

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)

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)

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.

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- (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

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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

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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.

Status: Point in time view as at 19/05/2019.

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- (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 dm² of surface area of the plastic material. If the risk

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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 dm² 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

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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 dm² 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

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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

Status: Point in time view as at 19/05/2019.

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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:

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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;

Status: Point in time view as at 19/05/2019.

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

- (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.

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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.

Status: Point in time view as at 19/05/2019.

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

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:

Status: Point in time view as at 19/05/2019.

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

- 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 \(Text with EEA relevance\).](#)

Status: Point in time view as at 19/05/2019.

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

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 dm² of food contact surface (mg/dm²).

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.

[^{F13} 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 nanof orm.

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.

Status: Point in time view as at 19/05/2019.

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

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

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

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 dm² 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:

Status: Point in time view as at 19/05/2019.

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

- a mg/dm² 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.

[^{F14} 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.

[^{F17} 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).

Status: Point in time view as at 19/05/2019.

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

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.

Status: Point in time view as at 19/05/2019.

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

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.

Status: Point in time view as at 19/05/2019.

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

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}.....]

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

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 product aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (no)	SML [mg/kg] (yes/no)	SML (T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on certification of compliance
1	12310	0266309	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 ₈ -C ₁₅) acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxy group.	

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

									Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C ₇ -C ₁₇), vinyl esters	no	yes	no	0,05			(1)
7	30370	—	acetylated acids, 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 occurring levels are included)	yes	no	no				
10	30612	—	acids, C ₂ -C ₂₄ ,	yes	no	no				

Status: Point in time view as at 19/05/2019.

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

			aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters						
11	30960	—	acids, yes aliphatic, monocarboxylic (C ₆ - C ₂₂), esters with polyglycerol	no	no				
12	31328	—	acids, yes fatty, from animal or vegetable food fats and oils	no	no				
13	33120	—	alcohols, yes aliphatic, monohydric, saturated, linear, primary (C ₄ - C ₂₄)	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		

Status: Point in time view as at 19/05/2019.

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

			C ₂₀) dimethylamines						
16	34230	—	alkyl(C ₈ - C ₂₂)sulphonic acids	yes no	no	no	6		
17	34281	—	alkyl(C ₈ - C ₂₂)sulphuric acids, linear, primary with an even number of carbon atoms	yes no	no	no			
18	34475	—	aluminium calcium hydroxide phosphite, hydrate	yes no	no	no			
19	39090	—	N,N- bis(2- hydroxyethyl) alkyl(C ₈ - C ₁₈)amine	yes no	no	no		(7)	
20	39120	—	N,N- bis(2- hydroxyethyl) alkyl(C ₈ - C ₁₈)amine hydrochlorides	yes no	no	no		(7)	SML(T) expressed excluding HCl
21	42500	—	carbonic acid, salts	yes no	no	no			
22	43200	—	castor oil, mono- and diglycerides	yes no	no	no			
23	43515	—	chlorides of choline esters of coconut oil	yes no	no	no	0,9		(1)

Status: Point in time view as at 19/05/2019.

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

			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)		

Status: Point in time view as at 19/05/2019.

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

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	—	ethylhydroxyethylcellulose	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				

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

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				

Status: Point in time view as at 19/05/2019.

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

			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			

Status: Point in time view as at 19/05/2019.

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

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 pyrophosphate	yes	no	no				

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

64	66695	—	methylcellulose	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	—	phosphoric acid, mono- and di-	yes	no	yes	0,05		

Status: Point in time view as at 19/05/2019.

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

			n-alkyl (C ₁₆ and C ₁₈) esters						
69	74400	—	phosphoric 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 [^{F1} shall] 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 acid, which may be	yes	no	yes		(31) (32)	

Status: Point in time view as at 19/05/2019.

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

			end-capped with acetic acid or fatty acids C ₁₂ -C ₁₈ or n-octanol and/or n-decanol						
74	77440	—	polyethylene glycol diricinolate	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	—	polyethylene glycol (EO = 1-30, typically 5)	yes	no	no	0,05		Only for use in PET

Status: Point in time view as at 19/05/2019.

