex V to the Plastics Regulation have to be applied.
- Annex III setting out the simulants for verification methods described in Articles 18(2) and 18(4) of the Plastics Regulation.
- The Annex to the Council Directive 85/572/EEC is amended and now referring to food simulants described in point 3 of Annex III to the Plastics Regulation.
- The DoC has to make reference to compliance with the Plastics Regulation.
- A **transitional period** has been introduced **until 31. December 2015** for issuing a DoC. Until that date, a DoC stating compliance with the Plastics Regulation can be issued if the supporting documentation is based on testing in accordance with the screening methods or verification methods of the Plastics Regulation or with methods in accordance with Council Directive 82/711/EEC (including simulants referred to in the Directive) (Article 22(2) of the Plastics Regulation).

[41] Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles, (OJ L 87, 2.4.2011, p.1).

Applicable as from 1 January 2016 (Article 22(3) and 23

- A DoC stating compliance with the Plastics Regulation can be issued if the supporting documentation is based on testing in accordance with the screening methods or the verification methods of the Plastics Regulation (Article 22(3)).
- The Union list for additives fully applies to additives
    - other than plasticizers used in plastic layers or coatings in caps and closures
    - used in glass fibre sizing for glass fibre reinforced plastics.

  In these applications only those additives listed in the Union list may be used. (Article 23 3rd and 4th subparagraph)

Overview transitional provisions

No	Parameter	Before May 2011	May 2011 - December 2012	January 2013 - December 2015	January 2016
1	Placing of products on the market in compliance with Directive 2002/72/EC	Yes	Yes, if the products have been lawfully placed on the market before	No	
2	Placing of products on the market in compliance with Regulation (EU) No 10/2011	No	Yes		
3	DoC referring to Directive 2002/72/EC	Yes		No	
4	Testing rules for FCM in contact with food	According to Directive 82/711/EEC	According to Regulation (EU) No 10/2011		
5	Simulants	According to Directives 82/711/EEC and 85/572/EEC		According to Regulation (EU) No 10/2011	
6	Testing in simulants; Enforcement for establishing non compliance	According to migration test in Directive 82/711/EEC		According to migration test in Regulation (EU) No 10/2011	
7	Testing in simulants: Industry establish compliance	According to migration test in Directive 82/711/EEC	According to migration test in Directive 82/711/EEC or Regulation (EU) No 10/2011		According to migration test in Regulation (EU) No 10/2011
8	Tests other than verification of migration	According to Directive 2002/72/EC	According to Regulation (EU) No 10/2011		
9	Additives in gaskets	Exhaustive list for plasticizers			Exhaustive list for all additives
10	Plastic layers in multi-material multilayers	Regulation (EC) No 1935/2004	Regulation (EU) No 10/2011, however products lawfully placed on market before can continue to be placed on the market	10/2011	
11	Additives used in glass fibre sizing	Regulation (EU) No 1935/2004 2002/72/EC (unclear legal status)	Regulation (EU) No 10/2011 risk assessment Art. 19		Regulation (EU) No 10/2011 exhaustive list for all additives
12	Plastics that are coated, printed or held together by adhesives Application of OML and SML to final article	Yes			
13	SML	Directive 2002/72/EC	Regulation (EU) No 10/2011, however see parameter 1	Regulation (EU) No 10/2011	
14	OML	10 mg/dm^2 or 60 mg/kg	10 mg/dm^2, however see parameter 1	10 mg/dm^2	

Examples

A manufacturer is producing a plastic container for holding food that was legally placed on the market before the 1st of May 2011. For this article a DoC compliant with Directive 2002/72/EC is available and a corresponding supporting documentation is available and compliant with Directives 2002/72/EC and 82/711/EEC.

CASE A

This type of container can be marketed until 31 December 2012 by the plastic manufacturer with the above mentioned DoC on the basis of the above mentioned supporting documentation.

Food industry can use this container until exhaustion of stock if it was purchased until 31 December 2012 with a DoC referring to Directive 2002/72/EC. Food packaged in such a container can remain on the market until expiry date (best before date). Articles on the market are subject to the rules of Directive 2002/72/EC.

Control of the containers by enforcement authorities should be performed on the basis of Directive 82/711/EEC.

