Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[(1)], and in particular Article 5(1)(a), (c), (d), (e), (f), (h), (i) and (j) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1935/2004 lays down the general principles for eliminating the differences between the laws of the Member States as regards food contact materials. Article 5(1) of that Regulation provides for the adoption of specific measures for groups of materials and articles and describes in detail the procedure for the authorisation of substances at EU level when a specific measure provides for a list of authorised substances.

(2) This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use and repeal Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs[(2)].

(3) Directive 2002/72/EC sets out basic rules for the manufacture of plastic materials and articles. The Directive has been substantially amended 6 times. For reasons of clarity the text should be consolidated and redundant and obsolete parts removed.

(4) In the past Directive 2002/72/EC and its amendments have been transposed into national legislation without any major adaptation. For transposition into national law usually a time period of 12 months is necessary. In case of amending the lists of monomers and additives in order to authorise new substances this transposition time leads to a retardation of the authorisation and thus slows down innovation. Therefore it seems appropriate to adopt rules on plastic materials and articles in form of a Regulation directly applicable in all Member States.

(5) Directive 2002/72/EC applies to materials and articles purely made of plastics and to plastic gaskets in lids. In the past these were the main use of plastics on the market. However, in recent years, besides materials and articles purely made of plastics, plastics are also used in combination with other materials in so called multi-material multi-layers. Rules on the use of vinyl chloride monomer laid down in 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[3] already apply to all plastics. Therefore it seems appropriate to extend the scope of this Regulation to plastic layers in multi-material multi-layers.

(6) Plastic materials and articles may be composed of different layers of plastics held together by adhesives. Plastic materials and articles may also be printed or coated with an organic or inorganic coating. Printed or coated plastic materials and articles as well as those held together by adhesives should be within the scope of the Regulation. Adhesives, coatings and printing inks are not necessarily composed of the same substances as plastics. Regulation (EC) No 1935/2004 foresees that for adhesives, coatings and printing inks specific measures can be adopted. Therefore plastic materials and articles that are printed, coated or held together by adhesives should be allowed to contain in the printing, coating or adhesive layer other substances than those authorised at EU level for plastics. Those layers may be subject to other EU or national rules.

(7) Plastics as well as ion exchange resins, rubbers and silicones are macromolecular substances obtained by polymerisation processes. Regulation (EC) No 1935/2004 foresees that for ion exchange resins, rubbers and silicones specific measures can be adopted. As those materials are composed of different substances than plastics and have different physico-chemical properties specific rules for them need to apply and it should be made clear that they are not within the scope of this Regulation.

(8) Plastics are made of monomers and other starting substances which are chemically reacted to a macromolecular structure, the polymer, which forms the main structural component of the plastics. To the polymer additives are added to achieve defined technological effects. The polymer as such is an inert high molecular weight structure. As substances with a molecular weight above 1 000 Da usually cannot be absorbed in the body the potential health risk from the polymer itself is minimal. Potential health risk may occur from non- or incompletely reacted monomers or other starting substances or from low molecular weight additives which are transferred into food via migration from the plastic food contact material. Therefore monomers, other starting substances and additives should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.

(9) The risk assessment of a substance to be performed by the European Food Safety Authority (hereinafter the Authority) should cover the substance itself, relevant impurities and foreseeable reaction and degradation products in the intended use. The risk assessment should cover the potential migration under worst foreseeable conditions of use and the toxicity. Based on the risk assessment the authorisation should if

necessary set out specifications for the substance and restrictions of use, quantitative restrictions or migration limits to ensure the safety of the final material or article.

(10) No rules have yet been set out at EU level for the risk assessment and use of colorants in plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.

(11) Solvents used in the manufacture of plastics to create a suitable reaction environment are expected to be removed in the manufacturing process as they are usually volatile. No rules have yet been set out at EU level for the risk assessment and use of solvents in the manufacture of plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.

(12) Plastics can also be made of synthetic or natural occurring macromolecular structures which are chemically reacted with other starting substances to create a modified macromolecule. Synthetic macromolecules used are often intermediate structures which are not fully polymerised. Potential health risk may occur from the migration of non- or incompletely reacted other starting substances used to modify the macromolecule or an incompletely reacted macromolecule. Therefore the other starting substances as well as the macromolecules used in the manufacture of modified macromolecules should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.

(13) Plastics can also be made by micro-organisms that create macromolecular structures out of starting substances by fermentation processes. The macromolecule is then either released to a medium or extracted. Potential health risk may occur from the migration of non- or incompletely reacted starting substances, intermediates or by-products of the fermentation process. In this case the final product should be risk assessed and authorised before its use in the manufacture of plastic materials and articles.

(14) Directive 2002/72/EC contains different lists for monomers or other starting substances and for additives authorised for the manufacture of plastic materials and articles. For monomers, other starting substances and additives the Union list is now complete, this means that only substances authorised at EU level may be used. Therefore a separation of monomers or other starting substances and of additives in separate lists due to their authorisation status is no longer necessary. As certain substances can be used both as monomer or other starting substances and as additive for reasons of clarity they should be published in one list of authorised substances indicating the authorised function.

(15) Polymers can not only be used as main structural component of plastics but also as additives achieving defined technological effects in the plastic. If such a polymeric additive is identical to a polymer that can form the main structural component of a plastic material the risk from polymeric additive can be regarded as evaluated if the monomers have already been evaluated and authorised. In such a case it should not be necessary to authorise the polymeric additive but it could be used on the basis of the authorisation of its monomers and other starting substances. If such a polymeric additive is not identical to a polymer that can form the main structural component of a plastic material then the risk of the polymeric additive can not be regarded as evaluated by evaluation of the monomers. In such a case the polymeric additive should be risk

assessed as regards its low molecular weight fraction below 1 000 Da and authorised before its use in the manufacture of plastic materials and articles.

(16) In the past no clear differentiation has been made between additives that have a function in the final polymer and polymer production aids (PPA) that only exhibit a function in the manufacturing process and are not intended to be present in the final article. Some substances acting as PPA had already been included in the incomplete list of additives in the past. These PPA should remain in the Union list of authorised substances. However, it should be made clear that the use of other PPA will remain possible, subject to national law. That situation should be reassessed at a later stage.

(17) The Union list contains substances authorised to be used in the manufacture of plastics. Substances such as acids, alcohols and phenols can also occur in form of salts. As the salts usually are transformed in the stomach to acid, alcohol or phenol the use of salts with cations that have undergone a safety evaluation should in principle be authorised together with the acid, alcohol or phenol. In certain cases, where the safety assessment indicates concerns on the use of the free acids, only the salts should be authorised by indicating in the list the name as '… acid(s), salts'.

(18) Substances used in the manufacture of plastic materials or articles may contain impurities originating from their manufacturing or extraction process. These impurities are non-intentionally added together with the substance in the manufacture of the plastic material (non-intentionally added substance – NIAS). As far as they are relevant for the risk assessment the main impurities of a substance should be considered and if necessary be included in the specifications of a substance. However it is not possible to list and consider all impurities in the authorisation. Therefore they may be present in the material or article but not included in the Union list.

(19) In the manufacture of polymers substances are used to initiate the polymerisation reaction such as catalysts and to control the polymerisation reaction such as chain transfer, chain extending or chain stop reagents. These aids to polymerisation are used in minute amounts and are not intended to remain in the final polymer. Therefore they should at this point of time not be subject to the authorisation procedure at EU level. Any potential health risk in the final material or article arising from their use should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment.

(20) During the manufacture and use of plastic materials and articles reaction and degradation products can be formed. These reaction and degradation products are non-intentionally present in the plastic material (NIAS). As far as they are relevant for the risk assessment the main reaction and degradation products of the intended application of a substance should be considered and included in the restrictions of the substance. However it is not possible to list and consider all reaction and degradation products in the authorisation. Therefore they should not be listed as single entries in the Union list. Any potential health risk in the final material or article arising from reaction and degradation products should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment.

(21) Prior to the establishment of the Union list of additives, other additives than those authorised at EU level could be used in the manufacture of plastics. For those additives which were permitted in the Member States, the time limit for the submission of data for their safety evaluation by the Authority with a view to their inclusion in the Union list expired on 31 December 2006. Additives for which a valid application was submitted within this time limit were listed in a provisional list. For certain additives on the provisional list a decision on their authorisation at EU level has not yet been taken. For those additives, it should be possible to continue to be used in accordance with national law until their evaluation is completed and a decision is taken on their inclusion in the Union list.

(22) When an additive included in the provisional list is inserted in the Union list or when it is decided not to include it in the Union list, that additive should be removed from the provisional list of additives.

(23) New technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles. These different properties may lead to different toxicological properties and therefore these substances should be assessed on a case-by-case basis by the Authority as regards their risk until more information is known about such new technology. Therefore it should be made clear that authorisations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles.

(24) Based on the risk assessment the authorisation should if necessary set out specific migration limits to ensure the safety of the final material or article. If an additive that is authorised for the manufacture of plastic materials and articles is at the same time authorised as food additive or flavouring substance it should be ensured that the release of the substance does not change the composition of the food in an unacceptable way. Therefore the release of such a dual use additive or flavouring should not exhibit a technological function on the food unless such a function is intended and the food contact material complies with the requirements on active food contact materials set out in Regulation (EC) No 1935/2004 and Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food[(4)]. The requirements of Regulations (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(5)] or (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[(6)] should be respected where applicable.

(25) According to Article 3(1)(b) of Regulation (EC) No 1935/2004 the release of substances from food contact materials and articles should not bring about unacceptable changes in the composition of the food. According to good manufacturing practice it is feasible to manufacture plastic materials in such a way that they are not releasing more than 10 mg of substances per 1 dm^2 of surface area of the plastic material. If the risk

assessment of an individual substance is not indicating a lower level, this level should be set as a generic limit for the inertness of a plastic material, the overall migration limit. In order to achieve comparable results in the verification of compliance with the overall migration limit, testing should be performed under standardised test conditions including testing time, temperature and test medium (food simulant) representing worst foreseeable conditions of use of the plastic material or article.

(26) The overall migration limit of 10 mg per 1 dm^2 results for a cubic packaging containing 1kg of food to a migration of 60 mg per kg food. For small packaging where the surface to volume ratio is higher the resulting migration into food is higher. For infants and small children which have a higher consumption of food per kilogram bodyweight than adults and do not yet have a diversified nutrition, special provisions should be set in order to limit the intake of substances migrating from food contact materials. In order to allow also for small volume packaging the same protection as for high volume packaging, the overall migration limit for food contact materials that are dedicated for packaging foods for infants and small children should be linked to the limit in food and not to the surface area of the packaging.

(27) In recent years plastic food contact materials are being developed that do not only consist of one plastic but combine up to 15 different plastic layers to attain optimum functionality and protection of the food, while reducing packaging waste. In such a plastic multi-layer material or article, layers may be separated from the food by a functional barrier. This barrier is a layer within food contact materials or articles preventing the migration of substances from behind that barrier into the food. Behind a functional barrier, non-authorised substances may be used, provided they fulfil certain criteria and their migration remains below a given detection limit. Taking into account foods for infants and other particularly susceptible persons, as well as the large analytical tolerance of the migration analysis, a maximum level of 0,01 mg/kg in food should be established for the migration of a non-authorised substance through a functional barrier. Substances that are mutagenic, carcinogenic or toxic to reproduction should not be used in food contact materials or articles without previous authorisation and should therefore not be covered by the functional barrier concept. New technologies that engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles, should be assessed on a case-by-case basis as regards their risk until more information is known about such new technology. Therefore, they should not be covered by the functional barrier concept.

(28) In recent years food contact materials and articles are being developed that consist of a combination of several materials to achieve optimum functionality and protection of the food while reducing packaging waste. In these multi-material multi-layer materials and articles plastic layers should comply with the same compositional requirements as plastic layers which are not combined with other materials. For plastic layers in a multi-material multi-layer which are separated from the food by a functional barrier the functional barrier concept should apply. As other materials are combined with the plastic layers and for these other materials specific measures are not yet adopted at EU level it is not yet possible to set out requirements for the final multi-material multi-layer

materials and articles. Therefore specific migration limits and the overall migration limit should not be applicable except for vinyl chloride monomer for which such a restriction is already in place. In the absence of a specific measure at EU level covering the whole multi-material multi-layer material or article Member States may maintain or adopt national provisions for these materials and articles provided they comply with the rules of the Treaty.

(29) Article 16(1) of Regulation (EC) No 1935/2004 provides that materials and articles covered by specific measures be accompanied by a written declaration of compliance stating that they comply with the rules applicable to them. To strengthen the coordination and responsibility of the suppliers at each stage of manufacture, including that of the starting substances, the responsible persons should document the compliance with the relevant rules in a declaration of compliance which is made available to their customers.

(30) Coatings, printing inks and adhesives are not yet covered by a specific EU legislation and therefore not subject to the requirement of a declaration of compliance. However, for coatings, printing inks and adhesives to be used in plastic materials and articles adequate information should be provided to the manufacturer of the final plastic article that would enable him to ensure compliance for substances for which migration limits have been established in this Regulation.

(31) Article 17(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[7] requires the food business operator to verify that foods are compliant with the rules applicable to them. To this end and subject to the requirement of confidentiality, food business operators should be given access to the relevant information to enable them to ensure that the migration from the materials and articles to food complies with the specifications and restrictions laid down in food legislation.

(32) At each stage of manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities. Such demonstration of compliance may be based on migration testing. As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing. Test results should be regarded as valid as long as formulations and processing conditions remain constant as part of a quality assurance system.

(33) When testing articles not yet in contact with food, for certain articles, such as films or lids, it is often not feasible to determine the surface area that is in contact with a defined volume of food. For these articles specific rules should be set out for verification of compliance.

(34) The setting of migration limits takes into account a conventional assumption that 1kg of food is consumed daily by a person of 60 kg bodyweight and that the food is packaged in a cubic container of 6 dm^2 surface area releasing the substance. For very small and very large containers the real surface area to volume of packaged food is varying a lot

from the conventional assumption. Therefore, their surface area should be normalised before comparing testing results with migration limits. These rules should be reviewed when new data on food packaging uses become available.

(35) The specific migration limit is a maximum permitted amount of a substance in food. This limit should ensure that the food contact material does not pose a risk to health. It should be ensured by the manufacturer that materials and articles not yet in contact with food will respect these limits when brought into contact with food under the worst foreseeable contact conditions. Therefore compliance of materials and articles not yet in contact with food should be assessed and the rules for this testing should be set out.

(36) Food is a complex matrix and therefore the analysis of migrating substances in food may pose analytical difficulties. Therefore test media should be assigned that simulate the transfer of substances from the plastic material into food. They should represent the major physico-chemical properties exhibited by food. When using food simulants standard testing time and temperature should reproduce, as far as possible, the migration which may occur from the article into the food.

(37) For determining the appropriate food simulant for certain foods the chemical composition and the physical properties of the food should be taken into account. Research results are available for certain representative foods comparing migration into food with migration into food simulants. On the basis of the results, food simulants should be assigned. In particular, for fat containing foods the result obtained with food simulant may in certain cases significantly overestimate migration into food. In these cases it should be foreseen that the result in food simulant is corrected by a reduction factor.

(38) The exposure to substances migrating from food contact materials was based on the conventional assumption that a person consumes daily 1 kg of food. However, a person ingests at most 200 g of fat on a daily basis. For lipophilic substances that only migrate into fat this should be taken into consideration. Therefore a correction of the specific migration by a correction factor applicable to lipophilic substances in accordance with the opinion of the Scientific Committee on Food (SCF)[(8)] and the opinion of the Authority[(9)] should be foreseen.

(39) Official control should establish testing strategies which allow the enforcement authorities to perform controls efficiently making best use of available resources. Therefore it should be admissible to use screening methods for checking compliance under certain conditions. Non-compliance of a material or article should be confirmed by a verification method.

(40) Basic rules on migration testing should be set out in this Regulation. As migration testing is a very complex issue, these basic rules can, however, not cover all foreseeable cases and details necessary for performing the testing. Therefore a EU guidance document should be established, dealing with more detailed aspects of the implementation of the basic migration testing rules.

(41) The updated rules on food simulants and migration testing provided by this Regulation will supersede those in Directive 78/142/EEC and the Annex to 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[10].

(42) Substances present in the plastic but not listed in Annex I to this Regulation have not necessarily been risk assessed as they had not been subject to an authorisation procedure. Compliance with Article 3 of Regulation (EC) No 1935/2004 for these substances should be assessed by the relevant business operator in accordance with internationally recognised scientific principles taking into account exposure from food contact materials and other sources.

(43) Recently additional monomers, other starting substances and additives have received a favourable scientific evaluation by the Authority and should now be added to the Union list.

(44) As new substances are added to the Union list the Regulation should apply as soon as possible to allow for manufacturers to adapt to technical progress and allow for innovation.

(45) Certain migration testing rules should be updated in view of new scientific knowledge. Enforcement authorities and industry need to adapt their current testing regime to these updated rules. To allow for this adaptation it seems appropriate that the updated rules only apply 2 years after the adoption of the Regulation.

(46) Business operators are currently basing their declaration of compliance on supporting documentation following the requirements set out in Directive 2002/72/EC. Declaration of compliance need, in principle, only to be updated when substantial changes in the production bring about changes in the migration or when new scientific data are available. In order to limit the burden to business operators, materials which have been lawfully placed on the market based on the requirements set out in Directive 2002/72/EC should be able to be placed on the market with a declaration of compliance based on supporting documentation in accordance with Directive 2002/72/EC until 5 years after the adoption of the Regulation.

(47) Analytical methods for testing migration and residual content of vinyl chloride monomer as described in Commission Directives 80/766/EEC of 8 July 1980 laying down the Community 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[11] and 81/432/EEC of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs[12] are outdated. Analytical methods should comply with the criteria set out in Article 11 of Regulation (EC) No 882/2004[13] 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. Therefore Directives 80/766/EEC and 81/432/EEC should be repealed.

(48) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1 This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.

2 This Regulation establishes specific requirements for the manufacture and marketing of plastic materials and articles:

a intended to come into contact with food; or

b already in contact with food; or

c which can reasonably be expected to come into contact with food.

Article 2

Scope

1 This Regulation shall apply to materials and articles which are placed on the EU market and fall under the following categories:

a materials and articles and parts thereof consisting exclusively of plastics;

b plastic multi-layer materials and articles held together by adhesives or by other means;

c materials and articles referred to in points a) or b) that are printed and/or covered by a coating;

d plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;

e plastic layers in multi-material multi-layer materials and articles.

2 This Regulation shall not apply to the following materials and articles which are placed on the EU market and are intended to be covered by other specific measures:

a ion exchange resins;

b rubber;

c silicones.

3 This Regulation shall be without prejudice to the EU or national provisions applicable to printing inks, adhesives or coatings.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(1) ‘plastic materials and articles’ means:

(a) materials and articles referred to in points (a), (b) and (c) of Article 2(1); and

(b) plastic layers referred to in Article 2(1)(d) and (e);

(2) 'plastic' means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles;

(3) 'polymer' means any macromolecular substance obtained by:

(a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or

(b) chemical modification of natural or synthetic macromolecules; or

(c) microbial fermentation;

(4) 'plastic multi-layer' means a material or article composed of two or more layers of plastic;

(5) 'multi-material multi-layer' means a material or article composed of two or more layers of different types of materials, at least one of them a plastic layer;

(6) 'monomer or other starting substance' means:

(a) a substance undergoing any type of polymerisation process to manufacture polymers; or

(b) a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or

(c) a substance used to modify existing natural or synthetic macromolecules;

(7) 'additive' means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article;

(8) 'polymer production aid' means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article;

(9) 'non-intentionally added substance' means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product;

(10) 'aid to polymerisation' means a substance which initiates polymerisation and/or controls the formation of the macromolecular structure;

(11) 'overall migration limit' (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants;

(12) 'food simulant' means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials;

(13) 'specific migration limit' (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants;

(14) 'total specific migration limit' (SML(T)) means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated;

(15) 'functional barrier' means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation;

(16) **[**F1'non-fatty food' means a food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table 2 of Annex III to this Regulation;**]**

(17) 'restriction' means limitation of use of a substance or migration limit or limit of content of the substance in the material or article;

(18) **[**F1'specification' means composition of a substance, purity criteria for a substance, physico-chemical characteristics of a substance, details concerning the manufacturing process of a substance or further information concerning the expression of migration limits;**]**

(19) **[**F2'hot-fill' means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F2 Inserted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Article 4

Placing on the market of plastic materials and articles

Plastic materials and articles may only be placed on the market if they:

(a) comply with the relevant requirements set out in Article 3 of Regulation (EC) No 1935/2004 under intended and foreseeable use; and

(b) comply with the labelling requirements set out in Article 15 of Regulation (EC) No 1935/2004; and

(c) comply with the traceability requirements set out in Article 17 of Regulation (EC) No 1935/2004; and

(d) are manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006[(14)]; and

(e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation.