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

			ether of butyl-2- cyano-3- (4- hydroxyphenyl) acrylate						
78	77897	—	polyethyleneglycol (EO = 1-50) monoalkylether (linear and branched, C ₈ - C ₂₀) sulphate, salts	yes	no	5			
79	80640	—	polyoxyalkyl (C ₂ - C ₄) dimethylpolysiloxane	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				
82	83325	—	propylhydroxyethylcellulose	yes	no				
83	83330	—	propylhydroxypropylcellulose	yes	no				
84	85601	—	silicates natural (with the exception	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

			of asbestos)						
85	85610	—	silicates, yes natural, silanated (with the exception of asbestos)	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	yes	no	no		(2)	

Status: Point in time view as at 19/05/2019.

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

			with ethyleneglycol						
90	92195	—	taurine, salts	yes	no	no			
91	92320	—	tetradecyl polyethyleneglycol ether of glycolic acid	yes	no	yes	15		
92	93970	—	tricyclohexane bis(hydrophthalate)	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 [F1simulant 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).

Status: Point in time view as at 19/05/2019.

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

									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 ($11 \times 10^{-6} \text{ m}^2/\text{s}$). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
95	95883	—	white mineral oils, paraffinic, derived from	yes	no	no			Average molecular weight not less than

Status: Point in time view as at 19/05/2019.

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

			petroleum based hydrocarbon feedstocks						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 thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types

Status: Point in time view as at 19/05/2019.

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

110	93520	0000059e02-9 00101914e0pherol	yes	no	no				
111	53600	0000060e04-benediaminetetraacetio acid	no	no	no				
112	64015	0000060133-13 acid	yes	no	no				
113	16780	0000064e17-5ol	yes	yes	no				
	52800								
114	55040	0000064f18-6c acid	yes	no	no				
115	10090	0000064a09-7 acid	yes	yes	no				
	30000								
116	13090	0000065b81-0 acid	yes	yes	no				
	37600								
117	21550	0000067c61-1 nol	no	yes	no				
118	23830	0000067263-0 propanol	yes	yes	no				
	81882								
119	30295	0000067a64-dne	yes	no	no				
120	49540	0000067d68-ethyl sulphoxide	yes	no	no				
121	24270	0000069a7e-7ylic acid	yes	yes	no				
	84640								
122	23800	0000071123-8 propanol	no	yes	no				
123	13840	0000071136-3 butanol	no	yes	no				
124	22870	0000071141-0 pentanol	no	yes	no				
125	16950	0000074e85-1 ene	no	yes	no				
126	10210	0000074a86-2 ene	no	yes	no				
127	26050	0000075v01-4 chloride	no	yes	no	ND			1 mg/ kg in final product
128	10060	0000075a07-0 aldehyde	yes	no	no		(1)		
129	17020	0000075e21-ene oxide	no	yes	no	ND			1 mg/ kg in final product (10)

Status: Point in time view as at 19/05/2019.

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

130	26110	0000075354	vinylidene chloride	yes	no	ND			(1)
131	48460	0000075137-6	yes difluoroethane	no	no				
132	26140	0000075387	vinylidene fluoride	yes	no	5			
133	14380	0000075446	nylon chloride	yes	no	ND		1 mg/kg in final product	(10)
	23155								
134	43680	0000075456	trichlorofluoromethane	no	no	6		Content of chlorofluoromethane less than 1 mg/kg of the substance	
135	24010	0000075569	propylene oxide	yes	no	ND		1 mg/kg in final product	
136	41680	0000076222	phosphoryl	yes	no	no			(3)
137	66580	0000077262-3	yes methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	no	yes		(5)		
138	93760	0000077407	butyl acetyl citrate	yes	no	no			(32)
139	14680	0000077929	citric acid	yes	yes	no			
	44160								
140	44640	0000077930	citric acid, triethyl ester	yes	no	no			(32)
141	13380	0000077499-6	trimethylolpropane	yes	yes	no	6		
	25600								
	94960								
142	26305	0000078087	triethoxysilanes	yes	no	0,05		Only to be	[F ⁹ (1)]

Status: Point in time view as at 19/05/2019.

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

									intended for infants ⁱ and young children ⁱ .
152	15610	0000080407-9	no dichlorodiphenyl sulphone	yes	no	0,05			
153	15267	0000080408-0	no diaminodiphenyl sulphone	yes	no	5			
154	13617	0000080409-1	no dihydroxydiphenyl sulphone	yes	no	0,05			
	16090								
155	23470	0000080456-8	no pinene	yes	no				
156	21130	0000080462-6	no acrylic acid, methyl ester	yes	no		(23)		
157	74880	0000080474-4	yes phthalic acid, dibutyl ester	yes	no	0,3	(32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles contacting non- fatty foods; technical support agent in polyolefins in concentrations up to 0,05 % in the

Status: Point in time view as at 19/05/2019.