CASE B

As from 31 December 2012 this type of container can be marketed by the manufacturer with an updated DoC that makes reference to compliance with the Plastics Regulation. The DoC can be based on screening test performed in accordance with the Plastics Regulation. Usually if the compliance was based in the past on a test in line with Article 8(2), (3) or (4) of Directive 2002/72/EC this would correspond now to a screening test. The DoC can be based on a migration test in line with Directive 82/711/EEC. The DoC can be based on a verification test in line with the Plastics Regulation. Supporting documents can be also other analysis and evidence on the safety or reasoning demonstrating compliance.

When food industry is purchasing the article as from 31 December 2012 the DoC should be updated with reference to the Plastics Regulation. Food industry can use this container until exhaustion of stock. Food packaged in such a container can remain on the market until expiry date (best before date). Articles on the market are subject to the rules of the Plastics Regulation.

Control authorities will require the availability of a DoC referring to the Plastics Regulation. Control authorities should perform their testing on the basis of screening and verification tests set out in the Plastics Regulation. The verification tests have to be performed using the simulant in Annex III to the Plastics Regulation and the test conditions in Annex V to the Plastics Regulation. If the verification test performed in simulants in accordance with Annex III and V comes to the conclusion that the SML and/or OML is not respected and compliance in food cannot be demonstrated then the article would not be compliant with the Plastics Regulation.

CASE C

As from 31 December 2015 this type of container can be marketed by the manufacturer with an updated DoC that makes reference to compliance with the Plastics Regulation. The DoC

can be based on screening test or on a verification test performed in accordance with the Plastics Regulation. Supporting documents can also include other analysis and evidence on the safety or reasoning demonstrating compliance.

Control authorities will require the availability of a DoC referring to the Plastics Regulation. Control authorities will require supporting documents in line with screening or verifications tests performed in accordance with the Plastics Regulation. They can also accept other analysis and evidence on the safety or reasoning demonstrating compliance. Control authorities should perform their testing on the basis of screening and verification tests set out in the Plastics Regulation. The verification tests have to be performed using the simulants in Annex III to the Plastics Regulation and the test conditions in Annex V to the Plastics Regulation. If the verification test performed in simulants in accordance with Annex III and V comes to the conclusion that the SML and/or OML is not respected and compliance in food cannot be demonstrated then the article would not be compliant with the Plastics Regulation.

CASE D

The composition or manufacturing of the container is changed between 1 May 2011 and 31 December 2012. In this case the article has not lawfully been marketed before 1 May 2011. The manufacturer has to update the supporting documents and has to issue a new DoC referring to the Plastics.

8 Annex I - Substances

8.1 Union List of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives, and polymer production aids (Table 1)

Additional explanations on the content of the different columns of the Union List in Table 1:

Column 1 (FCM substance No) contains the unique identifier of the substance in the European Commission database on food contact substances available at : https://webgate.ec.europa.eu/sanco_foods/main/?event=display. Each substance has only one unique substance ID consisting of up to 5 digits. This FCM substance No will be used consistently throughout the food contact materials area. This is the new identification system established in the Plastics Regulation replacing the former Ref Nos.

Column 2 (Ref. No) contains the EEC packaging material reference number previously used in Directive 2002/72/EC. The reference numbers are a 5 digit number and indicate if the use is as monomer (10000 to 29999) or if the use is as additive or polymer production aid (PPA) (30000 to 99999).

Column 3 (CAS No) contains the Chemical Abstracts Service (CAS) registry number. If a substance is not registered in the CAS registry or if the substance in the CAS registry does not exactly correspond to the authorised substance no CAS No is indicated. Where there is an inconsistency between the CAS No and the chemical name, the chemical name shall take precedence over the CAS No.

Column 4 (Substance Name) contains the chemical name of the substance as assigned by the Commission services based on the suggestion of the applicant and verified by EFSA.

Column 5 (use as additive or polymer production aid (yes/no)) contains an indication if the substance is authorised to be used as additive or PPA (yes) or if the substance is not authorised to be used as additive or PPA (no). If the substance is only authorised as PPA it is indicated (yes) and in the column Restrictions and specifications (Column 10) the use is restricted to PPA.

Column 6 (use as monomer or other starting substance (yes/no)) contains an indication if the substance is authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes) or if the substance is not authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (no).