CHAPTER II

COMPOSITIONAL REQUIREMENTS

SECTION 1

Authorised substances

Article 5

Union list of authorised substances

1 Only the substances included in the Union list of authorised substances (hereinafter referred to as the Union list) set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

2 The Union list shall contain:

a monomers or other starting substances;

b additives excluding colorants;

c polymer production aids excluding solvents;

d macromolecules obtained from microbial fermentation.

3 The Union list may be amended in accordance with the procedure established by Articles 8 to 12 of Regulation (EC) No 1935/2004.

Article 6

Derogations for substances not included in the Union list

1 By way of derogation from Article 5, substances other than those included in the Union list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to national law.

2 By way of derogation from Article 5, colorants and solvents may be used in the manufacture of plastic layers in plastic materials and articles subject to national law.

3 The following substances not included in the Union list are authorised subject to the rules set out in Articles 8, 9, 10, 11 and 12:

[[F1]a all salts of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;**]**

b mixtures obtained by mixing authorised substances without a chemical reaction of the components;

c when used as additives, natural or synthetic polymeric substances of a molecular weight of at least 1 000 Da, except macromolecules obtained from microbial fermentation, complying with the requirements of this Regulation, if they are capable of functioning as the main structural component of final materials or articles;

d when used as monomer or other starting substance, pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, except macromolecules obtained from microbial fermentation, if the monomers or starting substances required to synthesise them are included in the Union list.

4 The following substances not included in the Union list may be present in the plastic layers of plastic materials or articles:

a non-intentionally added substances;

b aids to polymerisation.

5 By derogation from Article 5, additives not included in the Union list may continue to be used subject to national law after 1 January 2010 until a decision is taken to include or not to include them in the Union list provided they are included in the provisional list referred to in Article 7.

Textual Amendments

F1 Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Article 7

Establishment and management of the provisional list

1 The provisional list of additives that are under evaluation by the European Food Safety Authority (hereinafter referred to as the Authority) that was made public by the Commission in 2008 shall be regularly updated.

2 An additive shall be removed from the provisional list:

a when it is included in the Union list set out in Annex I; or

b when a decision is taken by the Commission not to include it in the Union list; or

c if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.

SECTION 2

General requirements, restrictions and specifications

Article 8

General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

Article 9

Specific requirements on substances

1 Substances used in the manufacture of plastic layers in plastic materials and articles shall be subject to the following restrictions and specifications:

a the specific migration limit set out in Article 11;
b the overall migration limit set out in Article 12;
c the restrictions and specifications set out in column 10 of Table 1 of point 1 of Annex I;
d the detailed specifications set out in point 4 of Annex I.

2 Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I.

Article 10

General restrictions on plastic materials and articles

General restrictions related to plastic materials and articles are laid down in Annex II.

Article 11

Specific migration limits

1 Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).

F3 2 . . . . . .

[F1 3 By derogation from paragraph 1, additives which are also authorised as food additives by Regulation (EC) No 1333/2008 or as flavourings by Regulation (EC) No 1334/2008 shall not migrate into foods in quantities having a technical effect in the final foods and shall not:

a exceed the restrictions provided for in Regulation (EC) No 1333/2008 or in Regulation (EC) No 1334/2008 or in Annex I to this Regulation for foods for which their use is authorised as food additive or flavouring substances; or
b exceed the restrictions set out in Annex I to this Regulation in foods for which their use is not authorised as food additive or flavouring substances.**]**

[F2 4 Where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No 882/2004 that can confirm the absence of migration above a specified limit of detection.

For the purposes of the first subparagraph, unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F2 Inserted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F3 Deleted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Article 12

Overall migration limit

1 Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2).

2 By derogation from paragraph 1, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC[15] and 2006/125/EC[16], shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

CHAPTER III

SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES

Article 13

Plastic multi-layer materials and articles

1 In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

2 By derogation from paragraph 1, a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may:

a not comply with the restrictions and specifications set out in this Regulation except for vinyl chloride monomer as provided in Annex I; and/or

b be manufactured with substances not listed in the Union list or in the provisional list.

[[F1]3 Substances under paragraph 2(b) shall not migrate into food or food simulant, in accordance with Article 11(4). The detection limit set out in the second subparagraph of Article 11(4) shall apply to groups of substances if they are structurally and toxicologically related, including isomers or substances with the same relevant functional group, or to individual substances that are not related, and shall include possible set-off transfer.**]**

4 The substances not listed in the Union list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:

a substances classified as ‘mutagenic’, ‘carcinogenic’ or ‘toxic to reproduction’ in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and the Council[17];

b substances in nanoform.

5 The final plastic multi-layer material or article shall comply with the specific migration limits set out in Article 11 and the overall migration limit set out in Article 12 of this Regulation.

Textual Amendments

F1 Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Article 14

Multi-material multi-layer materials and articles

1 In a multi-material multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

2 By derogation from paragraph 1, in a multi-material multi-layer material or article a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may be manufactured with substances not listed in the Union list or the provisional list.

3 The substances not listed in the Union list or provisional list referred to in paragraph 2 shall not belong to either of the following categories:

a substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008;

b substances in nanoform.

4 By derogation from paragraph 1, Articles 11 and 12 of this Regulation do not apply to plastic layers in multi-material multi-layer materials and articles.

5 The plastic layers in a multi-material multi-layer material or article shall always comply with the restrictions for vinyl chloride monomer laid down in Annex I to this Regulation.

6 In a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law.

CHAPTER IV

DECLARATION OF COMPLIANCE AND DOCUMENTATION

Article 15

Declaration of compliance

1 At the marketing stages other than at the retail stage, a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

2 The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex IV.

3 The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall

be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

Article 16

Supporting documents

1 Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the national competent authorities on request.

2 That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V.

CHAPTER V

COMPLIANCE

Article 17

Expression of migration test results

1 To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.

2 By derogation from paragraph 1 for:

a containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,

b materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith,

c sheets and films that are not yet in contact with food,

d sheets and films containing less than 500 millilitres or grams or more than 10 litres,

the value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm^2 per kg of food.

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC.

3 By derogation from paragraph 1, for caps, gaskets, stoppers and similar sealing articles the specific migration value shall be expressed in:

[[F1]a mg/kg using the actual content of the container for which the closure is intended applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2;**]**

b mg/article if the intended use of the article is unknown.

4 For caps, gaskets, stoppers and similar sealing articles the overall migration value shall be expressed in:

a mg/dm^2 applying the total contact surface of sealing article and sealed container if the intended use of the article is known;

b mg/article if the intended use of the article is unknown.

Textual Amendments

F1 Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Article 18

Rules for assessing compliance with migration limits

1 For materials and articles already in contact with food verification of compliance with specific migration limits shall be carried out in accordance with the rules set out in Chapter 1 of Annex V.

2 For materials and articles not yet in contact with food verification of compliance with specific migration limits shall be carried out in food or in food simulants set out in Annex III in accordance with the rules set out in Chapter 2, Section 2.1 of Annex V.

3 For materials and articles not yet in contact with food screening of compliance with the specific migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 2, Section 2.2 of Annex V. If a material or article fails to comply with the migration limits in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 2.

[[F1]4 For materials and articles not yet in contact with food verification of compliance with the overall migration limit shall be carried out in food simulants as set out in Annex III in accordance with the rules set out in Chapter 3 of Annex V.**]**

5 For materials and articles not yet in contact with food screening of compliance with the overall migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 3, Section 3.4 of Annex V. If a material or article fails to comply with the migration limit in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 4.

6 The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.

[[F1]7 Before comparing specific and overall migration test results with the migration limits the correction factors set out in point 3 of Annex III and Chapter 4 of Annex V shall be applied in accordance with the rules set out therein.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Article 19

Assessment of substances not included in the Union list

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

CHAPTER VI

FINAL PROVISIONS

Article 20

Amendments of EU acts

The Annex to Council Directive 85/572/EEC[(18)] is replaced by the following:

'The food simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with a single food or specific groups of foods are set out in point 3 of Annex III to Commission Regulation (EU) No 10/2011.'

Article 21

Repeal of EU acts

Directives 80/766/EEC, 81/432/EEC, and 2002/72/EC are hereby repealed with effect from 1 May 2011.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation tables in Annex VI.

Article 22

Transitional provisions

1 Until 31 December 2012 the supporting documents referred to in Article 16 shall be based on the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

2 As from 1 January 2013 the supporting documents referred to in Article 16 for materials, articles and substances placed on the market until 31 December 2015, may be based on:

a the rules for migration testing set out in Article 18 of this Regulation; or

b the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

3 As from 1 January 2016, the supporting documents referred to in Article 16 shall be based on the rules for migration testing set out in Article 18, without prejudice to paragraph 2 of this Article.

4 Until 31 December 2015 additives used in glass fibre sizing for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19.

5 Materials and articles that have been lawfully placed on the market before 1 May 2011 may be placed on the market until 31 December 2012.

Article 23

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 May 2011.

The provision of Article 5 as regards the use of additives, others than plasticisers, shall apply for plastic layers or plastic coatings in caps and closures referred to in Article 2(1)(d), as from 31 December 2015.

The provision of Article 5 as regards the use of additives used in glass fibre sizing for glass fibre reinforced plastics, shall apply from 31 December 2015.

The provisions of Articles 18(2), 18(4) and 20 shall apply from 31 December 2012.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

ANNEX I

Substances

1. Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids

Table 1 contains the following information:

Column 1 (FCM substance No): the unique identification number of the substance

Column 2 (Ref. No): the EEC packaging material reference number

Column 3 (CAS No): the Chemical Abstracts Service (CAS) registry number

Column 4 (Substance Name): the chemical name

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

Column 6 (Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)): 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). If the substance is authorised as macromolecule obtained from microbial fermentation it is indicated (yes) and in the specifications it is indicated that the substance is a macromolecule obtained from microbial fermentation.

Column 7 (FRF applicable (yes/no)): an indication if for the substance the migration results can be corrected by the Fat Consumption Reduction Factor (FRF) (yes) or if they cannot be corrected by the FRF (no).

[[F1]Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is marked as ND (‘not-detectable’) if the substance is one in respect of which no migration is permitted, to be determined in accordance with Article 11(4).**]**

Column 9 (SML(T) [mg/kg] (group restriction No)): contains the identification number of the group of substances for which the group restriction in Column 1 in Table 2 of this Annex applies.

Column 10 (Restrictions and specifications): contains other restrictions than the specific migration limit specifically mentioned and it contains specifications related to the substance. In case detailed specifications are set out a reference to Table 4 is included.

Column 11 (Notes on verification of compliance): contains the Notes number which refers to the detailed rules applicable for verification of compliance for this substance included in Column 1 in Table 3 of this Annex.

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.

[[F3]. . . . . .**]**

TABLE 1

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	**Ref. No**	**CAS No**	**Substance name**	**Use as additive or polymer production aid(yes/ no)**	**Use as monomer or other starting substance or macromolecule obtained from microbial fermentation(yes/ no)**	**FRF applicable(yes/ no)**	**SML[mg/kg]**	**SML(T) [mg/ kg] (Group restriction No)**	**Restrictions and specifications**	**Notes on verification of compliance**
1	12310	0266309-43-7	albumin	no	yes	no				
2	12340	—	albumin, coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{22})	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)
5	25360	—	trialkyl(C_5-C_{15})acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxygroup.	

									Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C_7-C_{17}), vinyl esters	no	yes	no	0,05			(1)
7	30370	—	acetylacetic acid, salts	yes	no	no				
8	30401	—	acetylated mono- and diglycerides of fatty acids	yes	no	no		(32)		
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 occuring levels are included)	yes	no	no				
10	30612	—	acids, C_2-C_{24},	yes	no	no				

			aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters							
11	30960	—	acids, aliphatic, monocarboxylic (C_6-C_{22}), esters with polyglycerol	yes	no	no				
12	31328	—	acids, fatty, from animal or vegetable food fats and oils	yes	no	no				
13	33120	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{24})	yes	no	no				
14	33801	—	n-alkyl(C_{10}-C_{13})benzenesulphonic acid	yes	no	no	30			
15	34130	—	alkyl, linear with even number of carbon atoms (C_{12}-	yes	no	yes	30			

			C_{20}) dimethylamines							
16	34230	—	alkyl(C_8-C_{22})sulphonic acids	yes	no	no	6			
17	34281	—	alkyl(C_8-C_{22})sulphuric acids, linear, primary with an even number of carbon atoms	yes	no	no				
18	34475	—	aluminium calcium hydroxide phosphite, hydrate	yes	no	no				
19	39090	—	N,N-bis(2-hydroxyethyl)alkyl(C_8-C_{18})amine	yes	no	no		(7)		
20	39120	—	N,N-bis(2-hydroxyethyl)alkyl(C_8-C_{18})amine hydrochlorides	yes	no	no		(7)	SML(T) expressed excluding HCl	
21	42500	—	carbonic acid, salts	yes	no	no				
22	43200	—	castor oil, mono- and diglycerides	yes	no	no				
23	43515	—	chlorides of choline esters of coconut oil	yes	no	no	0,9			(1)

			fatty acids							
24	45280	—	cotton fibers	yes	no	no				
25	45440	—	cresols, butylated, styrenated	yes	no	no	12			
26	46700	—	5,7-di-tert-butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to 100 % w/w) and b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0 to 20 % w/w)	yes	no	no	5			
27	48960	—	9,10-dihydroxy stearic acid and its oligomers	yes	no	no	5			
28	50160	—	di-n-octyltin bis(n-alkyl(C_{10}-C_{16}) mercaptoacetate)	yes	no	no		(10)		

29	50360	—	di-n-octyltin bis(ethyl maleate)	yes	no	no		(10)		
30	50560	—	di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	yes	no	no		(10)		
31	50800	—	di-n-octyltin dimaleate, esterified	yes	no	no		(10)		
32	50880	—	di-n-octyltin dimaleate, polymers (n = 2-4)	yes	no	no		(10)		
33	51120	—	di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	yes	no	no		(10)		
34	54270	—	ethylhydroxymethylcellulose	yes	no	no				
35	54280	—	ethylhydroxypropylcellulose	yes	no	no				
36	54450	—	fats and oils, from animal or vegetable food sources	yes	no	no				
37	54480	—	fats and oils, hydrogenated, from animal or vegetable food sources	yes	no	no				

38	55520	—	glass fibers	yes	no	no				
39	55600	—	glass microballs	yes	no	no				
40	56360	—	glycerol, esters with acetic acid	yes	no	no				
41	56486	—	glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C_{14}-C_{18}) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C_{16}-C_{18})	yes	no	no				
42	56487	—	glycerol, esters with butyric acid	yes	no	no				
43	56490	—	glycerol, esters with	yes	no	no				

			erucic acid							
44	56495	—	glycerol esters with 12-hydroxystearic acid	yes	no	no				
45	56500	—	glycerol esters with lauric acid	yes	no	no				
46	56510	—	glycerol esters with linoleic acid	yes	no	no				
47	56520	—	glycerol esters with myristic acid	yes	no	no				
48	56535	—	glycerol esters with nonanoic acid	yes	no	no				
49	56540	—	glycerol esters with oleic acid	yes	no	no				
50	56550	—	glycerol esters with palmitic acid	yes	no	no				
51	56570	—	glycerol esters with propionic acid	yes	no	no				
52	56580	—	glycerol esters with ricinoleic acid	yes	no	no				

53	56585	—	glycerol esters with stearic acid	yes	no	no			
54	57040	—	glycerol monooleate, ester with ascorbic acid	yes	no	no			
55	57120	—	glycerol monooleate, ester with citric acid	yes	no	no			
56	57200	—	glycerol monopalmitate, ester with ascorbic acid	yes	no	no			
57	57280	—	glycerol monopalmitate, ester with citric acid	yes	no	no			
58	57600	—	glycerol monostearate, ester with ascorbic acid	yes	no	no			
59	57680	—	glycerol monostearate, ester with citric acid	yes	no	no			
60	58300	—	glycine, salts	yes	no	no			
62	64500	—	lysine, salts	yes	no	no			
63	65440	—	manganese pyrophosphite	yes	no	no			

64	66695	—	methylhydroxymethylcellulose	yes	no	no				
65	67155	—	mixture of 4-(2-benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl)stilbene, 4,4′-bis(2-benzoxazolyl) stilbene and 4,4′-bis(5-methyl-2-benzoxazolyl)stilbene	yes	no	no			Not more than 0,05 % (w/w) (quantity of substance used/ quantity of the formulation). Mixture obtained from the manufacturing process in the typical ratio of (58-62 %): (23-27 %): (13-17 %).	
66	67600	—	mono-n-octyltin tris(alkyl(C_{10}-C_{16}) mercaptoacetate)	yes	no	no		(11)		
67	67840	—	montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol	yes	no	no				

68	73160	—	phosphorous acid, mono- and di-n-alkyl (C_{16} and C_{18}) esters	yes	no	yes	0,05			
69	74400	—	phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester	yes	no	yes	30			
70	76463	—	polyacrylic acid, salts	yes	no	no		(22)		
71	76730	—	polydimethylsiloxane, γ-hydroxypropylated	yes	no	no	6			
72	76815	—	polyesters of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C_{12}-C_{22} fatty acids	yes	no	no		(32)	The fraction with molecular weight below 1 000 Da [F1shall] not exceed 5 % (w/w)	
73	76866	—	polyesters of 1,2-propanediol and/or 1,3-and/or 1,4-butanediol and/or polypropyleneglycol with adipic	yes	no	yes		(31) (32)		

			acid, which may be end-capped with acetic acid or fatty acids C_{12}-C_{18} or n-octanol and/or n-decanol							
74	77440	—	polyethylene glycol diricinoleate	yes	no	yes	42			
75	77702	—	polyethylene glycol esters of aliph. monocarb. acids (C_6-C_{22}) and their ammonium and sodium sulphates	yes	no	no				
76	77732	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	yes	no	no	0,05		Only for use in PET	

77	77733	—	polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	yes	no	no	0,05		Only for use in PET	
78	77897	—	polyethyleneglycol (EO = 1-50) monoalkylether (linear and branched, C_8-C_{20}) sulphate, salts	yes	no	no	5			
79	80640	—	polyoxyalkyl (C_2-C_4) dimethylpolysiloxane	yes	no	no				
80	81760	—	powders, flakes and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron	yes	no	no				
81	83320	—	propylhydroxyethylcellulose	yes	no	no				
82	83325	—	propylhydroxymethylcellulose	yes	no	no				
83	83330	—	propylhydroxypropylcellulose	yes	no	no				

84	85601	—	silicates, natural (with the exception of asbestos)	yes	no	no				
85	85610	—	silicates, natural, silanated (with the exception of asbestos)	yes	no	no				
86	86000	—	silicic acid, silylated	yes	no	no				
[F1 87	86285		Silicon dioxide, silanated	yes	no	no			For synthetic amorphous silicon dioxide, silanated: primary particles of 1–100 nm which are aggregated to a size of 0,1–1 μm and may form agglomerates within the size distribution of 0,3 μm to the mm size.	]

88	86880	—	sodium monoalkyl dialkylphenoxybenzenedisulphonate	yes	no	no	9			
89	89440	—	stearic acid, esters with ethyleneglycol	yes	no	no		(2)		
90	92195	—	taurine, salts	yes	no	no				
91	92320	—	tetradecyl polyethyleneglycol(EO = 3-8) ether of glycolic acid	yes	no	yes	15			
92	93970	—	tricyclodecanedimethanol bis(hexahydrophthalate)	yes	no	no	0,05			
93	95858	—	waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which [F1 simulant D1 and/ or D2] is laid down. Average molecular weight not less than 350 Da. Viscosity at 100 °C not less than	

									2,5 cSt (2,5 × 10^{-6} m^2/s). Content of hydrocarbons with Carbon number less than 25, not more than 40 % (w/w).
94	95859	—	waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity	yes	no	no			Average molecular weight not less than 500 Da. Viscosity at 100 °C not less than 11 cSt (11 × 10^{-6} m^2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
95	95883	—	white mineral oils,	yes	no	no			Average molecular weight

			paraffinic, derived from petroleum based hydrocarbon feedstocks						not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10^{-6} m^2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
96	95920	—	wood flour and fibers, untreated	yes	no	no			
97	72081/10	—	petroleum hydrocarbon resins (hydrogenated)	yes	no	no			Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermalpolymerisation of dienes and olefins of the aliphatic, alicyclic and/or

									monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing. Properties: — Viscosity at 120 °C: > 3 Pa.s, — Softening point: > 95 °C as determined by ASTM Method E 28-67,