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

										final product.
158	23380 76320	0000085	phthalic anhydride	yes	yes	no				
159	74560	0000085	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 baby foods for infants and

Status: Point in time view as at 19/05/2019.

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

									(c)	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	sa813-3 salicylic acid, 4-tert-butylphenyl ester	yes	no	yes	12			
[^{F10} 161	92160	000087	619(4)- tartaric acid	yes	no	no]
162	65520	0000087	78-7 nitro-	yes	no	no				
163	66400	0000088	224-4 methylene bis(4-ethyl-6-tert-butylphenol)	yes	no	yes	(13)			
164	34895	0000088	268-6 aminobenzamide	yes	no	no	0,05			Only for use in PET for water and beverages
165	23200 74480	0000088	699-3 phthalic acid	yes	yes	no				
166	24057	0000089	327-7 phthalic anhydride	yes	yes	no	0,05			

Status: Point in time view as at 19/05/2019.

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

167	25240	000009	1208-7 toluene diisocyanate	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
168	13075 15310	000009	1274-9 diamino-6- phenyl-1,3,5- triazine	no	yes	no	5			[F ⁹ (1)]
169	16240	000009	1397-4 dimethyl-4,4'- diisocyanatobiphenyl	no	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
170	16000	000009	2488-6 dihydroxybiphenyl	no	yes	no	6			
171	38080	000009	3588-3 benzoic acid, methyl ester	yes	no	no				
172	37840	000009	3589-0 benzoic acid, ethyl ester	yes	no	no				
173	60240	000009	4413-3 hydroxybenzoic acid, propyl ester	yes	no	no				
174	14740	000009	5648-7 cresol	no	yes	no				
175	20050	000009	60516 methacrylic acid, allyl ester	no	yes	no	0,05			
176	11710	000009	60516 acrylic acid, methyl ester	no	yes	no		(22)		
177	16955	000009	60516 ethylene carbonate	no	yes	no	30		SML expressed	

Status: Point in time view as at 19/05/2019.

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

									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	000009649-5	thiobis(6-tert-butyl-3-methylphenol)	yes	no	yes	0,48		
179	48800	000009722-4	dihydroxy-5,5'-dichlorodiphenylmethane	yes	no	yes	12		
[FII] 180	17160	000009753-0	phenol	no	yes	no		(33)	I
181	20890	000009763-2	acrylic acid, ethyl ester	no	yes	no		(23)	
182	19270	000009765-4	acrylic acid	no	yes	no			
183	21010	000009784-9	acrylic acid, isobutyl ester	no	yes	no		(23)	
184	20110	000009788-1	acrylic acid, butyl ester	no	yes	no		(23)	
185	20440	000009790-6	acrylic acid, diester	no	yes	no	0,05		

Status: Point in time view as at 19/05/2019.

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

			with ethyleneglycol						
186	14020	00000984564	4-butylphenol	no	yes	no	0,05		
187	22210	0000098683-9	methylstyrene	no	yes	no	0,05		
188	19180	00000991608	phthalic acid dichloride	no	yes	no		(27)	
189	60200	0000099476-3	hydroxybenzoic acid, methyl ester	yes	no	no			
190	18880	0000099996-7	hydroxybenzoic acid	no	yes	no			
191	24940	00001001009	phthalic acid dichloride	no	yes	no		(28)	
192	23187	—	phthalic acid	no	yes	no		(28)	
193	24610	0000100542-5	styrene	no	yes	no			
194	13150	0000100517-6	benzyl alcohol	no	yes	no			
195	37360	0000100552-7	benzaldehyde	no	no	no			(3)
196	18670	0000100607-0	hexamethylene tetramine	no	no	no		(15)	
	59280								
197	20260	00001014319	methacrylic acid, cyclohexyl ester	no	yes	no	0,05		
198	16630	00001014618	4,4'-methylenediphenyl diisocyanate	no	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
199	24073	00001019006	1,6-hexanediol diglycidyl ether	no	yes	no	ND		Not to be used for articles (8)

Status: Point in time view as at 19/05/2019.