Column 7 (FRF applicable (yes/no)) contains an indication on the applicability of the fat consumption reduction factor (FRF) in accordance with Annex V Chapter 4.1 of the Plastics Regulation for a given substance. If (yes) is indicated the migration results can be corrected by the FRF. If (no) is indicated the migration result cannot be corrected by the FRF. The Commission services based on the advice of EFSA decide for which substances the FRF is applicable. Criteria for the decision are based on the SCF opinion Scientific Committee on Food on *The introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials*. (expressed on 4 December 2002).[42] The criteria are the following: the substance is lipophilic (log Po/w > 3) and the value of its migration into simulants A, B and C should not exceed 1/10 of its SML.

Column 8 (SML [mg/kg]) contains the SML applicable to the substance. It is expressed in mg substance per kg food. In the case that there is more than one SML, the applicability of the SMLs is specified in column 10 on Restrictions and specifications. If migration should not be detectable, this is indicated with ND. If an SML is assigned not to a single substance but to a group of substances then this is not mentioned in column 8 but in column 9 where a reference is made to the group restriction.

ND: The detection limit of 0.01 mg substance per kg food does not include an analytical tolerance. The analytical tolerance to be applied depends on the analytical method used by the laboratory. This is a change to the rules formerly applicable in Directive 2002/72/EC. In that Directive the detection limit was listed as "0.02 mg/kg analytical tolerance included" assuming a detection limit of 0.01 mg/kg plus an analytical tolerance of 0.01 mg/kg. The analytical tolerance was thus established by law without any link to the actual performance of the analytical method.

Column 9 (Group restriction No) contains the identification number of the group of substances for which the group restriction in column 1 in Table 2 of Annex I to the Plastics Regulation applies. Some substances are part of different group restrictions or have an individual SML and are part of a group restriction. In these cases both limits apply at the same time. Example: for the substance 797, a plasticizer, 2 group SMLs apply which are referenced in Table 1 of Annex I. The first group is group 31 together with substance 73 and is linked to the toxicological evaluation of the polyester compound derived from the tolerable daily intake of 0.5 mg/kg. The second group is group 32 together with all other plasticizers and is linked to the fact that the migration of plasticizers should not exceed 60 mg/kg as sum of individual substances. This means that the substance itself cannot migrate in higher amounts than 30

[42] http://ec.europa.eu/food/fs/sc/scf/out149_en.pdf.

mg/kg and if other plasticizers are present, the migration of the sum of all plasticizers cannot be more than 60 mg/kg.

Column 10 (Restrictions and specifications) contains restrictions other than the SML listed in columns 8 and 9 and specifications related to the substance. Other restrictions can be for example residual content of the substance in the final product, limitation of the use to certain polymers or in contact with only certain types of food. It can restrict the use to only certain functions or behind a barrier layer. It contains only general specifications related to the substance such as molecular weight or viscosity. In case more detailed specifications as regards the composition are set out, a reference to Table 4 in Annex I to the Plastics Regulation is included.

Where in in column 10 of Table 1 it is mentioned "not to be used for articles in contact with fatty foods for which simulant D is laid down", simulant D should read simulant D1 or D2.

Column 11 (Notes on verification of compliance) contains a number which refers to the detailed rules applicable for verification of compliance included in Table 3 for this substance.

If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

The list of substances is also available as a searchable database at the following website https://webgate.ec.europa.eu/sanco_foods/main/?event=display. This searchable database contains, in addition to the authorised substances, those substances for which applications for authorisation have been submitted and allows the progress of the authorisation procedure to be followed.

8.2 Group restriction of substances (Table 2)

In certain cases when substances are closely chemically and toxicologically related or when a restriction should also cover reaction products a group restriction is assigned. Table 2 on Group restrictions includes the following information:

The **Group restriction No in column 1** contains the identification number of the group of substances for which the group restriction applies. The Group restriction No links Table 2 to Table 1 in Annex I.

The substances listed in **column 2 (FCM Substance No)** are subject to the group restriction listed in column 3.

Column 3 (SML(T) [mg/kg]) contains the total specific migration limit for the sum of substances applicable to a group of substances. The SML(T) is expressed in mg substance per kg food. If the migration of the substance shall be non-detectable, this is indicated with ND.

Column 4 (Group restriction specification) indicates the substance within the group of substances that should be taken as basis for expressing the migration result. As the molecular weight of the different substances within the group may vary the molecular weight of the substance listed in this column should be taken when expressing migration results.