									—	Bromine number: < 40 (ASTM D1159), — The colour of a 50 % solution in toluene < 11 on the Gardner scale, — Residual aromatic monomer ≤ 50 ppm,
98	17260 54880	00000500-00-0	formaldehyde	yes	yes	no		(15)		
99	19460 62960	00000500-21-5	lactic acid	yes	yes	no				
100	24490 88320	00000500-36-4	sorbitol	yes	yes	no				
101	36000	00000500-81-7	ascorbic acid	yes	no	no				
102	17530	00000500-99-7	glucose	no	yes	no				
103	18100 55920	00000556-81-5	glycerol	yes	yes	no				
104	58960	0000057-09-0	hexadecyltrimethylammonium bromide	yes	yes	no	6			
105	22780 70400	00000057-10-3	palmitic acid	yes	yes	no				
106	24550 89040	00000057-11-4	stearic acid	yes	yes	no				

107	25960	00000057-13-6	urea	no	yes	no				
108	24880	00000057-50-1	sucrose	no	yes	no				
109	23740 81840	00000057-55-6	1,2-propanediol	yes	yes	no				
110	93520	00000059-02-9 00101911-40-0	α-tocopherol	yes	no	no				
111	53600	00000060-00-4	ethylenediaminetetraacetic acid	no		no				
112	64015	00000060-33-3	linoleic acid	yes	no	no				
113	16780 52800	00000064-17-5	ethanol	yes	yes	no				
114	55040	00000064-18-6	formic acid	yes	no	no				
115	10090 30000	00000064-19-7	acetic acid	yes	yes	no				
116	13090 37600	00000065-85-0	benzoic acid	yes	yes	no				
117	21550	00000067-56-1	methanol	no	yes	no				
118	23830 81882	00000067-63-0	propanol	yes	yes	no				
119	30295	00000067-64-1	acetone	yes	no	no				
120	49540	00000067-68-5	dimethyl sulphoxide	yes	no	no				
121	24270 84640	00000069-72-7	salicylic acid	yes	yes	no				
122	23800	00000071-23-8	propanol	no	yes	no				
123	13840	00000071-36-3	butanol	no	yes	no				
124	22870	00000071-41-0	pentanol	no	yes	no				
125	16950	00000074-85-1	ethylene	no	yes	no				
126	10210	00000074-86-2	acetylene	no	yes	no				
127	26050	00000075-01-4	vinyl chloride	no	yes	no	ND		1 mg/kg in final product	

128	10060	0000075-07-0	acetaldehyde	no	yes	no		(1)		
129	17020	0000075-21-8	ethylene oxide	no	yes	no	ND		1 mg/kg in final product	(10)
130	26110	0000075-35-4	vinylidene chloride	no	yes	no	ND			(1)
131	48460	0000075-37-6	1,1-difluoroethane	yes	no	no				
132	26140	0000075-38-7	vinylidene fluoride	no	yes	no	5			
133	14380 23155	0000075-44-5	carbonyl chloride	no	yes	no	ND		1 mg/kg in final product	(10)
134	43680	0000075-45-6	chlorodifluoromethane	yes	no	no	6		Content of chlorofluoromethane less than 1 mg/kg of the substance	
135	24010	0000075-56-9	propylene oxide	no	yes	no	ND		1 mg/kg in final product	
136	41680	0000076-22-2	camphor	yes	no	no				(3)
137	66580	0000077-62-3	2,2′-methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	yes	no	yes		(5)		
138	93760	0000077-90-7	tri-n-butyl acetyl citrate	yes	no	no		(32)		
139	14680 44160	0000077-92-9	citric acid	yes	yes	no				
140	44640	0000077-93-0	citric acid, triethyl ester	yes	no	no		(32)		
141	13380	0000077-99-6	1,1,1-trimethylolpropane	yes	yes	no	6			

	25600 94960									
142	26305	0000078-08-0	vinyltriethoxysilane	yes	no	no	0,05		Only to be used as a surface treatment agent	[F9(1)]
143	62450	0000078-78-4	isopentane	yes	no	no				
144	19243 21640	0000078-79-5	2-methyl-1,3-butadiene	no	yes	no	ND		1 mg/kg in final product	
145	10630	0000079-06-1	acrylamide	no	yes	no	ND			
146	23890 82000	0000079-09-4	propionic acid	yes	yes	no				
147	10690	0000079-10-7	acrylic acid	no	yes	no		(22)		
148	14650	0000079-38-9	chlorotrifluoroethylene	no	no	no	ND			(1)
149	19990	0000079-39-0	methacrylamide	no	yes	no	ND			
150	20020	0000079-41-4	methacrylic acid	no	yes	no		(23)		
[F6151	13480 13607]	0000080-05-7	2,2-bis(4-hydroxyphenyl)propane	no	yes	no	0,05		Not to be used for the manufacture of polycarbonate infant[f] feeding bottles[g]. Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to	

									their spill proof characteristics, are intended for infants[i] and young children[j].	
152	15610	000008047-9	4,4'-dichlorodiphenyl sulphone	no	yes	no	0,05			
153	15267	000008048-0	4,4'-diaminodiphenyl sulphone	no	yes	no	5			
154	13617 16090	000008049-1	4,4'-dihydroxydiphenyl sulphone	no	yes	no	0,05			
155	23470	000008046-8	α-pinene	no	yes	no				
156	21130	000008021621-6	methacrylic acid, methyl ester	no	yes	no		(23)		
157	74880	000084742-2	phthalic acid, dibutyl ester	yes	no	no	0,3	(32)	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up	(7)

										to 0,05 % in the final product.
158	23380 76320	00000852-44-9	phthalic anhydride	yes	yes	no				
159	74560	00000856-87-7	phthalic acid, benzyl butyl ester	yes	no	no	30	(32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles; plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and

									(c)	baby foods for infants and young children as defined by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product.
160	84800	0000087-18-3	salicylic acid, 4-tert-butylphenyl ester	yes	no	yes	12			
[F10161	92160	000087-69-4	(+)-tartaric acid	yes	no	no				]
162	65520	0000087-78-5	mannitol	yes	no	no				
163	66400	0000088-24-4	2,2′-methylene bis(4-ethyl-6-tert-butylphenol)	yes	no	yes		(13)		
164	34895	0000088-68-6	2-aminobenzamide	yes	no	no	0,05		Only for use in PET for water and beverages	

165	23200 74480	00000088-99-3	ortho-phthalic acid	yes	yes	no				
166	24057	00000089-32-7	pyromellitic anhydride	yes	no	no	0,05			
167	25240	00000091-08-7	2,6-toluene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
168	13075 15310	00000091-76-9	2,4-diamino-6-phenyl-1,3,5-triazine	no	yes	no	5			[F9(1)]
169	16240	00000091-97-4	3,3′-dimethyl-4,4′-diisocyanatobiphenyl	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
170	16000	00000092-88-6	4,4′-dihydroxybiphenyl	no	yes	no	6			
171	38080	00000093-58-3	benzoic acid, methyl ester	yes	no	no				
172	37840	00000093-89-0	benzoic acid, ethyl ester	yes	no	no				
173	60240	00000094-13-3	4-hydroxybenzoic acid, propyl ester	yes	no	no				
174	14740	00000095-48-7	ortho-cresol	no	yes	no				
175	20050	00000096-05-9	methacrylic acid, allyl ester	yes	no	no	0,05			

176	11710	00000963-33-2	acrylic acid, methyl ester	no	yes	no		(22)		
177	16955	00000996-49-1	ethylene carbonate	no	yes	no	30		SML expressed as ethyleneglycol. Residual content of 5 mg ethylene carbonate per kg of hydrogel with max 10 g of hydrogel in contact with 1 kg of food.	
178	92800	00000964-64-5	4,4′-thiobis(6-tert-butyl-3-methylphenol)	yes	no	yes	0,48			
179	48800	00000972-28-4	2,2′-dihydroxy-5,5′-dichlorodiphenylmethane	yes	no	yes	12			
[F11 180	17160	00000977-53-0	eugenol	no	yes	no		(33)		]
181	20890	00000997-63-2	methacrylic acid, ethyl ester	yes	no			(23)		
182	19270	00000997-65-4	nalidixic acid	no	yes	no				
183	21010	00000997-86-9	methacrylic acid, isobutyl ester	yes	no			(23)		
184	20110	00000997-88-1	methacrylic acid,	yes	no			(23)		

			butyl ester							
185	20440	000009[illegible]-90-5	methacrylic acid, diester with ethyleneglycol	no	yes	no	0,05			
186	14020	000009[illegible]-45-4	4-tert-butylphenol	no	yes	no	0,05			
187	22210	000009[illegible]-83-9	α-methylstyrene	no	yes	no	0,05			
188	19180	000009[illegible]-63-8	isophthalic acid dichloride	no	yes	no		(27)		
189	60200	000009[illegible]-76-3	4-hydroxybenzoic acid, methyl ester	yes	no	no				
190	18880	000009[illegible]-96-7	*p*-hydroxybenzoic acid	no	yes	no				
191	24940	000010[illegible]-29-9	terephthalic acid dichloride	no	yes	no		(28)		
192	23187	—	phthalic acid	no	yes	no		(28)		
193	24610	000010[illegible]-42-5	styrene	no	yes	no				
194	13150	000010[illegible]-51-6	benzyl alcohol	no	yes	no				
195	37360	000010[illegible]-52-7	benzaldehyde	no	no	no				(3)
196	18670 59280	000010[illegible]-97-0	hexamethylenetetramine	yes	no	no		(15)		
197	20260	000010[illegible]-43-9	methacrylic acid, cyclohexyl ester	no	yes	no	0,05			
198	16630	000010[illegible]-68-8	diphenylmethane-4,4′-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as	(10)

									isocyanate moiety	
199	24073	00001011-90-6	resorcinol diglycidyl ether	no	yes	no	ND		Not to be used for articles in contact with fatty foods for which **[**[F1]simulant D1 and/ or D2**]** is laid down. For indirect food contact only, behind a PET layer.	(8)
200	51680	00001021-08-9	1,3-diphenylthiourea	yes	no	yes	3			
201	16540	00001022-31-0	diphenyl carbonate	no	yes	no	0,05			
202	23070	00001023-39-6	2,2′-(1,3-phenylenedioxy)diacetic acid	no	yes	no	0,05			**[**[F9](1)**]**
203	13323	00001024-47-9	1,3-bis(2-hydroxyethoxy)benzene	no	yes	no	0,05			
204	25180 92640	00001024-62-0	N,N,N′,N′-tetrakis(2-hydroxypropyl)ethylenediamine	yes	yes	no				
205	25385	00001024-70-5	triethylamine	no	yes	no			40 mg/ kg hydrogel at a ratio of 1 kg food	

									to a maximum of 1,5 grams of hydrogel. Only to be used in hydrogels intended for non-direct food contact use.	
206	11500	00001033-11-7	acrylic acid, 2-ethylhexyl ester	no	yes	no	0,05			
207	31920	00001033-23-1	azelaic acid, bis(2-ethylhexyl) ester	yes	no	yes	18	(32)		(2)
208	18898	00001037-99-4	N-(4-hydroxyphenyl) acetamide	no	yes	no	0,05			
209	17050	00001047-76-7	2-ethyl-1-hexanol	no	yes	no	30			
210	13390 14880	00001051-08-8	1,4-bis(hydroxymethyl)cyclohexane	no	yes	no				
211	23920	00001053-83-4	propionic acid, vinyl ester	no	yes	no		(1)		
212	14200 41840	00001059-60-2	caprolactam	yes	yes	no		(4)		
213	82400	00001062-64-4	1,2-propyleneglycol dioleate	yes	no	no				

214	61840	00001061-24-9	12-hydroxystearic acid	yes	no	no				
215	14170	00001063-31-0	benzoic anhydride	no	yes	no				
216	14770	00001064-44-5	*p*-cresol	no	yes	no				
217	15565	00001064-46-7	1,4-dichlorobenzene	no	yes	no	12			
218	11590	00001063-81-8	acrylic acid, isobutyl ester	no	yes	no		(22)		
219	14570 16750	00001064-28-5	epichlorohydrin	yes	no	no	ND		1 mg/kg in final product	(10)
220	20590	00001064-01-2	methacrylic acid, 2,3-epoxypropyl ester	yes	no	no	0,02			(10)
221	40570	00001064-97-8	butane	yes	no	no				
222	13870	00001061-98-9	butene	no	yes	no				
223	13630	00001064-99-0	butadiene	no	yes	no	ND		1 mg/kg in final product	
224	13900	00001072-20-7	butene	no	yes	no				
225	12100	00001071-13-1	butyl nitrile	yes	no	no	ND			
226	15272 16960	00001071-15-3	ethylenediamine	yes	no	no	12			
227	16990 53650	00001071-23-1	ethylene glycol	yes	no	no		(2)		
228	13690	00001071-36-0	1,3-butanediol	no	yes	no				
229	14140	00001071-93-6	benzoic acid	no	yes	no				
230	16150	00001081-07-9	dimethylaminoethanol	no	no	no	18			

231	10120	0000108-05-4	acetic acid, vinyl ester	no	yes	no	12			
232	10150 30280	0000108-24-7	acetic anhydride	yes	yes	no				
233	24850	0000108-30-6	succinic anhydride	no	yes	no				
234	19960	0000108-31-6	maleic anhydride	no	yes	no		(3)		
235	14710	0000108-39-4	*m*-cresol	no	yes	no				
236	23050	0000108-45-2	1,3-phenylenediamine	no	yes	no	ND			
237	15910 24072	0000108-46-3	1,3-dihydroxybenzene	no	yes	no	2,4			
238	18070	0000108-55-4	glutaric anhydride	no	yes	no				
[F12239	19975 25420 93720]	0000108-78-6	2,4,6-triamino-1,3,5-triazine	yes	yes	no	2,5			
240	45760	0000108-91-8	cyclohexylamine	yes	no	no				
[F10241	22960	0000108-95-2	phenol	no	yes	no	3			]
242	85360	0000109-43-3	sebacic acid, dibutyl ester	yes	no	no		(32)		
243	19060	0000109-53-5	isobutyl vinyl ether	no	yes	no	0,05			(10)
244	71720	0000109-66-0	pentane	yes	no	no				
245	22900	0000109-67-1	1-pentene	no	yes	no	5			
246	25150	0000109-99-9	tetrahydrofuran	yes	no	no	0,6			
247	24820 90960	0000110-15-6	succinic acid	yes	yes	no				
248	19540 64800	0000110-16-7	maleic acid	yes	yes	no		(3)		

249	17290 55120	0000110-17-8	fumaric acid	yes	yes	no				
250	53520	0000110-30-5	N,N'-ethylenebisstearamide	yes	no	no				
251	53360	0000110-31-6	N,N'-ethylenebisoleamide	yes	no	no				
252	87200	0000110-44-1	sorbic acid	yes	no	no				
253	15250	0000110-60-1	1,4-diaminobutane	no	yes	no				
254	13720 40580	0000110-63-4	1,4-butanediol	yes	yes	no		(30)		
255	25900	0000110-88-3	trioxane	no	yes	no	5			
256	18010 55680	0000110-94-1	glutaric acid	yes	yes	no				
[F11 257	13550 16660 51760	0000110-98-5 0025265-71-8]	dipropyleneglycol	yes	yes	no				
258	70480	0000111-06-8	palmitic acid, butyl ester	yes	no	no				
259	58720	0000111-14-8	heptanoic acid	yes	no	no				
260	24280	0000111-20-6	sebacic acid	no	yes	no				
261	15790	0000111-40-0	diethylenetriamine	no	yes	no	5			
262	35284	0000111-41-1	N-(2-aminoethyl)ethanolamine	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which [F1 simulant D1 and/or D2]	

									is laid down. For indirect food contact only, behind a PET layer.	
263	13326	0000111-46-6	diethyleneglycol	yes	yes	no		(2)		
	15760									
	47680									
264	22660	0000111-66-0	1-octene	no	yes	no	15			
265	22600	0000111-87-5	1-octanol	no	yes	no				
266	25510	0000112-27-6	triethyleneglycol	yes	yes	no				
	94320									
267	15100	0000112-30-1	1-decanol	no	yes	no				
268	16704	0000112-41-4	1-dodecene	no	yes	no	0,05			
269	25090	0000112-60-7	tetraethyleneglycol	yes	yes	no				
	92350									
270	22763	0000112-80-1	oleic acid	yes	yes	no				
	69040									
271	52720	0000112-84-5	erucamide	yes	no	no				
272	37040	0000112-85-6	behenic acid	yes	no	no				
273	52730	0000112-86-7	erucic acid	yes	no	no				
274	22570	0000112-96-9	octadecyl isocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
275	23980	0000115-07-1	propylene	no	yes	no				
276	19000	0000115-11-7	isobutene	no	yes	no				

277	18280	000011	5	1,2,3,4,7,7-hexachloro-5-norbornene-2,3-dicarboxylic anhydride	yes	no	ND			
278	18250	000011	5	1,2,3,4,7,7-hexachloro-5-norbornene-2,3-dicarboxylic acid	yes	no	ND			
279	22840 71600	000011	5	pentaerythritol	yes	no				
280	73720	000011	5	phosphoric acid, trichloroethyl ester	yes	no	no	ND		
281	25120	000011	6	tetrafluoroethylene	yes	no	no	0,05		
282	18430	000011	6	hexafluoropropylene	yes	no	no	ND		
283	74640	000011	7	phthalic acid, bis(2-ethylhexyl) ester	yes	no	no	1,5	(32)	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product.	(7)
284	84880	000011	9	salicylic acid, methyl ester	yes	no	no	30			
285	66480	000011	9	2,2'-methylene bis(4-methyl-6-	yes	no	yes		(13)		

			tert-butylphenol)								
286	38240		0000119-61-9	benzophenone	yes	no	yes	0,6			
287	60160		0000120-47-8	4-hydroxybenzoic acid, ethyl ester	yes	no	no				
288	24970		0000120-61-6	terephthalic acid, dimethyl ester	no	yes	no				
289	15880 24051		0000120-80-9	1,2-dihydroxybenzene	no	yes	no	6			
290	55360		0000121-79-9	gallic acid, propyl ester	yes	no	no		(20)		
291	19150		0000121-91-5	isophthalic acid	no	yes	no		(27)		
292	94560		0000122-20-3	triisopropanolamine	yes	no	no	5			
293	23175		0000122-52-1	phosphorous acid, triethyl ester	no	yes	no	ND		1 mg/kg in final product	(1)
294	93120		0000123-28-4	thiodipropionic acid, didodecyl ester	yes	no	yes		(14)		
295	15940 18867 48620		0000123-31-9	1,4-dihydroxybenzene	yes	yes	no	0,6			
296	23860		0000123-38-6	propionaldehyde	no	yes	no				
297	23950		0000123-62-6	propionic anhydride	no	yes	no				
298	14110		0000123-72-8	butyraldehyde	no	yes	no				
299	63840		0000123-76-2	levulinic acid	yes	no	no				
300	30045		0000123-86-4	acetic acid, butyl ester	yes	no	no				

301	89120	00001233-05-5	stearic acid, butyl ester	yes	no	no				
302	12820	00001234-99-5	azelaic acid	no	yes	no				
303	12130 31730	00001241-01-0	adipic acid	yes	yes	no				
304	14320 41960	00001242-07-2	caprylic acid	yes	yes	no				
305	15274 18460	00001244-09-4	hexamethylenediamine	yes	no	no	2,4			
306	88960	00001246-86-5	stearamide	yes	no	no				
307	42160	00001246-93-4	carbon dioxide	yes	no	no				
308	91200	00001264-13-6	sucrose acetate isobutyrate	yes	no	no				
309	91360	00001264-14-7	sucrose octaacetate	yes	no	no				
310	16390 22437	00001267-22-7	2,2-dimethyl-1,3-propanediol	no	yes	no	0,05			
311	16480 51200	00001267-42-1	dipentaerythritol	yes	no	no				
312	21490	00001267-98-7	methacrylonitrile	yes	no	no	ND			
313	16650 51570	00001274-13-9	diphenyl sulphone	yes	yes	no	3			
314	23500	00001278-89-3	β-pinene	no	yes	no				
315	46640	00001283-67-0	2,6-di-tert-butyl-p-cresol	yes	no	no	3			
316	23230	00001312-17-9	phthalic acid, diallyl ester	no	yes	no	ND			

317	48880	00001312-32-3	2,2′-dihydroxy-4-methoxybenzophenone	yes	no	yes		(8)		
318	48640	00001312-56-6	2,4-dihydroxybenzophenone	yes	no	no		(8)		
319	61360	00001312-57-7	2-hydroxy-4-methoxybenzophenone	yes	no	yes		(8)		
320	37680	00001360-60-7	benzoic acid, butyl ester	yes	no	no				
321	36080	00001379-66-6	L-ascorbyl palmitate	yes	no	no				
322	63040	00001388-22-7	lactic acid, butyl ester	yes	no	no				
323	11470	00001401-55-4	abietic acid, ethyl ester	no	yes	no		(22)		
324	83700	00001417-30-6	ricinoleic acid	yes	no	yes	42			
325	10780	00001462-31-1	acrylic acid, n-butyl ester	no	yes	no		(22)		
326	12763 35170	00001491-24-3	2-aminoethanol	yes	yes	no	0,05		Not to be used for articles in contact with fatty foods for which [F1 simulant D1 and/or D2] is laid down.	