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

									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.
200	51680	000010220819	2,2'-diphenylthiourea	yes	no	yes	3		
201	16540	000010220910	diphenyl carbonate	no	yes	no	0,05		
202	23070	000010221316	4,4'-oxydiphenylacetic acid	no	yes	no	0,05		[F9(1)]
203	13323	000010221419	bis(2-hydroxyethoxy)benzene	no	yes	no	0,05		
204	25180	000010226013	N,N'-tetrakis(2-hydroxypropyl)ethylenediamine	yes	yes	no			
	92640								
205	25385	000010227015	ethylamine	yes	no				40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel.

Status: Point in time view as at 19/05/2019.

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

									Only to be used in hydrogels intended for non-direct food contact use.
206	11500	0000103	adipic acid, 2-ethylhexyl ester	no	yes	no	0,05		
207	31920	0000103	adipic acid, bis(2-ethylhexyl) ester	yes	no	yes	18	(32)	(2)
208	18898	0000103	4-(4-hydroxyphenyl) acetamide	no	yes	no	0,05		
209	17050	0000104	276-7 ethyl-1-hexanol	no	yes	no	30		
210	13390 14880	0000105	408-8 bis(hydroxymethyl)cyclohexane	no	yes	no			
211	23920	0000105	384-1 acrylic acid, vinyl ester	no	yes	no		(1)	
212	14200 41840	0000105	602-1 lactam	yes	yes	no		(4)	
213	82400	0000105	162-4 propyleneglycol dioleate	yes	no	no			
214	61840	0000106	124-9 hydroxystearic acid	yes	no	no			
215	14170	0000106	adipic anhydride	no	yes	no			
216	14770	0000106	44-5 cresol	no	yes	no			

Status: Point in time view as at 19/05/2019.

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

217	15565	0000106144-7	no dichlorobenzene	yes	no	12			
218	11590	000010663-8	no acetic acid, isobutyl ester	yes	no		(22)		
219	14570	000010680-8	no ethylene glycol	yes	no	ND		1 mg/ kg in final product	(10)
	16750								
220	20590	000010691-2	no acrylic acid, 2,3-epoxypropyl ester	yes	no	0,02			(10)
221	40570	000010697-8	no Toluene	yes	no	no			
222	13870	0000106198-9	no butene	yes	no				
223	13630	000010699-1	no butadiene	yes	no	ND		1 mg/ kg in final product	
224	13900	0000107201-7	no butene	yes	no				
225	12100	000010721-1	no acrylonitrile	yes	no	ND			
226	15272	000010725-2	no ethylbenzene	yes	no	12			
	16960								
227	16990	000010727-1	no ethylene glycol	yes	no		(2)		
	53650								
228	13690	0000107183-0	no butanediol	yes	no				
229	14140	0000107502-6	no cyclohexane	yes	no				
230	16150	000010840-1	no ethylenediamine	yes	no	18			
231	10120	000010805-4	no acetic acid, vinyl ester	yes	no	12			
232	10150	000010824-7	yes anhydride	yes	no				
	30280								
233	24850	000010830-5	no anhydride	yes	no				

Status: Point in time view as at 19/05/2019.

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

234	19960	00001083166	maleic anhydride	no	yes	no		(3)		
235	14710	00001083774	2,4-cresol	no	yes	no				
236	23050	00001084452	4,4'-phenylenediamine	no	yes	no	ND			
237	15910	00001084463	2,4-dihydroxybenzene	no	yes	no	2,4			
	24072									
238	18070	00001085544	glutaric anhydride	no	yes	no				
[^{F12} 239	19975	00001082744	2,4,6-triamino-1,3,5-triazine	yes	yes	no	2,5			
	25420									
	93720]									
240	45760	00001089118	hexamethylenediamine	no	yes	no				
[^{F10} 241	22960	00001089521	phenol	no	yes	no	3			I
242	85360	00001094944	sebacic acid, dibutyl ester	yes	no	no		(32)		
243	19060	00001095357	isobutyl vinyl ether	no	yes	no	0,05			(10)
244	71720	00001096610	pentane	yes	no	no				
245	22900	00001094671	1-pentene	no	yes	no	5			
246	25150	00001094944	sebacic acid, dimethyl ester	yes	yes	no	0,6			
247	24820	00001105564	succinic acid	yes	yes	no				
	90960									
248	19540	00001104167	maleic acid	yes	yes	no		(3)		
	64800									
249	17290	00001104178	fumaric acid	yes	yes	no				
	55120									
250	53520	00001103305	N,N'-ethylenebisstearamide	yes	no	no				
251	53360	00001103306	N,N'-ethylenebisoleamide	yes	no	no				
252	87200	00001104416	sebacic acid	yes	no	no				

Status: Point in time view as at 19/05/2019.