8.3 Notes on verification of compliance (Table 3)

For certain substances, additional rules for testing compliance shall be respected. Even though a SML is set for substances in the columns 8 and/or 9 of Table 1 in Annex I to the Plastics Regulation the verification of compliance with the SML is not always feasible in food or food simulants. This may be due to the volatility or reactivity of the substance or due to other reasons. Also when the scientific opinion on the substance indicated that there is a risk of exceeding the SML under certain circumstances, additional rules for testing migration shall be respected. In such cases the content of Column 2 of Table 3 in Annex I indicates which approach to apply for verification of compliance. The Column 1 of Table 3 contains the Note No, that links Table 3 to Column 11 of Table 1.

8.4 Detailed specification on a substance (Table 4)

For certain substances, a detailed and extensive description of the restrictions and specifications, which cannot be included in Table 1 of Annex I, is required. These detailed specifications are included in Column 2 of Table 4. The Column 1 of Table 4 contains the FCM substance number, which links Table 4 to Column 1 of Table 1. Table 4 currently contains detailed specification on the macromolecule manufactured by microbial fermentation.

9 Annex II - Restrictions on materials and articles

Annex II contains two sections dealing with different type of restrictions applicable to materials and articles.

In the first section specific migration limits (SMLs) are set for certain cations. These may originate from authorised salts but also from substances not subject to listing in the Union list or they may also be present as impurity. The SML should be respected regardless of the source of migration.

In the second section the SML of primary aromatic amines is set to non-detectable. This means that the sum of all released primary aromatic amines shall not be detected with a detection limit of 0.01 mg/kg food or food simulant. Primary aromatic amines can be impurities in the substances used or are reaction or degradation products of colorants, adhesives or fillers. They may also originate from other sources. Primary aromatic amines are proven or suspect mutagenic carcinogens. Therefore they should not migrate in detectable amounts regardless of the source of migration. Only if a primary aromatic amine is authorised and included in Table 1 of Annex I to the Plastics Regulation would the SML mentioned in Table 1 of Annex I apply, instead of this general material specification.

10 Annex III - Food simulants

This Annex contains in Table 1 the list of food simulants assigned to be used in testing of migration for materials not yet in contact with food and for testing overall migration. The Annex assigns 5 different food simulants (A, B, C, D and E) representing the main food characteristics that are influencing migration.

Modified polyphenylene oxide (MPPO) is assigned as the simulant for dry foods. It is a porous polymer with a high molecular weight (500000 to 1000000 Da) a very high temperature stability (Tmax = 350 ºC), a high surface area and a low specific mass (0,23

g/cm3). The substance is commercially known as Tenax ®. The pore size range is important and the reference used is 60 mesh to 80 mesh. Caution should be used, as gas chromatograms obtained from extracts of new commercial MPPO have shown that unacceptably high levels of impurities may be present. Therefore, prior to its first use in this test procedure, the MPPO shall be purified by soxhlet extraction, using diethylether or acetone. MPPO cleaned in this way can be used repeatedly.

The appropriate food simulants for representative food groups have been assigned in Table 2. However, not all possible food groups are listed in the table but only those relating to major food consumption. For food groups not listed expert judgement should be used based on the similarities with other food groups to assign the appropriate simulant.

Where a foodstuff is listed under both a specific and a general heading, only the simulant(s) indicated under the specific heading needs to be used.

Where in Column 10 of Table 1 of Annex I to the Plastics Regulation is mentioned "not to be used for articles in contact with fatty foods for which simulant D is laid down", simulant D should read simulant D1 or D2.

Simulants other than those listed in Annex III to the Plastics Regulation can be used in the context of screening methods and are described in a separate Guidance document on migration testing.

11 Annex IV - Declaration of compliance

Annex IV to the Plastics Regulation contains the information that shall be included in the written declaration referred to in Article 15 (DoC). Detailed information on the DoC are made available in the "*Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain"*..

12 Annex V - Compliance testing

Detailed information on compliance testing is made available in a separate Guidance document on migration testing.

13 Abbreviations

The following abbreviations are used in this Guidance document

CAS Chemical Abstracts Service
DoC Declaration of Compliance
EFSA European Food Safety Authority
EURL European Reference Laboratory
FCM Food contact material
FRF Fat consumption reduction factor
MPPO Modified polyphenylene oxide
ND non-detectable
OML Overall migration limit
PPA Polymer production aid

QM Maximum permitted residual content of a substance in the final material or article as weight per weight
QMA Maximum permitted residual quantity of a substance in the final material or article expressed as weight per surface area
SML Specific migration limit
TPE Thermoplastic Elastomer