									For indirect food contact only, behind a PET layer.	
327	30140	0000141-78-6	acetic acid, ethyl ester	yes	no	no				
328	65040	0000141-82-2	malonic acid	yes	no	no				
329	59360	0000142-62-1	hexanoic acid	yes	no	no				
330	19470 63280	0000143-07-7	lauric acid	yes	yes	no				
331	22480	0000143-08-8	1-nonanol	no	yes	no				
332	69760	0000143-28-2	oleyl alcohol	yes	no	no				
333	22775 69920	0000144-62-7	oxalic acid	yes	yes	no	6			
334	17005	0000151-56-4	ethyleneimine	no	yes	no	ND			
335	68960	0000301-02-0	oleamide	yes	no	no				
336	15095 45940	0000334-48-5	n-decanoic acid	yes	yes	no				
337	15820	0000345-92-6	4,4′-difluorobenzophenone	no	yes	no	0,05			
338	71020	0000373-49-9	palmitoleic acid	yes	no	no				
339	86160	0000409-21-2	silicon carbide	yes	no	no				
[F13 340	47440	0000461-58-5	dicyanodiamide	yes	no	no	60			]
341	13180 22550	0000498-66-8	bicyclo[2.2.1]hept-2-ene	no	yes	no	0,05			
342	14260	0000502-44-3	caprolactone	no	yes	no		(29)		
343	23770	0000504-63-2	1,3-propanediol	no	yes	no	0,05			

[F10344	13810 21821]	00005051-65-7	1,3-butanediol formal	no	yes	no	0,05	15 30		(21)
345	35840	00005060-30-9	docosahexaenoic acid	yes	no	no				
346	10030	00005140-10-3	abietic acid	no	yes	no				
347	13050 25540	00005283-44-0	trimellitic acid	no	yes	no		(21)		
348	22350 67891	00005440-63-3	myristic acid	yes	yes	no				
349	25550	00005526-30-7	trimellitic anhydride	no	yes	no		(21)		
350	63920	00005577-59-5	lignoceric acid	yes	no	no				
351	21730	00005633-45-1	3-methyl-1-butene	no	yes	no	ND		Only to be used in polypropylene	(1)
352	16360	00005762-26-1	2,6-dimethylphenol	no	yes	no	0,05			
353	42480	00005840-98-8	docosahexaenoic acid, rubidium salt	yes	no	no	12			
354	25210	00005873-54-1	2,4-toluene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
355	20170	00005919-74-2	methacrylic acid, tert-butyl ester	yes	yes	no		(23)		
356	18820	00005921-41-6	1-hexene	no	yes	no	3			
357	13932	00005930-33-2	3-buten-2-ol	no	yes	no	ND		Only to be used	(1)

									as a co-monomer for the preparation of polymeric additive	
358	14841	00005994-64-4	4-cumylphenol	no	yes	no	0,05			
359	15970 48720	00006114-99-4	2,4-dihydroxybenzophenone	yes	yes	no		(8)		
360	57920	00006209-67-7	glycerol triheptanoate	yes	no	no				
361	18700	00006291-16-8	1,6-hexanediol	no	yes	no	0,05			
362	14350	00006300-08-0	carbon monoxide	no	yes	no				
363	16450	00006413-10-6	1,3-dioxolane	no	yes	no	5			
[F10364	15404	00006521-67-3	1,4:3,6-dianhydrosorbitol	no	yes	no	5		Only to be used as: (a) (b)	] a co-monomer in poly(ethylene-co-isosorbide terephthalate); a co-monomer at levels of up to 40 mole % of the diol component in

										combination with ethylene glycol and/ or 1,4-bis(hydroxymethyl)cyclohe for the production of polyesters. Polyesters made using dianhydrosorbitol together with 1,4-bis(hydroxymethyl)cyclohexane shall not be used in contact with foods containing more than 15 % alcohol.
365	11680	00006894-12-5	2-propenoic acid, isopropyl ester	no	yes	no		(22)		
366	22150	00006914-37-2	4-methyl-1-pentene	no	yes	no	0,05			
367	16697	00006938-23-2	1,12-dodecanedioic acid	no	yes	no				
368	93280	00006938-36-7	3,3'-thiodipropionic acid, dioctadecyl ester	no	yes	no		(14)		
369	12761	00006938-27-2	12-aminododecanoic acid	no	yes	no	0,05			

370	21460	00007604-93-0	methacrylic anhydride	no	yes	no		(23)		
371	11510 11830	00008184-57-1	acrylic acid, monoester with ethyleneglycol	no	yes	no		(22)		
372	18640	00008220-66-0	hexamethylene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
373	22390	00008406-05-3	naphthalenedicarboxylic acid, dimethyl ester	no	yes	no	0,05			
374	21190	00008677-43-9	methacrylic acid, monoester with ethyleneglycol	no	yes	no		(23)		
375	15130	00008721-05-9	1-decene	no	yes	no	0,05			
[F12 376	66905	00008721-50-4	N-methylpyrrolidone	yes	no	no	60			]
377	12786	00009194-30-2	3-aminopropyltriethoxysilane	no	yes	no	0,05		Residual extractable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the reactive surface treatment of inorganic fillers.	

									SML = 0,05 mg/kg when used for the surface treatment of materials and articles.	
378	21970	000092300-2	N-2-4 methylol	no	yes	no	0,05			
379	21940	000092442-5	N-2-5 methylol	no	yes	no	ND			
380	11980	000092560-1	acrylic acid, propyl ester	no	yes	no		(22)		
381	15030	000093188-4	1-vinyl-2-pyrrolidone	no	yes	no	0,05		Only to be used in polymers contacting foods for which simulant A is laid down	
382	19490	000094704-6	lauryllactam	no	yes	no	5			
383	72160	000094826-5	2-phenylindole	yes	no	yes	15			
384	40000	000099128-4	2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30			
385	11530	000099361-1	acrylic acid, 2-hydroxypropyl ester	no	yes	no	0,05		SML expressed as the sum of acrylic	(1)

									acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 0002918-23-2).	
386	55280	000103-24-1	gallic acid, octyl ester	yes	no	no		(20)		
387	26155	000107-63-5	2-vinylimidazole	no	yes	no	0,05			[F9(1)]
388	25080	000112-41-4	1-tetradecene	no	yes	no	0,05			
389	22360	000141-23-5	2,6-naphthalenedicarboxylic acid	no	yes	no	5			
390	55200	000166-52-5	gallic acid, dodecyl ester	yes	no	no		(20)		
[F1391	22932	000187-93-5	perfluoromethyl perfluorovinyl ether	no	yes	no	0,05		Only to be used in: — anti-stick coatings; — fluoro- and perfluoropolymers intended	]

										for repeated use applications where the contact ratio is 1 dm^2 surface in contact with at least 150 kg food.
392	72800	000124[illegible]-7	phosphonic acid, diphenyl 2-ethylhexyl ester	yes	no	yes	2,4			
393	37280	000130[illegible]-0	cerium nitrate	yes	no	no				
394	41280	000130[illegible]-0	calcium hydroxide	yes	no	no				
395	41520	000130[illegible]-8	calcium oxide	yes	no	no				
396	64640	000130[illegible]-8	magnesium hydroxide	yes	no	no				
397	64720	000130[illegible]-4	magnesium oxide	yes	no	no				
398	35760	000130[illegible]-4	antimony trioxide	yes	no	no	0,04		SML expressed as antimony	(6)
399	81600	000131[illegible]-3	potassium hydroxide	yes	no	no				
400	86720	000131[illegible]-2	sodium hydroxide	yes	no	no				
401	24475	000131[illegible]-2	sodium sulphide	no	yes	no				

402	96240	0001314-13-2	zinc oxide	yes	no	no				
403	96320	0001314-98-3	zinc sulphide	yes	no	no				
404	67200	0001317-33-5	molybdenum disulphide	yes	no	no				
405	16690	0001321-74-0	divinylbenzene	yes	no	ND		SML expressed as the sum of divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.	(1)	
406	83300	0001323-39-3	propyleneglycol monostearate	yes	no	no				
407	87040	0001330-43-4	sodium tetraborate	yes	no	no		(16)		
408	82960	0001330-80-9	propyleneglycol monooleate	yes	no	no				
409	62240	0001332-37-2	iron oxide	yes	no	no				
[F10410	62720	0001332-58-7	kaolin	yes	no	no			Particles] can be thinner than 100 nm only if incorporated at a quantity of less than 12 % w/w in an ethylene vinyl alcohol	

									copolymer (EVOH) inner layer of a multi-layer structure, in which the layer in direct contact with the food provides a functional barrier preventing migration of particles into the food.
411	42080	0001333-86-4	carbon black	yes	no	no			Primary particles of 10 – 300 nm which are aggregated to a size of 100 – 1 200 nm which may form agglomerates within the size distribution of 300

									nm – mm. Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w.	

412	45200	000133522-5	copper iodide	yes	no	no		(6)		
413	35600	000133621-6	ammonium hydroxide	yes	no	no				
414	87600	000133839-2	sorbitan monolaurate	yes	no	no				
415	87840	000133841-6	sorbitan monostearate	yes	no	no				
416	87680	000133843-8	sorbitan monooleate	yes	no	no				
417	85680	000134398-2	succinic acid	yes	no	no				
418	34720	000134428-1	aluminium oxide	yes	no	no				
419	92150	000140155-4	tannic acids	yes	no	no			According to the JECFA specifications	
420	19210	000145993-4	isophthalic acid, dimethyl ester	no	yes	no	0,05			
[F13421	13000	000147715-0	1,3-benzenedimethanamine	no	yes	no		(34)		]
422	38515	000153444-5	4,4'-bis(2-benzoxazolyl)stilbene	yes	no	yes	0,05			(2)
423	22937	000162358-8	perfluoropropylperfluorovinyl ether	no	yes	no	0,05			
424	15070	000164719-1	1,9-decadiene	no	yes	no	0,05			
425	10840	000166339-4	acrylic acid, tert-butyl ester	no	yes	no		(22)		
426	13510 13610	000167552-3	2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether	no	yes	no			In compliance with Commission Regulation (EC) No 1895/2005[a]	

427	18896	00016794-51-2	1-(hydroxymethyl)-1-cyclohexene	no	yes	no	0,05			
428	95200	00017091-73-2	1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	yes	no	no				
429	13210	00017619-73-8	tris(4-aminocyclohexyl)methane	no	yes	no	0,05			
430	95600	00018437-89-3	tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	yes	no	yes	5			
431	61600	00018432-95-6	2-hydroxy-4-n-octyloxybenzophenone	yes	no	yes		(8)		
432	12280	00020359-22-8	adipic anhydride	no	yes	no				
433	68320	00020827-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	yes	no	yes	6			
434	20410	00020882-04-6	2-methylacrylic acid, diester with 1,4-butanediol	no	yes	no	0,05			
435	14230	00021239-24-2	caprolactam, sodium salt	no	yes	no		(4)		
436	19480	00021469-71-6	lauric acid, vinyl ester	no	yes	no				
437	11245	00021564-87-1	acrylic acid, dodecyl ester	no	yes	no	0,05			(2)

[F12438	13303	000216	2-74-2	bis(2,6-diisopropylphenyl) carbodiimide	no	yes	no	0,05		Expressed as the sum of bis(2,6-diisopropylphenyl)carbodiimide and its hydrolysis product 2,6-diisopropylaniline	]
439	21280	000217	7-70-0	methacrylic acid, phenyl ester	no	yes	no		(23)		
440	21340	000221	0-28-8	methacrylic acid, propyl ester	no	yes	no		(23)		
441	38160	000231	5-68-6	benzoic acid, propyl ester	yes	no	no				
442	13780	000242	5-17-4	1,4-butanediol bis(2,3-epoxypropyl)ether	no	yes	no	ND		Residual content = 1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.	(10)
443	12788	000243	2-99-7	11-aminoundecanoic acid	no	yes	no	5			
444	61440	000244	0-22-4	2-(2′-hydroxy-5′-methylphenyl)benzotriazole	yes	no	no		(12)		
445	83440	000246	6-09-3	pyrophosphoric acid	yes	no	no				
446	10750	000249	5-35-4	acrylic acid, benzyl ester	no	yes	no		(22)		

447	20080	000249[illegible]-37-6	methacrylic acid, benzyl ester	no	yes	no		(23)		
448	11890	000249[illegible]-59-4	acrylic acid, n-octyl ester	no	yes	no		(22)		
[F11 449	49840	000250[illegible]-88-1	2-mercaptoethyl cetyl disulphide	yes	no	yes	0,05			]
450	24430	000256[illegible]-88-8	sebacic anhydride	no	yes	no				
451	66755	000268[illegible]-22-0	4-methyl-4-isothiazolin-3-one	yes	no	no	0,5		Only to be used in aqueous polymer dispersions and emulsions	
[F12 452	38885	000272[illegible]-22-6	2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	no	5			]
453	26320	000276[illegible]-02-7	vinyltrimethoxysilane	yes		no	0,05			(10)
454	12670	000285[illegible]-13-2	3-amino-3-aminomethyl-3,5,5-trimethylcyclohexane	no	yes	no	6			
455	20530	000286[illegible]-47-2	methacrylic acid, 2-(dimethylamino)-ethyl ester	yes		no	ND			
456	10810	000299[illegible]-08-5	acrylic acid, sec-butyl ester	no	yes	no		(22)		
457	20140	000299[illegible]-18-7	methacrylic acid,	yes		no		(23)		

			sec-butyl ester							
458	36960	0003061-75-4	behenamide	yes	no	no				
459	46870	0003135-18-0	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	yes	no	no				
460	14950	0003173-53-3	cyclohexyl isocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
461	22420	0003173-72-6	1,5-naphthalene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
462	26170	0003195-78-6	N-vinyl-N-methylacetamide	no	yes	no	0,02			[F9(1)]
463	25840	0003290-92-4	1,1,1-trimethylolpropane trimethacrylate	no	yes	no	0,05			
464	61280	0003293-97-8	2-hydroxy-4-n-hexyloxybenzophenone	yes	no	yes		(8)		
465	68040	0003333-62-8	7-[2H-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	yes	no	no				
466	50640	0003648-18-8	di-n-octyltin dilaurate	yes	no	no		(10)		

[F14467	14800 45600]	3724-65-0	crotonic acid	yes	yes	no		(35)		
468	71960	0003825-26-1	perfluorooctanoic acid, ammonium salt	no	no				Only to be used in repeated use articles, sintered at high temperatures	
469	60480	0003864-99-1	2-(2′-hydroxy-3,5′-di-tert-butylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)		
470	60400	0003896-11-5	2-(2′-hydroxy-3′-tert-butyl-5′-methylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)		
471	24888	0003965-55-7	sulphoisophthalic acid, monosodium salt, dimethyl ester	no	yes	no	0,05			
472	66560	0004066-02-8	2,2′-methylenebis(4-methyl-6-cyclohexylphenol)	yes	no	yes		(5)		
473	12265	0004074-90-2	adipic acid, divinyl ester	no	yes	no	ND		5 mg/kg in final product. Only to be used as co-monomer.	(1)
474	43600	0004080-31-3	1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	yes	no	no	0,3			

475	19110	000409817-9	isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
476	16570	000412873-8	methylenediphenyl ether-4,4'-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
477	46720	000413072-2	2,6-di-tert-butyl-4-ethylphenol	yes	no	yes	4,8			(1)
478	60180	000419413-5	3-hydroxybenzoic acid, isopropyl ester	yes	no	no				
479	12970	000419695-6	azelaic anhydride	no	yes	no				
480	46790	000422136-1	3,5-di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	yes	no	no				
481	13060	000442219-5	1,3,5-benzenetricarboxylic acid trichloride	no	yes	no	0,05		SML expressed as 1,3,5-benzenetricarboxylic acid	[F9(1)]
482	21100	000465534-9	methacrylic acid, isopropyl ester	no	yes	no		(23)		

483	68860	000472-48-5	octylphosphonic acid	yes	no	no	0,05			
484	13395	000476-20-7	2,2-bis(hydroxymethyl)propionic acid	no	yes	no	0,05			(1)
485	13560 15700	000512-43-0	1-isocyclohexylmethane-4,4′-diisocyanate	no		no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
486	54005	000513-44-7	ethylene-N-palmitamide-N′-stearamide	yes	no	no				
487	45640	000523-22-9	2-cyano-3,3-diphenylacrylic acid, ethyl ester	yes	no	no	0,05			
488	53440	000553-18-3	N,N′-ethylenebispalmitamide	yes	no	no				
489	41040	000574-32-2	calcium 2-hydroxybutyrate	yes	no	no				
490	16600	000587-54-1	diphenylmethane-2,4′-diisocyanate	no		no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
491	82720	000618-11-2	1,2-propyleneglycol distearate	yes	no	no				
492	45650	000619-23-0	2-ethylhexyl 2-cyano-3,3-diphenylacrylic acid, ester	yes	no	no	0,05			

493	39200	000620	bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	yes	no	no	1,8			
494	62140	000630	hypophosphorous acid	yes	no	no				
495	35160	000664	6-amino-1,3-dimethyluracil	yes	no	no	5			
496	71680	000668	pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no				
497	95020	000684	2,2,4-trimethyl-1,3-pentanediol diisobutyrate	yes	no	no	5		Only to be used in single-use gloves	
498	16210	000686	3,3′-dimethyl-4,4′-diaminodicyclohexylmethane	no	yes	no	0,05		Only to be used in polyamides	(5)
499	19965 65020	000691	maleic acid	yes	yes	no			In case of use as a monomer only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis	

500	38560	00071282-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	yes	no	yes	0,6			
501	34480	—	aluminium fibers, flakes and powders	yes	no	no				
502	22778	00074564-64-0	4,4′-oxybis(benzenesulphonyl azide)	no	yes	no	0,05			[F9(1)]
503	46080	00075539-39-9	β-dextrin	yes	no	no				
504	86240	00076131-86-9	silicon dioxide	yes	no	no			For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size.	
505	86480	00076131-90-5	sodium bisulphite	yes	no	no		(19)		
506	86920	00076132-00-0	sodium nitrite	yes	no	no	0,6			

507	59990	0007647-01-0	hydrochloric acid	yes	no	no				
508	86560	0007647-14-5	sodium bromide	yes	no	no				
509	23170 72640	0007664-38-2	phosphoric acid	yes	yes	no				
510	12789 35320	0007664-41-7	ammonia	yes	yes	no				
511	91920	0007664-93-9	sulphuric acid	yes	no	no				
512	81680	0007681-11-0	potassium iodide	yes	no	no		(6)		
513	86800	0007681-82-5	sodium iodide	yes	no	no		(6)		
514	91840	0007704-34-9	sulphur	yes	no	no				
515	26360 95855	0007732-18-5	water	yes	yes	no			In compliance with Directive 98/83/EC[b]	
516	86960	0007757-82-6	sodium sulphite	yes	no	no		(19)		
517	81520	0007758-02-3	potassium bromide	yes	no	no				
518	35845	0007771-44-0	lactidonic acid	yes	no	no				
519	87120	0007772-98-7	sodium thiosulphate	yes	no	no		(19)		
520	65120	0007773-01-5	manganese chloride	yes	no	no				
521	58320	0007782-42-5	graphite	yes	no	no				
522	14530	0007782-50-5	chlorine	no	yes	no				
523	45195	0007787-70-4	copper bromide	yes	no	no				
524	24520	0008001-22-7	soybean oil	no	yes	no				
525	62640	0008001-39-6	japan wax	yes	no	no				
526	43440	0008001-75-0	lecithin	yes	no	no				

527	14411 42880	00080011	79-4 castor oil	yes	yes	no				
528	63760	00080021	43-5 lecithin	yes	no	no				
529	67850	00080031	53-7 montan wax	yes	no	no				
530	41760	00080061	44-8 candelilla wax	yes	no	no				
531	36880	00080121	89-3 beeswax	yes	no	no				
532	88640	00080131	07-8 soybean oil, epoxidised	yes	no	no	60 30(*)	(32)	(*)	In the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive