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

253	15250	0000110160-1	160-1 diaminobutane	no	yes	no				
254	13720	0000110164-4	164-4 butanediol	yes	yes	no		(30)		
	40580									
255	25900	0000110188-3	188-3 hexane	no	yes	no	5			
256	18010	0000110194-1	194-1 tartaric acid	yes	yes	no				
	55680									
[^{F1} 257	13550	0000110198-5	198-5 propylene glycol	yes	yes	no				
	16660	0025265-71-8								
	51760	I								
258	70480	0000111008-1	1008-1 fatty acid, butyl ester	yes	no	no				
259	58720	0000111018-1	1018-1 heptanoic acid	yes	no	no				
260	24280	0000111020-1	1020-1 sebacic acid	no	yes	no				
261	15790	0000111040-1	1040-1 ethylene diamine	yes	yes	no	5			
262	35284	0000111042-1	1042-1 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.

Status: Point in time view as at 19/05/2019.

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

263	13326	0000111466-0	ethylene glycol	yes	no		(2)		
	15760								
	47680								
264	22660	0000111466-0	octene	no	yes	no	15		
265	22600	0000111487-5	octanol	no	yes	no			
266	25510	0000112476-0	ethylene glycol	yes	no				
	94320								
267	15100	0000112430-1	decanol	no	yes	no			
268	16704	0000112441-4	dodecene	no	yes	no	0,05		
269	25090	0000112607-0	ethylene glycol	yes	no				
	92350								
270	22763	0000112861-0	acid	yes	yes	no			
	69040								
271	52720	0000112845-0	amides	no	no				
272	37040	0000112856-0	acid	yes	no	no			
273	52730	0000112867-0	acid	yes	no	no			
274	22570	0000112069-0	decyl isocyanate	yes	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
275	23980	0000115007-0	polyene	no	yes	no			
276	19000	0000115147-0	isobutene	no	yes	no			
277	18280	0000115127-6	chloroendomethylenetetrahydrophthalic anhydride	yes	no	no			
278	18250	0000115128-6	chloroendomethylenetetrahydrophthalic acid	yes	no	no			
279	22840	0000115077-0	acrylonitril	yes	no				
	71600								
280	73720	0000115096-0	phosphonic acid,	no	no	ND			

Status: Point in time view as at 19/05/2019.

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

			trichloroethyl ester						
281	25120	000011644-1	hexafluoroethylene	yes	no	0,05			
282	18430	000011645-1	hexafluoropropylene	yes	no	ND			
283	74640	000011731-1	phthalic acid, bis(2-ethylhexyl) ester	yes	no	1,5	(32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles contacting non-fatty foods; technical support agent in concentrations up to 0,1 % in the final product.
284	84880	000011935-1	salicic acid, methyl ester	yes	no	30			
285	66480	000011947-1	methylene bis(4-methyl-6-tert-butylphenol)	yes	no	yes	(13)		
286	38240	000011962-1	benzophenone	no	yes	0,6			
287	60160	000012044-8	hydroxybenzoic acid, ethyl ester	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

288	24970	0000120106	terephthalic acid, dimethyl ester	yes	no				
289	15880 24051	0000120180-9	1,2-dihydroxybenzene	no	yes	no	6		
290	55360	0000121701	terephthalic acid, propyl ester	yes	no	no		(20)	
291	19150	0000121101	isophthalic acid	yes	no			(27)	
292	94560	0000122403	2,2,4,4-tetrahydro-3H-pyridinol	yes	no	no	5		
293	23175	0000122502	phosphonic acid, triethyl ester	yes	no	no	ND		1 mg/kg in final product (1)
294	93120	0000123403	2,2-dipropionic acid, didodecyl ester	no	yes			(14)	
295	15940 18867 48620	0000123414-9	1,2-dihydroxybenzene	yes	yes	no	0,6		
296	23860	0000123306	propanal	yes	no				
297	23950	0000123606	propanoic anhydride	no	yes	no			
298	14110	0000123572	2-butanone	yes	no				
299	63840	0000123156	butyric acid	yes	no	no			
300	30045	0000123864	terephthalic acid, butyl ester	yes	no	no			
301	89120	0000123855	terephthalic acid, butyl ester	yes	no	no			
302	12820	0000123201	acetic acid	no	yes	no			
303	12130 31730	0000124110	acetic acid	yes	yes	no			

Status: Point in time view as at 19/05/2019.

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

304	14320	0000124007-2	407-2 eprylic acid	yes	yes	no			
	41960								
305	15274	0000124004-4	404-4 methylenediamine	yes	no	no	2,4		
	18460								
306	88960	0000124006-5	406-5 amides	yes	no	no			
307	42160	0000124010-0	410-0 carbon dioxide	yes	no	no			
308	91200	0000126013-6	613-6 sucrose acetate isobutyrate	yes	no	no			
309	91360	0000126014-7	614-7 sucrose octaacetate	yes	no	no			
310	16390	0000126232-7	623-7 dimethyl-1,3- propanediol	no	yes	no	0,05		
	22437								
311	16480	0000126050-9	650-9 D-glucitol	yes	yes	no			
	51200								
312	21490	0000126081-7	681-7 acrylonitrile	yes	yes	no	ND		
313	16650	0000127063-0	763-0 phenyl sulphone	yes	yes	no	3		
	51570								
314	23500	0000127091-3	791-3 pinene	no	yes	no			
315	46640	0000128236-0	823-0 tert- butyl- p- cresol	yes	no	no	3		
316	23230	0000131017-0	117-0 phthalic acid, diallyl ester	no	yes	no	ND		
317	48880	0000131253-3	125-3 2,4- dihydroxy-4- methoxybenzophenone	yes	no	yes	(8)		
318	48640	0000131256-6	125-6 2,6- dihydroxybenzophenone	yes	no	no	(8)		
319	61360	0000131257-7	125-7 2,4- hydroxy-4- methoxybenzophenone	yes	no	yes	(8)		
320	37680	0000136007-0	607-0 benzoic acid,	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

			butyl ester						
321	36080	0000137	666-6 butyl palmitate	yes	no	no			
322	63040	0000138	22-7 lauric acid, butyl ester	yes	no	no			
323	11470	0000140	88-5 lauric acid, ethyl ester	no	yes	no		(22)	
324	83700	0000141	22-0 lauric acid	yes	no	yes	42		
325	10780	0000141	32-1 lauric acid, n-butyl ester	no	yes	no		(22)	
326	12763 35170	0000141	243-5 aminoethanol	yes	yes	no	0,05		Not to be used for articles in contact with fatty foods for which [F1simulant D1 and/or D2] is laid down. For indirect food contact only, behind a PET layer.
327	30140	0000141	78-6 lauric acid, ethyl ester	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

328	65040	000014182-2	phenolic acid	yes	no	no			
329	59360	000014262-2	salicylic acid	yes	no	no			
330	19470	000014310-7	acetic acid	yes	yes	no			
	63280								
331	22480	000014310-8	nonanol	no	yes	no			
332	69760	000014328-2	ethyl alcohol	yes	no	no			
333	22775	000014462-7	acetic acid	yes	yes	no	6		
	69920								
334	17005	000015164-4	benzoin	yes	no	no	ND		
335	68960	000030102-0	amide	yes	no	no			
336	15095	000033448-5	decanoic acid	yes	yes	no			
	45940								
337	15820	000034549-6	difluorobenzophenone	no	yes	no	0,05		
338	71020	000037349-3	salicylic acid	yes	no	no			
339	86160	000040951-2	silicon carbide	yes	no	no			
[^{F13} 340	47440	000046158-5	diacrylamide	no	no	no	60		I
341	13180	000049866-8	heptene	no	no	no	0,05		
	22550								
342	14260	000050249-3	lactone	yes	no	no	(29)		
343	23770	000050413-2	propanediol	no	yes	no	0,05		
[^{F10} 344	13810	000050516-7	butanediol formal	no	yes	no	0,05	15 30	(21)
	21821]								
345	35840	000050630-9	acetic acid	yes	no	no			
346	10030	000051440-6	acetic acid	no	yes	no			
347	13050	000052844-0	lactic acid	no	yes	no	(21)		
	25540								

Status: Point in time view as at 19/05/2019.