									Oxirane < 8 %, iodine number < 6.	2006/125/EC, the SML is lowered to 30 mg/kg.
533	42720	00080158-6-9	carnauba wax	yes	no	no				
534	80720	00080177-1-6	polyphosphoric acids	yes	no	no				
535	24100 24130 24190 83840	00080500-09-7	rosin	yes	yes	no				
536	84320	00080501-15-5	rosin, hydrogenated, ester with methanol	yes	no	no				
537	84080	00080502-26-8	rosin, ester with pentaerythritol	yes	no	no				
538	84000	00080503-31-5	rosin, ester with glycerol	yes	no	no				
539	24160	00080521-16-6	rosin tall oil	no	yes	no				
540	63940	00080621-15-5	lignosulphonic acid	yes	no	no	0,24		Only to be used as dispersant for plastics dispersions	

541	58480	0009000-01-5	gum arabic	yes	no	no				
542	42640	0009000-11-7	carboxymethylcellulose	yes	no	no				
543	45920	0009000-16-2	carrageenan	yes	no	no				
544	58400	0009000-30-0	guar gum	yes	no	no				
545	93680	0009000-65-1	tragacanth gum	yes	no	no				
546	71440	0009000-69-5	pectin	yes	no	no				
547	55440	0009000-70-8	gelatin	yes	no	no				
548	42800	0009000-71-9	casein	yes	no	no				
549	80000	0009002-88-4	polyethylene wax	yes	no	no				
550	81060	0009003-07-0	polypropylene wax	yes	no	no				
551	79920	0009003-11-6 0106392-12-5	poly(ethylene-propylene) glycol	yes	no	no				
552	81500	0009003-39-8	polyvinylpyrrolidone	yes	no	no			The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC[c]	
553	14500 43280	0009004-34-6	cellulose	yes	yes	no				
554	43300	0009004-36-8	cellulose acetate butyrate	yes	no	no				
555	53280	0009004-57-3	ethylcellulose	yes	no	no				
556	54260	0009004-58-4	hydroxyethylcellulose	yes	no	no				
557	66640	0009004-59-5	methylethylcellulose	yes	no	no				
558	60560	0009004-62-0	hydroxyethylcellulose	yes	no	no				
559	61680	0009004-64-2	hydroxypropylcellulose	yes	no	no				

560	66700	000904-65-3	methylhydroxypropylcellulose	yes	no	no				
561	66240	000904-67-5	methylcellulose	yes	no	no				
562	22450	000904-70-0	inulin	no	yes	no				
563	78320	000904-07-1	polyethyleneglycol monoricinoleate	no	yes	42				
564	24540 88800	000905-22-8	seaweed, edible	yes	yes	no				
565	61120	000905-27-0	hydroxyethyl starch	yes	no	no				
566	33350	000905-32-7	algin acid	yes	no	no				
567	82080	000905-37-2	propyleneglycol alginate	yes	no	no				
568	79040	000905-64-5	polyethyleneglycol sorbitan monolaurate	no	no	no				
569	79120	000905-65-6	polyethyleneglycol sorbitan monooleate	no	no	no				
570	79200	000905-66-7	polyethyleneglycol sorbitan monopalmitate	no	no	no				
571	79280	000905-67-8	polyethyleneglycol sorbitan monostearate	no	no	no				
572	79360	000905-70-3	polyethyleneglycol sorbitan trioleate	no	no	no				
573	79440	000905-71-4	polyethyleneglycol sorbitan tristearate	no	no	no				
574	24250 84560	000906-04-6	rubber, natural	yes	yes	no				
575	76721	006138-49-6	polydimethylsiloxane (Mw > 6 800 Da)	no	no	no			Viscosity at 25 °C not less than 100 cSt (100	

									$\times 10^{-6}$ m^2/s)	
576	60880	000903	2-hydroxyethylmethylcellulose	yes	no	no				
577	62280	000904	isobutylene-1-butene copolymer	yes	no	no				
578	79600	000904	polyethyleneglycol tridecyl ether phosphate	yes	no	no	5		For materials and articles intended for contact with aqueous foods only. Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono- and dialkyl ester) with a maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether.
579	61800	000904	hydroxypropyl starch	yes	no	no				
580	46070	001001	6-20-3 dextrin	yes	no	no				
581	36800	001002	barium nitrate	yes	no	no				
582	50240	001003	bis-(3-octyltin bis(2-ethylhexyl maleate)	yes	no	no		(10)		

583	40400	00100431-11-5	boron nitride	yes	no	no		(16)		
584	13620 40320	00100410043-35-3	boric acid	yes	yes	no		(16)		
585	41120	00100443-52-4	calcium chloride	yes	no	no				
586	65280	00100443-84-2	manganese hypophosphite	yes	no	no				
587	68400	00100994-45-8	erucamide	no	yes	no	5			
588	64320	00103777-86-2	lithium iodide	yes	no	no		(6)		
589	52645	00104360-09-1	cis-13-eicosenamide	yes	no	no				
590	21370	00105951-80-9	methacrylic acid, 2-sulphoethyl ester	no	yes	no	ND			(1)
591	36160	00106052-59-1	stearyl stearate	yes	no	no				
592	34690	00110972-59-9	ammonium magnesium carbonate hydroxide	yes	no	no				
593	44960	00111042-68-3	cobalt oxide	yes	no	no				
594	65360	00111129-60-5	manganese oxide	yes	no	no				
595	19510	00111132-73-3	lignocellulose	no	yes	no				
596	95935	00111138-66-2	xanthan gum	yes	no	no				
597	67120	00120125-22-2	zinc	yes	no	no				
598	41600	00120414-77-7 00372933-22-4	calcium sulphoaluminate	yes	no	no				
599	36840	00120778-55-5	barium tetraborate	yes	no	no		(16)		
600	60030	00120720-90-1	hydromagnesite	yes	no	no				
601	35440	00121242-97-9	ammonium bromide	yes	no	no				
602	70240	00121989-22-5	ozokerite	yes	no	no				
603	83460	00122699-78-2	pyrophyllite	yes	no	no				

604	60080	00123041-65-3	hydrotalcite	yes	no	no			
605	11005	00125422-39-2	acrylic acid, dicyclopentenyl ester	no	yes	no	0,05		(1)
606	65200	00126268-48-9	manganese hydroxide	yes	no	no			
607	62245	00127511-22-3	zinc phosphide	yes	no	no		Only to be used in PET polymers and copolymers	
608	40800	00130034-12-8	4,4'-butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	yes	no	yes	6		
609	83455	00134455-66-2	pyrophosphorous acid	no	no	no			
610	93440	00134637-67-7	titanium dioxide	yes	no	no			
611	35120	00135600-34-9-1	aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	yes	no	no			
612	16694	00138111-50-2	1,3-divinyl-2-imidazolidinone	no	yes	no	0,05		(10)
613	95905	00139837-10-8	wollastonite	yes	no	no			
614	45560	00144647-13-1	cristobalite	yes	no	no			
615	92080	00148078-36-6	talc	yes	no	no			
616	83470	00148083-60-7	sepiolite	yes	no	no			
617	10660	00152142-89-8	acrylamido-2-	no	yes	no	0,05		

			methylpropanesulphonic acid							
618	51040	001553579-2	octyltin mercaptoacetate	yes	no	no		(10)		
619	50320	001557158-1	octyltin bis(2-ethylhexyl mercaptoacetate)	yes	no	no		(10)		
620	50720	001557160-5	octyltin dimaleate	yes	no	no		(10)		
621	17110	001621975-3	ethylidenebicyclo[2,2,1]hept-2-ene	no	yes	no	0,05			(9)
622	69840	001626009-6	ethylpalmitamide	no	yes	yes	5			
623	52640	001638988-1	dotriacontane	yes	no	no				
624	18897	001671266-4	hydroxy-2-naphthalenecarboxylic acid	no	yes	no	0,05			
625	36720	001719400-2	lanthanum hydroxide	yes	no	no				
626	57800	001864157-1	glycerol tribehenate	yes	no	no				
627	59760	001956921-2	hydrazine	yes	no	no				
628	96190	002042758-1	zinc hydroxide	yes	no	no				
629	34560	002164551-2	aluminium hydroxide	yes	no	no				
630	82240	002278812-8	1,2-propyleneglycol dilaurate	yes	no	no				
631	59120	002312876-7	hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	yes	no	yes	45			
632	52880	002367609-7	ethoxybenzoic acid,	yes	no	no	3,6			

			ethyl ester							
633	53200	00239492-66-8	2-ethoxy-2′-ethyloxanilide	yes	no	yes	30			
634	25910	00248004-44-0	tripropyleneglycol	yes	no					
635	40720	00250131-16-5	tert-butyl-4-hydroxyanisole	yes	no	no	30			
636	31500	00251344-51-4	acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	yes	no	no	0,05	(22)	SML expressed as acrylic acid, 2-ethylhexyl ester	
637	71635	00251519-96-6	pentaerythritol dioleate	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which [F1simulant D1 and/or D2] is laid down	
638	23590 76960	00253228-68-3	polyethyleneglycol	yes	yes	no				
639	23651 80800	00253228-69-4	polypropyleneglycol	yes	yes	no				
640	54930	00253597-01-5	formaldehyde-1-naphthol, copolymer	no	no	no	0,05			
[F1641	22331	00255136-64-8	mixture of (35-45 % w/w)	no	yes	no	0,05			]

			1,6-diamino-2,2,4-trimethylhexane and (55-65 % w/w)1,6-diamino-2,4,4-trimethylhexane							
642	64990	0025736-09-2	maleic anhydride-styrene, copolymer, sodium salt	yes	no	no			The fraction with molecular weight below 1 000 Da [F1shall] not exceed 0,05 % (w/w)	
643	87760	0026266-57-9	sorbitan monopalmitate	yes	no	no				
644	88080	0026266-58-0	sorbitan trioleate	yes	no	no				
645	67760	0026401-86-5	mono-n-octyltin tris(isooctyl mercaptoacetate)	yes	no	no		(11)		
646	50480	0026401-97-8	di-n-octyltin bis(isooctyl mercaptoacetate)	yes	no	no		(10)		
647	56720	0026402-22-3	glycerol monohexanoate	yes	no	no				
648	56880	0026402-26-7	glycerol monooctanoate	yes	no	no				
649	47210	0026427-06-6	di-n-octyltin acid polymer	yes	no	no			Molecular unit = $(C_8H_{18}S_3Sn_2)n$ (n = 1,5-2)	
650	49600	0026636-01-1	dimethyltin bis(isooctyl mercaptoacetate)	yes	no	no		(9)		

651	88240	0026658-19-5	sorbitan tristearate	yes	no	no				
652	38820	0026741-53-7	bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	yes	no	yes	0,6			
653	25270	0026747-90-0	2,4-toluene diisocyanate dimer	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
654	88600	0026836-47-5	sorbitol monostearate	yes	no	no				
655	25450	0026896-48-0	tricyclodecanedimethanol	no	yes	no	0,05			
656	24760	0026914-43-2	styrenesulphonic acid	no	yes	no	0,05			
657	67680	0027107-89-7	mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	yes	no	no		(11)		
658	52000	0027176-87-0	dodecylbenzenesulphonic acid	yes	no	no	30			
659	82800	0027194-74-7	1,2-propyleneglycol monolaurate	yes	no	no				
660	47540	0027458-90-8	di-tert-dodecyl disulphide	yes	no	yes	0,05			
661	95360	0027676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	yes	no	yes	5			
662	25927	0027955-94-8	1,1,1-tris(4-hydroxyphenol)ethane	no	yes	no	0,005		Only to be used in polycarbonates	[F9(1)]

663	64150	00282901-79-1	alpha-linolenic acid	yes	no	no				
664	95000	00289311-67-1	trimethylolpropane trimethacrylate-methyl methacrylate copolymer	no	no	no				
665	83120	00290312-28-3	1,2-propyleneglycol monopalmitate	yes	no	no				
666	87280	00291680-98-1	sorbitan dioleate	yes	no	no				
667	55190	00292004-02-2	gadoleic acid	yes	no	no				
668	80240	00298943-75-7	polyglycerol ricinoleate	yes	no	no				
669	56610	00302333-64-8	glycerol monobehenate	yes	no	no				
670	56800	00308992-52-8	glycerol monolaurate diacetate	yes	no	no		(32)		
671	74240	00315708-04-4	phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	yes	no	no				
672	76845	00318312-53-5	polyester of 1,4-butanediol with caprolactone	yes	no	no		(29) (30)	The fraction with molecular weight below 1 000 Da [F1shall] not exceed 0,5 % (w/w)	
673	53670	00325099-06-9	ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	yes	no	yes	6			

674	46480	00326474-67-9	dibenzylidene sorbitol	yes	no	no				
675	38800	00326877-8-8	bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	yes	no	yes	15			
676	50400	00335682-99-9	octyltin bis(isooctyl maleate)	yes	no	no		(10)		
677	82560	00335871-20-1	propyleneglycol dipalmitate	yes	no	no				
678	59200	00350741-76-2	hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	yes	no	yes	6			
679	39060	00359581-30-6	bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	yes	no	yes	5			
680	94400	00364433-68-2	methylenebis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	yes	no	no	9			
681	18310	00366531-82-4	hexadecanol	no	yes	no				
682	53270	00372059-89-5	ethylcarboxymethylcellulose	yes	no	no				
683	66200	00372061-01-2	methylcarboxymethylcellulose	yes	no	no				
684	68125	00372449-96-5	nepheline syenite	yes	no	no				
685	85950	00372963-97-2	silicic acid, magnesium-sodium-fluoride salt	yes	no	no	0,15		SML expressed as fluoride. Only to be used	

									in layers of multi-layer materials not coming into direct contact with food.	
686	61390	00373539-59-6	hydroxymethylcellulose	yes	no	no				
687	13530 13614	00381032-06-9	2,2-bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	no	yes	no	0,05			
688	92560	00386137-73-3	tetrakis(2,4-di-tert-butylphenyl)-4,4′-biphenylylene diphosphonite	yes	no	yes	18			
689	95280	00406011-76-5	1,3,5-tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	yes	no	yes	6			
690	92880	00414845-86-9	1,6-hexamethylene bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate)	yes	no	yes	2,4			
691	13600	00474653-97-4	3,3-bis(3-methyl-4-hydroxyphenyl)-2-indolinone	no	yes	no	1,8			
692	52320	00520472-50-3	3-(4-dodecylphenyl)indole	yes	no	yes	0,06			

693	88160	0054140-20-4	sorbitan tripalmitate	yes	no	no				
694	21400	0054276-35-6	methacrylic acid, sulphopropyl ester	yes	no	no	0,05			(1)
695	67520	0054849-38-6	monomethyltin tris(isooctyl mercaptoacetate)	yes	no	no		(9)		
696	92205	0057569-40-1	terephthalic acid, diester with 2,2′-methylenebis(4-methyl-6-tert-butylphenol)	yes	no	no				
697	67515	0057583-34-3	monomethyltin tris(ethylhexyl mercaptoacetate)	yes	no	no		(9)		
698	49595	0057583-35-4	dimethyltin bis(ethylhexyl mercaptoacetate)	yes	no	no		(9)		
699	90720	0058446-52-9	stearoylbenzoylmethane	yes	no	no				
700	31520	0061167-58-6	acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	yes	no	yes	6			
701	40160	0061269-64-2	N,N′-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	yes	no	no	2,4			
702	87920	0061752-68-2	sorbitan tetrastearate	yes	no	no				
703	17170	0061788-47-4	fatty acids, coco	no	yes	no				

704	77600	0061788-85-0	polyethyleneglycol ester of hydrogenated castor oil	yes	no	no				
705	10599/90 10599/91	0061788-89-4	acids, fatty, unsaturated (C_{18}), dimers, non hydrogenated, distilled and non-distilled	no	yes	no		(18)		(1)
706	17230	0061790-12-3	fatty acids, tall oil	no	yes	no				
707	46375	0061790-53-2	diatomaceous earth	yes	no	no				
708	77520	0061791-12-6	polyethyleneglycol ester of castor oil	yes	no	no	42			
709	87520	0062568-11-0	sorbitan monobehenate	yes	no	no				
710	38700	0063397-60-2	bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	yes	no	yes	18			
711	42000	0063438-20-2	(2-carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)	yes	no	yes	30			
712	42960	0064147-40-6	castor oil, dehydrated	yes	no	no				
[F10713	43480	0064365-11-3 0007440-44-0]	charcoal, activated	yes	no	no			Only for use in PET at maximum 10 mg/kg of polymer.	

									Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Regulation (EU) No 231/2012[d] with exception of ash content which can be up to 10 % (w/w).	
714	84400	0064365-17-9	rosin, hydrogenated, ester with pentaerythritol	yes	no	no				
715	46880	0065140-91-2	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	yes	no	no	6			
716	60800	0065447-77-0	1-(2-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	yes	no	no	30			
717	84210	0065997-06-0	rosin, hydrogenated	yes	no	no				

718	84240	0065997-13-9	rosin, hydrogenated, ester with glycerol	yes	no	no				
719	65920	0066822-56-4	methacryloyloxyethyl-N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt - octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers	yes	no	no				
720	67360	0067649-66-4	mono-n-dodecyltin tris(isooctyl mercaptoacetate)	yes	no	no		(25)		
721	46800	0067845-93-6	3,5-di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	yes	no	no				
722	17200	0068308-53-2	fatty acids, soya	no	yes	no				
723	88880	0068412-29-3	starch, hydrolysed	yes	no	no				
724	24903	0068425-17-2	syrups, hydrolysed starch, hydrogenated	no	yes	no			In compliance with the purity criteria for maltitol	

									syrup E 965(ii) as laid down in Commission Directive 2008/60/EC[e]	
[F15]										
726	83599	0068442-12-6	reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	yes	no	yes		(9)		
727	43360	0068442-85-1	cellulose regenerated	yes	no	no				
728	75100	0068515-48-0 0028553-12-0	phthalic acid, diesters with primary, saturated C_8-C_{10} branched alcohols, more than 60 % C_9	yes	no	no		(26) (32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles; plasticiser in single-use materials and articles contacting non-fatty foods except

										for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC;
									(c)	technical support agent in concentrations up to 0,1 % in the final product.
729	75105	0068515-49-1 0026761-40-0	phthalic acid, diesters with primary, saturated C_9-C_{11}	yes	no	no		(26) (32)	Only to be used as: (a)	(7) plasticiser in repeated

		alcohols more than 90 % C_{10}						(b)	use materials and articles; plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC;
								(c)	technical support agent in concentrations

										up to 0,1 % in the final product.
730	66930	0068554-70-1	methylsilsesquioxane	no	yes	no			Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane	
731	18220	0068564-88-5	N-heptylaminoundecanoic acid	no	yes	no	0,05			(2)
732	45450	0068610-51-5	p-cresol-dicyclopentadiene-isobutylene, copolymer	yes	no	yes	5			
733	10599/92 10599/93	0068783-41-5	Alkyds, fatty, unsaturated (C_{18}), dimers, hydrogenated, distilled and non-distilled	no	yes	no		(18)		(1)
734	46380	0068855-54-9	Diatomaceous earth, soda ash flux-calcined	yes	no	no				
735	40120	0068951-50-8	bis(polyethyleneglycol)hydroxymethylphosphonate				0,6			
736	50960	0069226-44-4	n-octyltin ethyleneglycol bis(mercaptoacetate)	yes	no	no		(10)		
737	77370	0070142-34-6	poly(ethyleneglycol)-dipolyhydroxystearate	yes	no	no				

738	60320	007032-28-7	2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	yes	no	yes	1,5			
739	70000	007033-92-1	2,2′-oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no				
740	81200	007187-69-8	poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl) imino]	yes	no	yes	3			
741	24070 83610	007313-82-6	resin acids and rosin acids	yes	yes	no				
742	92700	007830-42-1	2,2,4,4-tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	yes	no	yes	5			
743	38950	007972-28-8	bis(4-ethylbenzylidene)sorbitol	yes	no	no				
[F14744	18888	080181-31-3	3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	no	yes	no		(35)	The substance is used as product obtained by bacterial fermentation.	]