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

348	22350 67891	0000544	163-8 no phthalic acid	yes	yes	no			
349	25550	0000552	10-7 no phthalic anhydride	yes	yes	no		(21)	
350	63920	0000557	159-5 no phthalic acid	yes	no	no			
351	21730	0000563	345-1 no methyl-1- butene	yes	yes	no	ND		Only to be used in polypropylene (1)
352	16360	0000576	226-1 no dimethylphenol	yes	yes	no	0,05		
353	42480	0000584	008 no phthalic acid, rubidium salt	yes	no	no	12		
354	25210	0000584	284-9 no toluene diisocyanate	yes	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety (10)
355	20170	0000585	0716 no acrylic acid, tert- butyl ester	yes	yes	no		(23)	
356	18820	0000592	141-6 no hexene	yes	yes	no	3		
357	13932	0000598	332-3 no buten-2- ol	yes	yes	no	ND		Only to be used as a co-monomer for the preparation of polymeric additive (1)
358	14841	0000599	464-4 no cumylphenol	yes	yes	no	0,05		

Status: Point in time view as at 19/05/2019.

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

359	15970 48720	000061149-4	yes	yes	no	(8)			
			dihydroxybenzophenone						
360	57920	000062057-7	yes	no	no				
			glycerol triheptanoate						
361	18700	000062911-8	no	yes	no	0,05			
			hexanediol						
362	14350	000063048-0	no	yes	no				
			carbon monoxide						
363	16450	000064610-0	no	yes	no	5			
			dioxolane						
[^{F10} 364	15404	000065217-3,6-	no	yes	no	5		Only to be used as:]
			dianhydrosorbitol					(a)	a co-monomer in poly(ethylene-co-isorbide terephthalate);
								(b)	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)cyclohexane for the production

Status: Point in time view as at 19/05/2019.

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

									final product expressed as isocyanate moiety
373	22390	0000840265-3	naphthalenedicarboxylic acid, dimethyl ester	no	yes	no	0,05		
374	21190	0000868771-6	acrylic acid, monoester with ethyleneglycol	no	yes	no		(23)	
375	15130	0000872405-9	decene	no	yes	no	0,05		
[^{F12} 376]	66905	0000872450-4	methylpyrrolidone	yes	no	no	60]
377	12786	0000919330-2	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

Status: Point in time view as at 19/05/2019.

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

									materials and articles.
378	21970	0000923	202-4 methylmethacrylamide	no	yes	no	0,05		
379	21940	0000924	2-5 methylolacrylamide	no	yes	no	ND		
380	11980	0000925	6-6 acrylic acid, propyl ester	no	yes	no		(22)	
381	15030	0000931	8-8 dioctane	yes	no	no	0,05		Only to be used in polymers contacting foods for which simulant A is laid down
382	19490	0000947	4-6 lactam	yes	no	no	5		
383	72160	0000948	265-2 phenylindole	yes	no	yes	15		
384	40000	0000991	284-4 bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30		
385	11530	0000999	6-6 acrylic acid, 2-hydroxypropyl ester	no	yes	no	0,05		SML (1) expressed as the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-

Status: Point in time view as at 19/05/2019.

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

									hydroxyisopropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 0002918-23-2).	
386	55280	0001034	4011-4 oleic acid, octyl ester	yes	no	no		(20)		
387	26155	0001072	163-5 vinylimidazole	no	yes	no	0,05			[F ⁹ (1)]
388	25080	0001120	436-1 tetradecene	no	yes	no	0,05			
389	22360	0001141	238-4 naphthalenedicarboxylic acid	no	yes	no	5			
390	55200	0001166	5215 acid, dodecyl ester	yes	no	no		(20)		
[F ¹ 391	22932	0001187	035 perfluoromethyl perfluorovinyl ether	yes	no	no	0,05		Only to be used in: — —] anti-stick coatings; fluoro- and perfluoropolymers intended for repeated use applications where the contact ratio

Status: Point in time view as at 19/05/2019.

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

									is 1 dm ² surface in contact with at least 150 kg food.
392	72800	0001241	Phosphoric acid, diphenyl 2-ethylhexyl ester	no	yes	2,4			
393	37280	0001302	Carbonic acid	yes	no	no			
394	41280	0001305	Calcium hydroxide	yes	no	no			
395	41520	0001305	Calcium oxide	yes	no	no			
396	64640	0001309	Magnesium hydroxide	yes	no	no			
397	64720	0001309	Magnesium oxide	yes	no	no			
398	35760	0001309	Antimony trioxide	yes	no	no	0,04	SML (6) expressed as antimony	
399	81600	0001310	Potassium hydroxide	yes	no	no			
400	86720	0001310	Sodium hydroxide	yes	no	no			
401	24475	0001313	Sulfur sulphide	no	yes	no			
402	96240	0001314	Zinc oxide	yes	no	no			
403	96320	0001314	Zinc sulphide	yes	no	no			
404	67200	0001317	Iron disulphide	yes	no	no			
405	16690	0001321	Toluene	no	yes	no	ND	SML (1) expressed as the	

Status: Point in time view as at 19/05/2019.