									In compliance with the specifications mentioned in the Table 4 of Annex I.
745	68145	00804102	2,2′,2″-nitrilo(triethyl tris(3,3′,5,5′-tetra-tert-butyl-1,1′-bi-phenyl-2,2′-diyl)phosphite)	yes	no	yes	5		SML expressed as sum of phosphite and phosphate
746	38810	00806930	bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	yes	no	yes	5		SML expressed as sum of phosphite and phosphate
747	47600	00840306	di-n-dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes		(25)	
748	12765	00844341	N-(2-aminoethyl)-β-alanine, sodium salt	no	yes	no	0,05		
749	66360	00852092	2,2′-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	yes	no	yes	5		
750	66350	00852092	2,2′-methylenebis(4,6-di-tert-butylphenyl)	yes	no	no	5		

			lithium phosphate							
751	81515	0087189-25-0	poly(zinc glycerolate)	yes	no	no				
[F1 752	39890	0087826-45-3 0069158-41-4 0054686-97-4 0081541-12-0	bis(4-methylbenzylidene)sorbitol	yes	no	no				]
753	62800	0092704-41-1	kaolin, calcined	yes	no	no				
754	56020	0099880-64-5	glycerol dibehenate	yes	no	no				
755	21765	0106246-33-7	4,4′-methylenebis(3-chloro-2,6-diethylaniline)	no	yes	no	0,05			(1)
756	40020	0110553-27-0	2,4-bis(octylthiomethyl)-6-methylphenol	yes	no	yes		(24)		
757	95725	0110638-71-6	vermiculite, reaction product with citric acid, lithium salt	yes	no	no				
758	38940	0110675-26-8	2,4-bis(dodecylthiomethyl)-6-methylphenol	yes	no	yes		(24)		
759	54300	0118337-09-0	2,2′-ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	yes	no	yes	6			
760	83595	0119345-01-6	reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-	yes	no	no	18		Composition: — 4,4′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3)	

		di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl						—	(36-46 % w/w (*)), 4,3′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)), 3,3′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)), 4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)), tris(2,4-di-tert-butylphenyl)phosphite

									(CAS No 0031570-04-4) (9-18 % w/ w (*)),
								—	4,4′-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0 bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0112949-97-0) (< 5 % w/ w (*))
								(*)	Quantity of substance used/ quantity of formulation
								Other specifications:	
								—	Phosphor content of min. 5,4 % to max. 5,9 %,
								—	Acid value of max. 10 mg

									—	KOH per gram, Melt range of 85–110 °C,
761	92930	01202183-0	triethyleneglycol bis(5-tert-butyl-4-hydroxy-3-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	yes	no	no	6			
762	31530	01239683-2	2-[1-(2-hydroxy-3,5-di-tert-pentylphenyl)ethyl]-4,6-di-tert-pentylphenyl acrylate	yes	no	yes	5			
763	39925	01292283-3	1,3,5-tris(methoxymethyl)-2,5-dimethylhexane	yes	no	yes	0,05			
764	13317	01324599-5	N,N′-bis[4-(ethoxycarbonyl)phenyl]-1,4,5,8-naphthalenetetracarboxydiimide	no	yes	no	0,05		Purity > 98,1 % (w/w). Only to be used as co-monomer (max 4 %) for polyesters (PET, PBT).	
765	49485	01347012-4	2,4-dimethyl-6-(1-methylpentadecyl)phenol	yes	no	yes	1			
766	38879	01358615-2	bis(3,4-dimethylbenzylidene)sorbitol	yes	no	no				

767	38510	01365041-26	1,6-bis(3-aminopropyl)ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	yes	no	no	5			
768	34850	01439255-92	Amines, bis(hydrogenated tallow alkyl) oxidised	yes	no	no			Not to be used for articles in contact with fatty foods for which [F1 simulant D1 and/or D2] is laid down. Only to be used in: (a) (b)	(1) polyolefins at 0,1 % (w/w) concentration and in PET at 0,25 % (w/w) concentration.

769	74010	01456508-8	phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	yes	no	yes	5		SML expressed as sum of phosphite and phosphate
770	51700	01473152-2	2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	yes	no	no	0,05		
771	34650	01518411-5	aluminium hydroxybis [2,2′-methylenebis (4,6-di-tert-butylphenyl) phosphate]	yes	no	no	5		
772	47500	01532501-3	N,N′-dicyclohexyl-2,6-naphthalene dicarboxamide	yes	no	no	5		
773	38840	01548623-3	bis(2,4-dicumylphenyl)pentaerythritol-diphosphite	yes	no	yes	5		SML expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)
774	95270	01617172-4	2,4,6-tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite	yes	no	yes	2		SML expressed as sum of phosphite, phosphate and the

									hydrolysis product = TTBP	
775	45705	01664121-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester	yes	no	no		(32)		
776	76723	01678833-6	poly[dimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4′-diisocyanate	yes	no	no			The fraction with molecular weight below 1 000 Da [F1shall] not exceed 1,5 % (w/w)	
777	31542	01742542-3	2-propenoic acid, methyl ester, telomer with 1-dodecanethiol, C_{16}-C_{18} alkyl esters	yes	no	no			0,5 % in final product	(1)
778	71670	01786715-8	pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	yes	no	yes	0,05			
[F1779	39815	01821219-2	2,7-bis(methoxymethyl)fluorene	yes	no	yes	0,05			[F9(2)]]
780	81220	01922684-64-7	poly[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-	yes	no	no	5			

			triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-α-[N,N,N′,N′-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-ω-N,N,N′,N′-tetrabutyl-1,3,5-triazine-2,4-diamine]							
781	95265	022709916-8-7	1,3,5-tris(4-benzoylphenyl) benzene	yes	no	no	0,05			
782	76725	066147	poly(dimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	yes	no	no			The fraction with molecular weight below 1 000 Da [F1shall] not exceed 1 % (w/w)	
783	55910	073615	glycerides, C2-3, castor-oil mono-,	yes	no	no		(32)		

			hydrogenated, acetates							
[F10 784	95420	074507-63-5	1,3,5-tris (2,2-di-methylpropanamido) benzene	yes	no	no	5			]
785	24910	000010-21-0	terephthalic acid	yes	no		(28)			
786	14627	000117-21-5	3-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 3-chlorophthalic acid	
787	14628	000118-45-6	4-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 4-chlorophthalic acid	
788	21498	000253-35-0	[3-(methacryloxy)propyl]trimethoxysilane	no	yes	no	0,05		Only to be used as a surface treatment agent of inorganic fillers	(1) (11)
789	60027	—	hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw:	yes	no	no			Average molecular weight not less than 440 Da. Viscosity at 100 °C not less than 3,8 cSt (3,8 $\times 10^{-6}$ m^2/s).	(2)

			440–12 000)							
790	80480	009075-86-8 / 082451-48-7	poly[6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino)] hexa-methylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino)]	yes	no	no	5		Average molecular weight not less than 2 400 Da. Residual content of morpholine ≤ 30 mg/kg, of N,N′-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine < 15 000 mg/kg, and of 2,4-dichloro-6-morpholino-1,3,5-triazine ≤ 20 mg/kg.
791	92470	010699043-16	N4,N6,N′,N″,N″-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine	yes	no	no	0,05		
792	92475	020325-33-5	3,3′,5,5′-tetrakis(tert-butyl)-2,2′-dihydroxybiphenyl, cyclic	yes	no	yes	5		SML expressed as the sum of phosphite

			ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid						and phosphate form of the substance and the hydrolysis products
793	94000	0000102-71-6	triethanolamine		no	no	0,05		SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine
[F12 794	18117	0000079-14-1	glycolic acid	no	yes	no			Only to be used for manufacture of polyglycolic acid (PGA) for (i) indirect food contact behind polyesters such as polyethylene terephthalate (PET) or polylactic acid (PLA); and (ii) direct food contact of a blend]

									of PGA up to 3 % w/w in PET or PLA.	
795	40155	012417253-8	N,N′-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N′-diformylhexamethylenediamine	yes	no	no	0,05			(2) (12)
796	72141	001860252-4	2,2′-(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]	yes	no	yes	0,05		SML including the sum of its hydrolysis products	
[F12 797	76807	007301826-5	polyesters of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)		]
798	92200	000642284-2	terephthalic acid, bis(2-ethylhexyl)ester	yes	no	no	60	(32)		
[F10 799	77708		polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C_8-C_{22}) alcohols	yes	no	no	1,8		In compliance with the maximum ethylene oxide content as laid down in the purity criteria for	]

									food additives in Commission Regulation (EU) No 231/2012.	
800	94425	00008677-13-0	triethyl phosphonoacetate	yes	no	no			Only for use in PET	
801	30607	—	acids, C_2-C_{24}, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt	yes	no	no				
802	33105	0146340-15-0	alcohols, C_{12}-C_{14} secondary, β-(2-hydroxyethoxy), ethoxylated	yes	no	no	5			(12)
803	33535	0152261-33-1	alkenes(C_{20}-C_{24}) copolymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine	yes	no	no			Not to be used for articles in contact with fatty foods for which [F1 simulant D1 and/or D2] is laid down.	(13)

									Not to be used in contact with alcoholic foods.
804	80510	101012	poly(80-73-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid	yes	no	no			Only to be used as polymer production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS)
805	93450	—	titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]	yes	no	no			The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w
806	14876	000107-97-7	cyclohexanedicarboxylic acid	no	yes	no	5		Only to be used for manufacture of polyesters

[F11807	93485	—	titanium nitride, nanoparticles	yes	no	no			No migration of titanium nitride nanoparticles. Only to be used in polyethylene terephthalate (PET) up to 20 mg/kg. In the PET, the agglomerates have a diameter of 100-500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.	]
808	38550	088207-34-4	bis(4-propylbenzylidene)propylsorbitol	yes	no	no	5		SML including the sum of its hydrolysis products	
809	49080	085228289-4	2-(2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-	yes	no	yes	0,05		Only for use in PET	(6) (14) (15)

			benzo[de]isoquinolin-1,3(2H)-dione							
810	68119		neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid	yes	no	no	5	(32)	Not to be used for articles in contact with fatty foods for which [F1simulant D1 and/or D2] is laid down.	
811	80077	0068441-17-8	polyethylene waxes, oxidised	yes	no	no	60			
[F12812	80350	0124578-12-7	poly(12-hydroxystearic acid)-polyethyleneimine copolymer	yes	no	no			Only to be used in plastics up to 0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.	]
813	91530	—	sulphosuccinic acid alkyl (C_4-C_{20}) or cyclohexyl diesters, salts	yes	no	no	5			
814	91815	—	sulphosuccinic acid	yes	no	no	2			

			monoalkyl (C_{10}-C_{16}) polyethyleneglycol esters, salts							
815	94985	—	trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid	yes	no	no	5	(32)	Not to be used for articles in contact with fatty foods for which [F1 simulant D1 and/or D2] is laid down	
816	45704	—	cis-1,2-cyclohexanedicarboxylic acid, salts	yes	no	no	5			
817	38507	—	cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts	yes	no	no	5		Not to be used with polyethylene in contact with acidic foods. Purity ≥ 96 %.	
818	21530	—	methallylsulphonic acid, salts	yes	yes	no	5			
819	68110	—	neodecanoic acid, salts	yes	no	no	0,05		Not to be used in polymers contacting	

									fatty foods. Not to be used for articles in contact with fatty foods for which [F1simulant D1 and/ or D2] is laid down. SML expressed as neodecanoic acid.	
820	76420	—	pimelic acid, salts	yes	no	no				
821	90810	—	stearoyl-2-lactylic acid, salts	yes	no	no				
[F16822	71938		Perchloric acid, salts	yes	no	no	0,002			(4)]
823	24889	—	5-Sulphoisophthalic acid, salts	no	yes	no	5			
854	71943	0329238-24-6	perfluoro-2-methoxy-acetic acid, α-substituted with the copolymer of perfluoro-1,2-propylene	yes	no	no			Only to be used in concentrations up to 0,5 % w/w in the polymerisation of	

			glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropyloxy groups						fluoropolymers that are processed at temperatures at or above 340 °C and are intended for use in repeated use articles	
[F17 855	40560		(butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate	no	no				Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below.	
[F18 856	40563	25101-28-4	(butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate	no	no				Only to be used in: — rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or	]

										below; or
									—	at up to 40 % w/w in blends of styrene acrylonitrile copolymer (SAN)/ poly(methyl methacrylate) (PMMA) repeat-use articles at room temperature or below, and when either in contact only with aqueous, acidic and/or low alcoholic (< 20 %) foodstuffs for less than 1 day, or when in contact only with dry foodstuffs for any

										duration of time.
857	66765	003795[illegible]	(ethyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % at room temperature or below.	]
[F7[X1858	38565	009049839-0	3,9-bis[2-(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]undecane	yes	no	yes	0,05		SML expressed as the sum of the substance and its oxidation product 3-[(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)prop-2-enoyloxy)-1,1-dimethylethyl]-9-[(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]-undecane in equilibrium with its para quinone	(2)]]

									methid tautomer.
[F4 859			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform	no	no				Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 998 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of]

									those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.
860	71980	005179[illegible]	perfluoro[2-(poly(n-propoxy))propanoic acid]		no	no			Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles
861	71990	001325[illegible]	perfluoro[2-(n-propoxy)propanoic acid]		no	no			Only to be used in the polymerisation of fluoropolymers that are processed at

									temperatures at or above 265 °C and are intended for use in repeated use articles	
[F12 862	15180	00180853-02-4	3,4-diacetoxy-1-butene	no	yes	no	0,05		SML including the hydrolysis product 3,4-dihydroxy-1-butene Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers.	(17) (19)]
[F17 863	15260	00006461-29-3	1,10-decanediamine	no	yes	no	0,05		Only to be used as a co-monomer for manufacturing polyamide articles for repeated use in contact with aqueous, acidic and dairy	]

									foodstuffs at room temperature or for short term contact up to 150 °C.	
864	46330	00000562-06-4	2,4-diamino-6-hydroxypyrimidine	yes	no	no	5		Only to be used in rigid poly(vinyl chloride) (PVC) in contact with non-acidic and non-alcoholic aqueous food	
[F11 865	40619	00253222-90-0	(butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer	yes	no	no			Only to be used in: (a) rigid poly(vinyl chloride) (PVC) at a maximum level of 1 % w/w; (b) polylactic acid (PLA) at a maximum	]

										level of 5 % w/ w.
866	40620	—	(butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 7 %	
867	40815	004047[illegible]-03-2	(butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %	
[F11 868	53245	000901[illegible]-88-2	(butyl acrylate, methyl methacrylate) copolymer	yes	no	no			Only to be used in: (a) (b)	] rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % w/ w; polylactic acid (PLA) at

									(c)	a maximum level of 5 % w/ w; polyethylene terephthalate (PET) at a maximum level of 5 % w/ w.
869	66763	00271366-15-8	(butyl acrylate, methyl methacrylate, styrene) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 3 %	
870	95500	01605354-46-6	N,N′,N″-tris(2-methylcyclohexyl)-1,2,3-propanetricarboxamide	yes	no	no	5			
[F2871		02879166-80-3	docosanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly	yes	no	no			Only to be used in polyolefins at levels of up to 20 weight %. These polyolefins	(23)]

			(oxy-1,2-ethanediyl) and 1-propene						shall only be used in contact with foods for which Table 2 of Annex III assigns food simulant E, at ambient temperature or below, and when migration of the total oligomeric fraction of less than 1 000 Da does not exceed 50 µg/kg food.	
[F19872		00066072	41-6 phenyl-3,3-bis(4-hydroxyphenyl)	no	yes phthalimidine	no	0,05		To be used only as a co-monomer in polycarbonate copolymers	(20)]
[F17873	93460		titanium dioxide reacted	yes	no	no			Reaction product of titanium	

			with octyltriethoxysilane						dioxide with up to 2 % w/w surface treatment substance octyltriethoxysilane, processed at high temperatures.
[F7874	16265	015606500-8	dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyloxy, ω-3-dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyl polydimethylsiloxane	no	yes	no	0,05	(33)	Only to be used as comonomer in siloxane modified polycarbonate. The oligomeric mixture shall be characterised by the formula $C_{24}H_{38}Si_2O_5(SiOC_2H_6)_n$ (50 > n ≥ 26).]
875	80345	005812822-6	poly(12-hydroxystearic acid) stearate	yes	no	yes	5		
878	31335	—	acids, fatty (C_8-C_{22}) from animal or vegetable fats and oils, esters with branched alcohols,	yes	no	no			

			aliphatic, monohydric, saturated, primary (C_3-C_{22})							
879	31336	—	acids, fatty (C_8-C_{22}) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C_1-C_{22})	yes	no	no				
[F10 880	31348		acids, fatty (C_8-C_{22}), esters with pentaerythritol'	yes	no	no				
881	25187	00030102-6	2,2,4,4-tetramethylcyclobutane-1,3-diol	no	yes	no	5		Only for: (a) repeated use articles for long term storage at room temperature or below and hotfill;	]

									(b)	single use materials and articles as a co-monomer at a maximum use level of 35 mole % of the diol component of polyesters, and if such materials and articles are for long term storage at room temperature or below of food types which have an alcohol content of up to 10 %

										and for which Table 2 of Annex III does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles.
882	25872	000241629-46-6	2,3,6-trimethylphenol	no	yes	no	0,05			
883	22074	000445773-1-0	methyl-1,5-pentanediol	no	yes	no	0,05		Only to be used in materials in contact with food at a surface to mass ratio up to 0,5 dm^2/kg	
884	34240	009108217-6	alkyl(C_{10}-C_{21})sulphonic acid, esters with phenol	yes	no	no	0,05		Not to be used for articles in	

									contact with fatty foods for which **[**[F1]simulant D1 and/ or D2**]** is laid down.
885	45676	026324-54-8	cyclic oligomers of (butylene terephthalate)	yes	no	no			Only to be used in poly(ethylene terephthalate) (PET), poly(butylene terephthalate) (PBT), polycarbonate (PC), polystyrene (PS) and rigid poly(vinyl chloride) (PVC) plastics in concentrations up to 1 % w/ w, in contact with aqueous, acidic and alcoholic foods, for long term storage at room temperature.

[F17894	93360	00165455-54-3	thiodipropionic acid, ditetradecyl ester	yes	no	no		(14)		
895	47060	01710903-93-5	3-(3,5-di-tert-butyl-4-hydroxyphenyl)propanoic acid, esters with C13-C15 branched and linear alcohols	yes	no	no	0,05		Only to be used in polyolefins in contact with foods other than fatty/ high-alcoholic and dairy products.	
896	71958	09584453-41-8	perfluoro-3-[(3-methoxy-propoxy)propanoic acid], ammonium salt	yes	no	no			Only to be used in the polymerisation of fluoropolymers when: — processed at temperatures higher than 280 °C for at least 10 minutes, — processed at temperatures higher than 190 °C up to 30	

										% w/ w for use in blends with polyoxymethylene polymers and intended for repeated use articles.
[F7902		000128-44-9	1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	yes	no	no			The substance shall comply with the specific purity criteria as set out in Commission Regulation (EU) No 231/2012[h].	]
[F4903		37486-69-4	2,4-perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether]	yes	no	no			Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for: (a)	] repeated and single use materials and articles

									(b)	when sintered or processed (non-sintered) at temperatures at or above 360 °C for at least 10 minutes or at higher temperatures for equivalent shorter times; repeated use materials and articles when processed (non-sintered) at temperatures from 300 °C and up to 360 °C for at least 10 minutes.

923	39150	000012-40-1	N,N-bis(2-hydroxyethyl)dodecanamide	yes	no	no	5		The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, [F1shall] not result in a migration of diethanolamine higher than 0,3 mg/kg food.	(18)
924	94987		trimethylolpropane, mixed triesters and diesters with n-octanoic and n-decanoic acids	yes	no	no	0,05		Only for use in PET in contact with all types of foods other than fatty, high-alcoholic and dairy products.	
926	71955	0908020-52-0	perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt	yes	no	no			Only to be used in the polymerisation of fluoropolymers	

									that are processed at temperatures higher than 300 °C for at least 10 minutes.	
[F4969		24937-78-8	Styrene-vinyl acetate copolymer wax	yes	no	no			Only to be used as a polymeric additive up to 2 % w/w in polyolefins. The migration of low molecular weight oligomeric fraction below 1 000 Da shall not exceed 5 mg/kg food.	]
971	25885	000245-09-4	1,2,4-trimethyl trimellitate	yes	no				Only to be used as a co-monomer up to 0,35 % w/w to produce modified polyesters intended to be	(17)

									used in contact with aqueous and dry foodstuffs containing no free fat at the surface.
972	45197	0012158-74-6	copper hydroxide phosphate	yes	no	no			
973	22931	0019430-93-4	(perfluorobutyl)ethylene	yes	no	no			Only to be used as a co-monomer up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures.
[F16974	74050	939402-02-5	phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	yes	no	yes	10		SML expressed as the sum of the phosphite and phosphate forms of the substance, 4-tert-amylphenol and 2,4-di-tert-amylphenol. The migration]]

									of 2,4-di-tert-amylphenol shall not exceed 1 mg/kg food.	
[F7 979	79987	—	(polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer	yes	no	no			Only to be used in polyethylene terephthalate (PET) at a maximum level of 5 % w/w.	]
[F19 988		3634-83-1	1,3-bis(isocyanatomethyl)benzene	no	yes	no		(34)	SML(T) applies to the migration of its hydrolysis product, 1,3-benzenedimethanamine To be used only as co-monomer in the manufacture of a middle layer coating on a poly(ethylene terephthalate) polymer film in a multilayer film	]
[F4 998			(butadiene, ethyl	yes	no	no			Only to be	

		acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform						used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of

									particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.	
[F20 1007		976-56-7	diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate		yes	no			Only to be used up to 0,2 % w/w based on the final polymer weight in the polymerisation process to manufacture poly(ethylene terephthalate) (PET).	
1016			(methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform	yes	no	no			Only to be used up to: (a) (b)	10 % w/w in non-plasticised PVC; 15 % w/w in non-plasticised PLA.]

									The final material shall be used at room temperature or below.	
1017		25618-55-7	polyglycerol	yes	no	no			To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275 °C.	
[F20 1030			montmorillonite clay modified by dimethyldialkyl(C16-C18)ammonium chloride	yes	no	no			Only to be used up to 12 % (w/w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room temperature or below.	]

									The sum of the specific migration of 1-chlorohexadecane and 1-chlorooctadecane shall not exceed 0,05 mg/kg food. Can contain platelets in the nanoform that are only in one dimension thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer.	
[F2 1031		3238-40-2	Furan-2,5-dicarboxylic acid	no	yes	no	5		Only to be used as a monomer in the production	(22) (23)

									of polyethylene furanoate. The migration of the oligomeric fraction of less than 1 000 Da shall not exceed 50 µg/kg food (expressed as furan-2,5-dicarboxylic acid).	
1034		3710-30-3	1,7-octadiene	no	yes	no	0,05		Only to be used as a crosslinking co-monomer in the manufacture of polyolefins for contact with any type of foods for long term storage at room temperature, including when packaged under	]

									hot-fill conditions.
1043			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform	no	no			Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 998, the restriction of 10 % w/w applies to the sum of	]

									those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.
[F2 1045		1190931-27-1	perfluoro(acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt		no	no			Only to be used as a polymer production aid during the manufacture of fluoropolymers under high temperature conditions of at least 370 °C.
1046			zinc oxide, nanoparticles, coated with [3-(methacryloxy)propyl] trimethoxysilane (FCM No 788)	yes	no	no			Only to be used in unplasticised polymers. The restrictions and specifications specified for FCM substance

									No 788 shall be respected.	
1048		624-03-3	ethylene glycol dipalmitate	yes	no	no		(2)	Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils.	
1050			zinc oxide, nanoparticles, uncoated	yes	no	no			Only to be used in unplasticised polymers.	
1051		42774-15-2	N,N′-bis(2,2,6,6-tetramethyl-4-piperidinyl) isophthalamide	yes	no	no	5			
1052		1455-42-2	2,4,8,10-tetraoxaspiro[5,5]undecane-3,9-diethanol,β3,β3,β9,β9-tetramethyl- (‘SPG’)	no	yes	no	5		Only to be used as a monomer in the production of polyesters. The migration of oligomers of less than 1 000 Da shall not exceed	(22) (23)

									50 µg/kg food (expressed as SPG).	
1053			fatty acids, C16–18 saturated, esters with dipentaerythritol	yes	no	no			Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils	]
[F20 1055		7695-91-2 58-95-7	α-tocopherol acetate	yes	no	no			Only to be used as antioxidant in polyolefins.	(24)
[F21 1059		147398-31-0	poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate)	yes	no	no		(35)	Only to be used alone or blended with other polymers in contact with foods for which food simulant E is assigned in Table 2 of	]

									Annex III.	
1060			ground sunflower seed hulls	yes	no	no			Only to be used at room temperature or below in contact with foods for which Table 2 of Annex III assigns food simulant E. The seed hulls shall be obtained from sunflower seeds that are fit for human consumption. The processing temperature of the plastic containing the additive shall not exceed 240 °C.	
[F22 1061		80512-44-3	2,3,4′-trifluorobenzophenone	no	yes	no			Only to be used as a co-	]

									monomer in the manufacture of polyether ether ketone plastics up to 0,3 % w/w of the final material.
1062			mixture composed of 97 % tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3 % hexamethyldisilazane (HMDS) with CAS No 999-97-3	no	yes	no			Only to be used for the production of recycled PET and at up to 0,12 % (w/w).]
[F22 1063		1547-26-2	2,3,3,4,4,5,5-heptafluoro-1-pentene	no	yes	no			Only to be used together with tetrafluoroethylene and/or ethylene co-monomers to manufacture fluorocopolymers for application as polymer processing aid at up to 0,2 % w/w of the

									food contact material, and when the low-molecular mass fraction below 1 500 Da in the fluorocopolymer does not exceed 30 mg/kg.	
1064		39318-18-8	tungsten oxide	yes	no	no	0,05		Stoichiometry: WO_n, n = 2,72-2,90	(25)
1065		85711-28-0	mixture of methyl-branched and linear C_{14}-C_{18} alkanamides, derived from fatty acids	yes	no	no	5		Only to be used in the manufacture of articles made of polyolefins, and which do not come into contact with foods for which food simulant D2 is assigned in Table 2 of Annex III.	(26)]

[F14 1066		23985-75-2	1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylic acid, dimethyl ester	no	yes	no	0,05		Only to be used as a co-monomer in the manufacture of a polyester non-food contact layer in a plastic multilayer material, which is to be used only in contact with foods for which food simulants A, B, C and/or D1 are assigned in Table 2 of Annex III. The specific migration limit in column 8 refers to the sum of the substance and	]

									of its dimers (cyclic and open chain).	
[F21 1067		616-38-6	dimethyl carbonate	no	yes	no			Only to be used: a)	(27)] with 1,6-hexanediol in the manufacture of polycarbonate pre-polymers that are used at up to 30 % to manufacture thermoplastic polyurethanes with 4,4′-methylenediphenyldiisocya and diols, such as polypropylene glycol and 1,4-butanediol. The resulting material shall only be applied in repeated

										use articles intended to come into short–term contact (≤ 30 min at room temperature) with food for which simulants A and/or B are assigned in Table 2 of Annex III; or
									b)	for the production of other polycarbonates and/or under other conditions provided that the migration of dimethyl carbonate does not exceed 0,05

										mg/kg food and that the migration of all polycarbonate oligomers with a molecular weight below 1 000 Da together does not exceed 0,05 mg/kg food.
[F14 1068		2530-83-8	[3-(2,3-epoxypropoxy)propyl]trimethoxysilane	no	yes	no			Only to be used as a component of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC),	]

									polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for the substance and 0,06 mg/kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer).	
[F21 1069		75-28-5	isobutane	yes	no	no			Only to be used as a blowing agent.	]

a	OJ L 302, 19.11.2005, p. 28.
b	OJ L 330, 5.12.1998, p. 32.
c	OJ L 253, 20.9.2008, p. 1.
d	**[**F4Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).**]**
e	OJ L 158, 18.6.2008, p. 17.
f	**[**F5**[**F6Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).**]**
g	This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.**]**
h	**[**F7OJ L 83, 22.3.2012, p. 1.**]**
i	**[**F8Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013.
j	Young children as defined in Article 2(2)(b) of Regulation (EU) No 609/2013.**]**

Editorial Information

X1 Substituted by Corrigendum to Commission Regulation (EU) No 1183/2012 of 30 November 2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Official Journal of the European Union L 338 of 12 December 2012).

Textual Amendments

F4 Inserted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F5 Inserted by 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 (Text with EEA relevance).

F6 Substituted by Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (Text with EEA relevance).

F7 Inserted by Commission Regulation (EU) No 1183/2012 of 30 November 2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F8 Inserted by Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (Text with EEA relevance).

F9 Deleted by Commission Regulation (EU) 2017/752 of 28 April 2017 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F10 Substituted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F11 Substituted by Commission Regulation (EU) No 1183/2012 of 30 November 2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F12 Substituted by Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F13 Substituted by Commission Regulation (EU) No 202/2014 of 3 March 2014 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F14 Substituted by Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F15 Deleted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F16 Substituted by Commission Regulation (EU) 2018/831 of 5 June 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F17 Inserted by Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F18 Substituted by Commission Regulation (EU) 2018/79 of 18 January 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F19 Inserted by Commission Regulation (EU) No 202/2014 of 3 March 2014 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F20 Inserted by Commission Regulation (EU) 2017/752 of 28 April 2017 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F21 Inserted by Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

F22 Inserted by Commission Regulation (EU) 2018/79 of 18 January 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

2. Group restriction of substances

Table 2 on Group restrictions contains the following information:

Column 1 (Group restriction No): contains the identification number of the group of substances for which the group restriction applies. It is the number referred to in Column 9 in Table 1 of this Annex.

Column 2 (FCM substance No): contains the unique identification numbers of the substances for which the group restriction applies. It is the number referred to in Column 1 in Table 1 of this Annex.

Column 3 (SML (T) [mg/kg]): contains the total specific migration limit for the sum of substances applicable to this group. It is expressed in mg substance per kg food. It is indicated ND if the substance shall not migrate in detectable quantities.

Column 4 (Group restriction specification): contains an indication of the substance whose molecular weight forms the basis for expression of the result.

TABLE 2

(1)	(2)	(3)	(4)
Group Restriction No	**FCM substance No**	**SML (T)[mg/kg]**	**Group restriction specification**
1	128 211	6	expressed as acetaldehyde
[F1 2	89 227 263 1048	30	expressed as ethyleneglycol]
3	234 248	30	expressed as maleic acid
4	212 435	15	expressed as caprolactam
5	137 472	3	expressed as the sum of the substances
6	412 512 513 588	1	expressed as iodine
7	19 20	1,2	expressed as tertiary amine
8	317 318 319 359 431 464	6	expressed as the sum of the substances
9	650 695 697 698 726	0,18	expressed as tin
10	28 29 30 31 32 33 466 582 618 619 620 646 676	0,006	expressed as tin

	736		
11	66 645 657	1,2	expressed as tin
12	444 469 470	30	expressed as the sum of the substances
13	163 285	1,5	expressed as the sum of the substances
[F12 14	294 368 894]	5	expressed as the sum of the substances and their oxidation products
[F10 15	98 196 344	15	expressed as formaldehyde]
16	407 583 584 599	6	expressed as boron Without prejudice to the provisions of Directive 98/83/EC
17	4 167 169 198 274 354 372 460 461 475 476 485 490 653	ND	expressed as isocyanate moiety
18	705 733	0,05	expressed as the sum of the substances
19	505 516 519	10	expressed as SO_2
20	290 386 390	30	expressed as the sum of the substances
21	347 349	5	expressed as trimellitic acid
22	70 147	6	expressed as acrylic acid

	176 218 323 325 365 371 380 425 446 448 456 636		
23	150 156 181 183 184 355 370 374 439 440 447 457 482	6	expressed as methacrylic acid
24	756 758	5	expressed as the sum of the substances
25	720 747	0,05	sum of mono-n-dodecyltin tris(isooctylmercaptoacetate), di-n-dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride
26	728 729	9	expressed as the sum of the substances
27	188 291	5	expressed as isophthalic acid
28	191 192 785	7,5	expressed as terephthalic acid
29	342 672	0,05	expressed as the sum of 6-hydroxyhexanoic acid and caprolactone

[F10 30	254 344 672	5	expressed as 1,4-butanediol**]**
31	73 797	30	expressed as the sum of the substances
32	8 72 73 138 140 157 159 207 242 283 532 670 728 729 775 783 797 798 810 815	60	expressed as the sum of the substances
[F7 33	180 874	ND	expressed as eugenol**]**
[F19 34	421 988	0,05	Expressed as 1,3-benzenedimethanamine**]**
[F21 35	467 744 1059	0,05	expressed as crotonic acid**]**

3. Notes on verification of compliance

Table 3 on notes on verification of compliance contains the following information:

Column 1 (Note No): contains the identification number of the Note. It is the number referred to in Column 11 in Table 1 of this Annex.

Column 2 (Notes on verification of compliance): contains rules that shall be respected when testing for compliance of the substance with specific migration limits or other restrictions or it contains remarks on situations where there is a risk of non-compliance.

TABLE 3

(1)	(2)
Note No	**Notes on verification of compliance**

(1)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of an analytical method.
(2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.
(3)	There is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the final product does not comply with Article 3(1) c of the Framework Regulation (EC) No 1935/2004.
[F11(4)	Compliance testing when there is a fat contact **[**F1shall**]** be performed using saturated fatty food simulants as simulant D2.**]**
(5)	Compliance testing when there is a fat contact **[**F1shall**]** be performed using isooctane as substitute of simulant D2 (unstable).
(6)	Migration limit might be exceeded at very high temperature.
(7)	If testing in food is performed, Annex V 1.4 shall be taken into account.
(8)	Verification of compliance by residual content per food contact surface area (QMA); QMA = 0,005 mg/6 dm^2.
(9)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of analytical method for migration testing. The ratio surface to quantity of food shall be lower than 2dm^2/kg.
(10)	Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.
(11)	Only a method of analysis for the determination of the residual monomer in the treated filler is available.
(12)	There is a risk that the SML could be exceeded from polyolefins.
(13)	Only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available.

(14)	There is a risk that the SML could be exceeded from plastics containing more than 0,5 % w/w of the substance.
(15)	There is a risk that the SML could be exceeded in contact with foods with high alcoholic content.
(16)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE) containing more than 0,3 % w/w of the substance when in contact with fatty foods
(17)	Only a method for determination of the residual content of the substance in the polymer is available
[F17(18)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)
(19)	There is a risk that the OML could be exceeded in direct contact with aqueous foods from ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers**]**
[F19(20)	The substance contains aniline as an impurity; verification of compliance with the restriction set for primary aromatic amines in Annex II (2) is necessary**]**
[F4(21)	In case of reaction with foods or simulants verification of compliance shall include verification that the migration limits of the hydrolysis products, formaldehyde and 1,4-butanediol, are not exceeded.**]**
[F2(22)	When used in contact with non-alcoholic foods for which Table 2 of Annex III assigns food simulant D1, food simulant C shall be used for verification of compliance instead of food simulant D1.
(23)	When a final material or article containing this substance is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample,

	a sufficient sample shall be supplied to the competent authority on its request.**]**
[F20(24)	The substance or its hydrolysis products are authorised food additives and compliance with Article 11(3) shall be verified.**]**
[F22(25)	When used as reheat agent in polyethylene terephthalate (PET) verification of compliance with the specific migration limit is not required; in all other cases compliance with the specific migration limit shall be verified in accordance with Article 18; the specific migration limit is expressed as mg tungsten/kg food.
(26)	Migration of stearamide, listed in Table 1 under FCM substance No 306 to which no specific migration limit applies, shall be excluded from verification of the compliance of the migration of the mixture with the specific migration limit laid down for the mixture.**]**
[F21(27)	When a final material or article containing this substance and produced under conditions other than those described in point (a) column 10 of Table 1 is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in point (b) column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.**]**

4. Detailed specification on substances

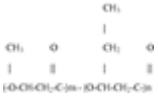
Table 4 on detailed specifications on substances contains the following information

Column 1 (FCM substance No): contains the unique identification number of the substances referred to in Column 1 in Table 1 of Annex I to which the specification applies.

Column 2 (Detailed specification on the substance): contains the specification on the substance.

TABLE 4

(1)	(2)

FCM substance No	Detailed specification on the substance	
744	Definition	The copolymers are produced by the controlled fermentation of Alcaligenes eutrophus using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wildtype organism Alcaligenes eutrophus strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/ working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications
	Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)
	CAS number	0080181-31-3
	Structural formula	 where n/(m + n) greater than 0 and less or equal to 0,25

	Average molecular weight	Not less than 150 000 Daltons (measured by gel permeation chromatography)
	Assay	Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydoxy-pentanoate) analysed after hydrolysis as a mixture of 3-D-hydro-xybutanoic and 3-D-hydroxypentanoic acids
	Description	White to off-white powder after isolation
	Characteristics	
	Identification tests:	
	Solubility	Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water
	[F14Restriction	Specific migration limit for crotonic acid is 0,05 mg/kg food]
	Purity	Prior to granulation the raw material copolymer powder must contain:
	— nitrogen,	Not more than 2 500 mg/kg of plastic
	— zinc,	Not more than 100 mg/kg of plastic
	— copper,	Not more than 5 mg/kg of plastic
	— lead,	Not more than 2 mg/kg of plastic
	— arsenic,	Not more than 1 mg/kg of plastic
	— chromium,	Not more than 1 mg/kg of plastic

ANNEX II

Restrictions on materials and articles

[F1 1. Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

Aluminium = 1 mg/kg food or food simulant

Barium = 1 mg/kg food or food simulant

Cobalt = 0,05 mg/kg food or food simulant

Copper = 5 mg/kg food or food simulant

Iron = 48 mg/kg food or food simulant

Lithium = 0,6 mg/kg food or food simulant

Manganese = 0,6 mg/kg food or food simulant

Zinc = 5 mg/kg food or food simulant.**]**

[F1 2. Primary aromatic amines which are not listed in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant in accordance with Article 11(4). The detection limit referred to in the second subparagraph of Article 11(4) applies to the sum of primary aromatic amines released.**]**

ANNEX III

Food simulants

1. Food simulants

For demonstration of compliance for plastic materials and articles not yet in contact with food the food simulants listed in Table 1 below are assigned.

*[*F1 *TABLE 1*

List of food simulants

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
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E**]**

2. General assignment of food simulants to foods

Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances. Food simulant B shall be used for those foods which have a pH below 4.5. Food simulant C shall be used for alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.

Food simulants D1 and D2 are assigned for foods that have a lipophilic character and are able to extract lipophilic substances. Food simulant D1 shall be used for alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions. Food simulant D2 shall be used for foods which contain free fats at the surface.

Food simulant E is assigned for testing specific migration into dry foods.

[F1 3. Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food

For testing migration from materials and articles not yet in contact with food the food simulants that corresponds to a certain food category shall be chosen according to Table 2 below.

For testing migration from materials and articles intended to come into contact with foods not listed in Table 2 below, or a combination of foods, the general food simulant assignments in point 2 shall be used for specific migration testing, and for overall migration testing the food simulant assignments in point 4 shall be applicable.

Table 2 contains the following information:

— Column 1 (Reference number): contains the reference number of the food category

— Column 2 (Description of food): contains a description of the foods covered by the food category

— Column 3 (Food simulants): contains sub-columns for each of the food simulants

The food simulant for which a cross is contained in the respective sub-column of column 3 shall be used when testing migration of materials and articles not yet in contact with food.

For food categories where in sub-column D2 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

For food category 01.04 food simulant D2 shall be replaced by 95 % ethanol.

For food categories where in sub-column B the cross is followed by (*) the testing in food simulant B can be omitted if the food has a pH of more than 4,5.

For food categories where in sub-column D2 the cross is followed by (**) the testing in food simulant D2 can be omitted if it can be demonstrated that there is no ‘fatty contact’ with the plastic food contact material.**]**

TABLE 2

food category specific assignment of food simulants

(1)	(2)	(3)					
Reference number	**Description of food**	**Food simulants**					
		A	**B**	**C**	**D1**	**D2**	**E**
01	**Beverages**						

01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:						
	A. Clear drinks: Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract		X(*)	X			
	B. cloudy drinks: juices and nectars and soft drinks		X(*)		X		

	containing fruit pulp, musts containing fruit pulp, liquid chocolate						
01.02	Alcoholic beverages of an alcoholic strength of between 6 %vol and 20 %.			X			
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors				X		
01.04	Miscellaneous: undenaturated ethyl alcohol		X(*)			Substitute 95 % ethanol	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**						
02.01	Starches						X
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)						X

02.03	Cereal flour and meal						X
02.04	Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta						X
02.05	Pastry, biscuits, cakes, bread, and other bakers' wares, dry:						
	A.	With fatty substances on the surface				X/3	
	B.	Other					X
02.06	Pastry, cakes, bread, dough and other bakers' wares, fresh:						
	A.	With fatty substances on the surface				X/3	
	B.	Other					X
03	**Chocolate, sugar and**						

	products thereof Confectionery products						
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes					X/3	
03.02	Confectionery products:						
	A.	In solid form:					
	I.	With fatty substances on the surface				X/3	
	II.	Other					X
	B.	In paste form:					
	I.	With fatty substances on the surface				X/2	
	II.	Moist		X			
03.03	Sugar and sugar products						
	A.	In solid form: crystal					X

		or powder					
	B.	Molasses, sugar syrups, honey and the like	X				
04	**Fruit, vegetables and products thereof**						
⌊[F1]04.01	Fruit, fresh or chilled:						
	A.	unpeeled and uncut					X/10
	B.	peeled and/ or cut	X	X (*)			⌋
04.02	Processed fruit:						
	A.	Dried or dehydrated fruits, whole, sliced, flour or powder					X
	B.	Fruit in the form of purée, preserves, pastes or in		X(*)	X		

		its own juice or in sugar syrup (jams, compote, and similar products)					
	C.	Fruit preserved in a liquid medium:					
	I.	In an oily medium				X	
	II.	In an alcoholic medium			X		
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):						
	A.	Shelled, dried, flaked or powdered					X
	B.	Shelled and roasted					X

	C.	In paste or cream form	X			X	
[F1 04.04	Vegetables, fresh or chilled:						
	A.	unpeeled and uncut					X/10
	B.	peeled and/ or cut	X	X (*)			]
[F1 04.05	Processed vegetables: A.	Dried or dehydrated vegetables whole, sliced or in the form of flour or powder.					X
	B.	(*obsolete*)					
	C.	Vegetables in the form of purée, preserves, pastes or in its own juice (including		X (*)	X		

		pickled and in brine).					
	D.	Preserved vegetables:					
	I.	In an oily medium	X			X	
	II.	In an alcoholic medium			X		]
05	**Fats and oils**						
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)					X	
05.02	Margarine, butter and other fats and oils made from water emulsions in oil					X/2	
06	**Animal products and eggs**						
06.01	Fish:						
	A.	Fresh, chilled,	X			X/3(**)	

		processed, salted or smoked including fish eggs					
	B.	Preserved fish:					
	I.	In an oily medium	X			X	
	II.	In an aqueous medium	X(*)	X			
06.02	Crustaceans and molluscs (including oysters, mussels, snails)						
	A.	Fresh within the shell					
	B.	Shell removed, processed, preserved or cooked with the shell					
	I.	In an oily medium	X			X	
	II.	In an	X(*)	X			

		aqueous medium					
06.03	Meat of all zoological species (including poultry and game):						
	A.	X Fresh, chilled, salted, smoked				X/4(**)	
	B.	X Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams				X/4(**)	
	C.	X Marinated meat products in an oily medium				X	
06.04	Preserved meat:						
	A.	X In an fatty or oily medium				X/3	

	B. In an aqueous medium	X(*)		X		
06.05	Whole eggs, egg yolk, egg white					
	A. Powdered or dried or frozen					X
	B. Liquid and cooked			X		
07	**Milk products**					
07.01	Milk					
	A. Milk and milk based drinks whole, partly dried and skimmed or partly skimmed			X		
	B. Milk powder including infant formula (based on whole milk powder)					X
07.02	Fermented milk such as	X(*)		X		

	yoghurt, buttermilk and similar products						
07.03	Cream and sour cream		X(*)		X		
07.04	Cheeses:						
	A.	Whole, with not edible rind					X
	B.	Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese				X/3(**)	
	C.	Processed cheese (soft cheese, cottage cheese and similar)	X(*)		X		
	D.	Preserved cheese:					
	I.	In an oily medium	X			X	

	II. In an aqueous medium (feta, mozarella, and similar)	X(*)		X		
08	**Miscellaneous products**					
08.01	Vinegar	X				
08.02	Fried or roasted foods:					
	A. Fried potatoes, fritters and the like	X			X/5	
	B. Of animal origin	X			X/4	
08.03	Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents					
	A. Powdered or dried:					

	I.	With fatty character				X/5	
	II.	Other					X
	B.	any other form than powdered or dried:					
	I.	With fatty character	X	X(*)		X/3	
	II.	Other	X(*)	X			
08.04	Sauces:						
	A.	With aqueous character	X(*)	X			
	B.	With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/ water mixtures e.g. coconut based sauces	X	X(*)		X	
08.05	Mustard (except powdered mustard under		X	X(*)		X/3(**)	

	heading 08.14)						
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff						
	A. With fatty substances on the surface	X				X/5	
	B. Other						X
08.07	Ice-creams			X			
08.08	Dried foods:						
	A. With fatty substances on the surface					X/5	
	B. Other						X
08.09	Frozen or deep-frozen foods						X
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.		X(*)		X		
08.11	Cocoa:						

	A.	Cocoa powder, including fat-reduced and highly fat reduced					X
	B.	Cocoa paste				X/3	
08.12	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered						X
08.13	Aromatic herbs and other herbs such as camomile, mallow, mint, tea, lime blossom and others						X
08.14	Spices and seasonings in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron,						X

	salt and other						
08.15	Spices and seasoning in oily medium such as pesto, curry paste					X	

[F23 4. Food simulant assignment for testing overall migration

For tests to demonstrate compliance with the overall migration limit food simulants shall be chosen as set out in Table 3:

TABLE 3

Food simulant assignment for demonstrating compliance with the overall migration limit

Foods covered	**Food simulants in which testing shall be performed**
all types of food	1. distilled water or water of equivalent quality or food simulant A; 2. food simulant B; and 3. food simulant D2.
all types of food except for acidic foods	1. distilled water or water of equivalent quality or food simulant A; and 2. food simulant D2.
[F14 all aqueous and alcoholic foods and milk products with a pH ≥ 4,5	food simulant D1
all aqueous and alcoholic foods and milk products with a pH < 4,5	food simulant D1 and food simulant B]
all aqueous foods and alcoholic foods up to an alcohol content of 20 %	food simulant C
all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 %	1. food simulant C; and 2. food simulant B.]

Textual Amendments

F23 Substituted by Commission Regulation (EU) 2017/752 of 28 April 2017 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

[F2 5. General derogation to the assignment of food simulants

By derogation from the assignments of food simulants in points 2 to 4 of this Annex, where testing with several food simulants is required, a single food simulant shall be sufficient if on the basis of evidence acquired using generally recognised scientific methods this food simulant is shown to be the most severe food simulant for the particular material or article being tested under the applicable time and temperature conditions selected in accordance with Chapters 2 and 3 of Annex V.

The scientific basis on which this derogation is used shall in such cases form part of the documentation required under Article 16 of this Regulation.]

ANNEX IV

Declaration of compliance

The written declaration referred to in Article 15 shall contain the following information:

(1) the identity and address of the business operator issuing the declaration of compliance;

(2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;

(3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;

(4) the date of the declaration;

(5) [F1 confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;]

(6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;

(7) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;

(8) specifications on the use of the material or article, such as:

(i) type or types of food with which it is intended to be put in contact;

(ii) time and temperature of treatment and storage in contact with the food;

(iii) **[**[F23]the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information;**]**

(9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

ANNEX V

COMPLIANCE TESTING

For testing compliance of migration from plastic food contact materials and articles the following general rules apply.

CHAPTER 1

Testing for specific migration of materials and articles already in contact with food

1.1. Sample preparation

The material or article shall be stored as indicated on the packaging label or under conditions adequate for the packaged food if no instructions are given. The food shall be removed from contact with the material or article before its expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality or safety.

1.2. Conditions of testing

The food shall be treated in accordance with the cooking instructions on the package if the food is to be cooked in the package. Parts of the food which are not intended to be eaten shall be removed and discarded. The remainder shall be homogenised and analysed for migration. The analytical results shall always be expressed on the basis of the food mass that is intended to be eaten, in contact with the food contact material.

1.3. Analysis of migrated substances

The specific migration is analysed in the food using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

[[F1]1.4. **Account of substances originating from other sources**

In case there is evidence linked to the food sample that a substance partially or wholly originates from a source or sources other than the material or article for which the test is being carried out, the test results shall be corrected for the amount of that substance originating from the other source or sources before comparing the test results to the applicable specific migration limit.**]**

CHAPTER 2

Testing for specific migration of materials and articles not yet in contact with food

2.1. Verification method

Verification of compliance of migration into foods with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use taking into account paragraphs 1.4, 2.1.1, 2.1.6 and 2.1.7.

Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests according to the rules set out in paragraphs 2.1.1 to 2.1.7.

2.1.1. Sample preparation

The material or article shall be treated as described by accompanying instructions or by provisions given in the declaration of compliance.

Migration is determined on the material or article or, if this is impractical, on a specimen taken from the material or article, or a specimen representative of this material or article. For each food simulant or food type, a new test specimen is used. Only those parts of the sample which are intended to come into contact with foods in actual use shall be placed in contact with the food simulant or the food.

2.1.2. Choice of food simulant

Materials and articles intended for contact with all types of food shall be tested with food simulant A, B and D2. However, if substances that may react with acidic food simulant or foods are not present testing in food simulant B can be omitted.

Materials and articles intended only for specific types of foods shall be tested with the food simulants indicated for the food types in Annex III.

2.1.3. Conditions of contact when using food simulants

[[F1]The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

By way of derogation to the conditions set out in Tables 1 and 2, the following rules apply:

(i) If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place;

(ii) if the material or article during it intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment;

(iii) if the material or article is intended to be employed only for hot-fill conditions, only a 2-hour test at 70 °C shall be carried out. However, if the material or article is intended to be used also for storage at room temperature or below, the test conditions set out

in Tables 1 and 2 of this Section or in Section 2.1.4 of this Chapter apply depending on the duration of storage.

If the testing conditions representative for the worst foreseeable conditions of intended use of the material or article, are not technically feasible in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a migration test shall be done using food simulant E if the temperature under the worst foreseeable conditions of intended use exceeds 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.**]**

TABLE 1

[F1Selection of test time]

Contact time in worst foreseeable use	**[F1Time to be selected for testing]**
t ≤ 5 min	5 min
5 min < t ≤ 0,5 hour	0,5 hour
0,5 hours < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 6 hours	6 hours
6 hours < t ≤ 24 hours	24 hours
1 day < t ≤ 3 days	3 days
3 days < t ≤ 30 days	10 days
Above 30 days	See specific conditions

[F1TABLE 2

Selection of test temperature

Worst foreseeable contact temperature	**Contact temperature to be selected for testing**
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C
70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C[a]
121 °C < T ≤ 130 °C	130 °C[a]
130 °C < T ≤ 150 °C	150 °C[a]
150 °C < T < 175 °C	175 °C[a]

a This temperature shall be used only for food simulants D2 and E. For applications heated under pressure, migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.**]**

175 °C < T ≤ 200 °C	200 °C[a]
T > 200 °C	225 °C[a]

a This temperature shall be used only for food simulants D2 and E. For applications heated under pressure, migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.**]**

[F1 2.1.4. *Specific conditions for contact times above 30 days at room temperature and below*

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at 60 °C(19).

(a) Testing for 10 days at 20 °C shall cover all storage times at frozen condition. This test can include the freezing and defrosting processes if labelling or other instructions ensure that 20 °C is not exceeded and the total time above – 15 °C does not exceed 1 day in total during the foreseeable intended use of the material or article.

(b) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes.

(c) Testing for 10 days at 50 °C shall cover all storage times of up to 6 months at room temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes.

(d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes.

(e) For storage at room temperature the testing conditions can be reduced to 10 days at 40 °C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

(f) For worst foreseeable conditions of intended use not covered by the test conditions set out in points (a) to (e), the testing time and temperature conditions shall be based on the following formula:

$t2 = t1 * \mathrm{Exp}(9627 * (1/T2 - 1/T1))$

t1 is the contact time

t2 is the testing time

T1 is the contact temperature in Kelvin. For room temperature storage this is set at 298K (25 °C). For refrigerated conditions it is set at 278K (5 °C). For frozen storage it is set at 258 K (– 15 °C).

T2 is the testing temperature in Kelvin.**]**

2.1.5. Specific conditions for combinations of contact times and temperature

[F1 If a material or article is intended for different applications covering different combinations of contact time and temperature the testing shall be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence.**]**

If the material or article is intended for a food contact application where it is successively subject to a combination of two or more times and temperatures, the migration test shall be carried

out subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

2.1.6. Repeated use articles

If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test.

However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limits are not exceeded on the first test, no further test is necessary.

[[F1]The material or article shall respect the specific migration limit already in the first test for substances that are prohibited from migrating or from being released in detectable quantities under Article 11(4).**]**

2.1.7. Analysis of migrating substances

At the end of the prescribed contact time, the specific migration is analysed in the food or food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

2.1.8. Verification of compliance by residual content per food contact surface area (QMA)

For substances which are unstable in food simulant or food or for which no adequate analytical method is available it is indicated in Annex I that verification of compliance shall be undertaken by verification of residual content per 6 dm^2 of contact surface. For materials and articles between 500 ml and 10 l the real contact surface is applied. For materials and articles below 500 ml and above 10 l as well as for articles for which it is impractical to calculate the real contact surface the contact surface is assumed to be 6 dm^2 per kg food.

2.2. Screening approaches

[[F1]To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as the verification method described in section 2.1.**]**

2.2.1. Replacing specific migration by overall migration

To screen for specific migration of non-volatile substances, determination of overall migration under test conditions at least as severe as for specific migration can be applied.

2.2.2. Residual content

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration.

[[F1]2.2.3. *Migration modelling*

To screen for specific migration, the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed in a way that must never underestimate real levels of migration.**]**

[[F1]2.2.4. *Food simulant substitutes*

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2.**]**

[[F2]2.2.5. *Single test for successive combinations of time and temperature*

If the material or article is intended for a food contact application where it is successively subject to two or more time and temperature combinations, a single migration contact test time can be defined based on the highest contact test temperature from Section 2.1.3 and/or 2.1.4 by using the equation as described in point (f) of Section 2.1.4. The reasoning justifying that the resulting single test is at least as severe as the combined time and temperature combinations shall be documented in the supporting documentation provided for in Article 16.**]**

CHAPTER 3

Testing for overall migration

Overall migration testing shall be performed under the standardised testing conditions set out in this chapter.

3.1. Standardised testing conditions

The overall migration test for materials and articles intended for the food contact conditions described in column 3 of Table 3 shall be performed for the time specified and at the temperature specified in column 2. For test OM5 the test can be performed either for 2 hours at 100 °C (food simulant D2) or at reflux (food simulant A, B, C, D1) or for 1 hour at 121 °C. The food simulant shall be chosen in accordance with Annex III.

If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

***[**[F1]TABLE 3*

Standardised conditions for testing the overall migration

Column 1	Column 2	Column 3
Test number	**Contact time in days [d] or hours [h] at contact temperature in [°C] for testing**	**Intended food contact conditions**
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C ≤ T ≤ 100

		°C for a maximum of t = 120/2^((T-70)/10) minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of t = 120/2^((T-70)/10) minutes, which are not followed by long term room temperature or refrigerated storage.
OM4	1 h at 100 °C	High temperature applications for all types of food at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.**]**

[[F1]Test OM7 also covers food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents the worst case conditions for food simulant D2 in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in Section 3.2.

Test OM6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B, C and D1 in contact with non-polyolefins.

Test OM5 covers also food contact conditions described for OM1, OM2, OM3, and OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM2 covers also food contact conditions described for OM1 and OM3.**]**

[[F1]3.2. **Substitute overall migration tests for tests with food simulant D2**

If it is not technically feasible to perform one or more of the tests OM1 to OM6 in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a test shall be done using food simulant E in case the worst foreseeable conditions of use exceed 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2 the test can be replaced by either test OM8 or test OM9 as appropriate given the intended or foreseeable use. Both tests involve testing at two test conditions for which a new test sample shall be used for

each test. The test condition that results in the highest overall migration shall be used to establish compliance with this Regulation.

Test number	Test conditions	Intended food contact conditions	Covers the intended food contact conditions described in
OM8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only	OM1, OM3, OM4, OM5 and OM6
OM9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature	OM1, OM2, OM3, OM4, OM5 and OM6**]**

[[F1]3.3. **Verification of compliance**

3.3.1. *Single use articles and materials*

At the end of the prescribed contact time, to verify compliance the overall migration is analysed in the food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

3.3.2. *Repeated use articles and materials*

The applicable overall migration test shall be carried out three times on a single sample using another portion of food simulant on each occasion. The migration shall be determined using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004. The overall migration in the second test shall be lower than in the first test, and the overall migration in the third test shall be lower than in the second test. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third test.

If it is not technically feasible to test the same sample three times, such as when testing in oil, the overall migration test can be carried out by testing different samples for three different periods of time lasting one, two and three times the applicable contact test time. The difference between the third and the second test results shall be considered to represent the overall migration. Compliance shall be verified on the basis of this difference, which shall not exceed the overall migration limit. In addition, it shall not be higher than the first result and the difference between the second and the first test results.

By derogation from the first paragraph, if, on the basis of scientific evidence, it is established that for the material or article being tested the overall migration does not increase in the second and third tests and if the overall migration limit is not exceeded in the first test, the first test alone shall be sufficient.**]**

3.4. Screening approaches

[[F1]To screen if a material or article complies with the migration limits, any of the following approaches can be applied which are considered at least as severe as the verification method described in Sections 3.1 and 3.2.**]**

3.4.1. Residual content

To screen for overall migration the migration potential can be calculated based on the residual content of migratable substances determined in a complete extraction of the material or article.

[[F1]3.4.2. *Food simulant substitutes*

To screen for overall migration, food simulants can be replaced if based on scientific evidence the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex III.**]**

CHAPTER 4

Correction factors applied when comparing migration test results with migration limits

4.1. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF)

For lipophilic substances for which in Annex I it is indicated in column 7 that the FRF is applicable the specific migration can be corrected by the FRF. The FRF is determined according to the formula FRF = (g fat in food/kg of food)/200 = (% fat × 5)/100.

The FRF shall be applied according to the following rules.

The migration test results shall be divided by the FRF before comparing with the migration limits.

The correction by the FRF is not applicable in the following cases:

(a) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 2006/141/EC and 2006/125/EC;

(b) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm^2/kg.

[[F1]The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.**]**

[[F2]When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table 2 of Annex III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.**]**

[F3]4.2. Correction of migration into food simulant D2

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[F3]4.3. Combination of correction factors 4.1 and 4.2.

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ANNEX VI

Correlation tables

Directive 2002/72/EC	**This Regulation**
Article 1(1)	Article 1
Article 1(2), (3) and (4)	Article 2
Article 1a	Article 3
Article 3(1), Article 4(1) and Article 5	Article 5
Article 4(2), Article 4a(1) and (4), Article 4d, Annex II (2) and (3) and Annex III (2) and (3)	Article 6
Article 4a(3) and (6)	Article 7
Annex II (4) and Annex III (4)	Article 8
Article 3(1) and Article 4(1)	Article 9
Article 6	Article 10
Article 5a(1) and Annex I (8)	Article 11
Article 2	Article 12
Article 7a	Article 13
Article 9(1) and (2)	Article 15
Article 9(3)	Article 16
Article 7 and Annex I (5a)	Article 17
Article 8	Article 18
Annex II (3) and Annex III (3)	Article 19
Annex I, Annex II, Annex IV, Annex IVa, Annex V Part B, and Annex VI	Annex I
Annex II (2), Annex III (2) and Annex V, Part A	Annex II
Article 8(5) and Annex VIa	Annex IV
Annex I	Annex V

Directive 93/8/EEC	**This Regulation**
Article 1	Article 11
Article 1	Article 12
Article 1	Article 18
Annex	Annex III
Annex	Annex V

Directive 97/48/EC	**This Regulation**
Annex	Annex III
Annex	Annex V

(**1**) OJ L 338, 13.11.2004, p. 4.

(**2**) OJ L 220, 15.8.2002, p. 18.

(**3**) OJ L 44, 15.2.1978, p. 15.

(**4**) OJ L 135, 30.5.2009, p. 3.

(**5**) OJ L 354, 31.12.2008, p. 16.

(**6**) OJ L 354, 31.12.2008, p. 34.

(**7**) OJ L 31, 1.2.2002, p. 1.

(**8**) SCF opinion of 4 December 2002 on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials. http://ec.europa.eu/food/fs/sc/scf/out149_en.pdf

(**9**) Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to the introduction of a Fat (consumption) Reduction Factor for infants and children, The EFSA Journal (2004) 103, 1-8.

(**10**) OJ L 297, 23.10.1982, p. 26.

(**11**) OJ L 213, 16.8.1980, p. 42.

(**12**) OJ L 167, 24.6.1981, p. 6.

(**13**) OJ L 165, 30.4.2004, p. 1.

(**14**) OJ L 384, 29.12.2006, p. 75.

(**15**) OJ L 401, 30.12.2006, p. 1.

(**16**) OJ L 339, 6.12.2006, p. 16.

(**17**) OJ L 353, 31.12.2008, p. 1.

(**18**) OJ L 372, 31.12.1985, p. 14.

(**19**) **[**[F1]When testing at these accelerated test conditions the test specimen shall not undergo any physical or other changes compared to the real conditions of use, including a phase transition of the material.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Status:
Point in time view as at 31/01/2019.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011.