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

									sum of divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.
406	83300	0001323432-3	propyleneglycol monostearate	yes	no	no			
407	87040	0001330504-4	sodium tetraborate	yes	no	no	(16)		
408	82960	0001330482-9	propyleneglycol monooleate	yes	no	no			
409	62240	0001332137-2	zinc oxide	yes	no	no			
[^{F10} 410	62720	0001332158-7	zinc	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

Status: Point in time view as at 19/05/2019.

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

									in direct contact with the food provides a functional barrier preventing migration of particles into the food.
411	42080	0001333	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

Status: Point in time view as at 19/05/2019.

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

									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	0001335	235 copper iodide	yes	no	no	(6)		
413	35600	0001336	216 antimony hydroxide	yes	no	no			
414	87600	0001338	012 sorbitan monolaurate	yes	no	no			
415	87840	0001338	011 sorbitan monostearate	yes	no	no			
416	87680	0001338	018 sorbitan monooleate	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

417	85680	0001343	18-2 sulfuric acid	yes	no	no			
418	34720	0001344	28-1 aluminum oxide	yes	no	no			
419	92150	0001401	55-4 fatty acids	yes	no	no			According to the JECFA specifications
420	19210	0001459	03-4 isophthalic acid, dimethyl ester	yes	no	no	0,05		
^{F13} 421	13000	0001477	55-0 benzenedimethanamine	no	yes	no		(34)	I
422	38515	0001533	44-5 bis(2-benzoxazolyl)stilbene	yes	no	yes	0,05		(2)
423	22937	0001623	05-8 isopropylperfluorovinyl ether	yes	no	no	0,05		
424	15070	0001647	16-1 decadiene	no	yes	no	0,05		
425	10840	0001663	09-4 acrylic acid, tert-butyl ester	no	yes	no		(22)	
426	13510 13610	0001675	22-3 bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether	no	yes	no			In compliance with Commission Regulation (EC) No 1895/2005 ^a
427	18896	0001679	45-2 (hydroxymethyl)-1-cyclohexene	no	yes	no	0,05		
428	95200	0001709	17-5 trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	yes	no	no			
429	13210	0001761	17-4 aminocyclohexylmethane	no	yes	no	0,05		

Status: Point in time view as at 19/05/2019.

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

430	95600	000184310B,34	tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane	yes	no	yes	5		
431	61600	0001843205-6	hydroxy-4-n-octyloxybenzophenone	yes	no	yes		(8)	
432	12280	0002035475-8	anhydride	no	yes	no			
433	68320	0002082701-1	3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	yes	no	yes	6		
434	20410	0002082811-7	acrylic acid, diester with 1,4-butanediol	yes	yes	no	0,05		
435	14230	0002123241-1	lactam, sodium salt	yes	yes	no		(4)	
436	19480	0002146171-6	acid, vinyl ester	no	yes	no			
437	11245	0002156071-1	acetic acid, dodecyl ester	no	yes	no	0,05		(2)
[^{F12} 438	13303	0002162574-2	(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	0002177701-1	acrylic acid,	yes	yes	no		(23)	

Status: Point in time view as at 19/05/2019.

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

			phenyl ester						
440	21340	0002210	2818 methacrylic acid, propyl ester	yes	no		(23)		
441	38160	0002315	6826 sebacic acid, propyl ester	yes	no	no			
442	13780	0002425	174-8 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.
443	12788	0002432	199-7 aminoundecanoic acid	no	yes	no	5		
444	61440	0002440	22024 hydroxy-5'-methylphenyl)benzotriazole	yes	no	no		(12)	
445	83440	0002466	0903 phosphoric acid	yes	no	no			
446	10750	0002495	3544 acetic acid, benzyl ester	no	yes	no		(22)	
447	20080	0002495	3544 methacrylic acid, benzyl ester	yes	no			(23)	
448	11890	0002499	5044 acetic acid, n-octyl ester	no	yes	no		(22)	
449	49840	0002500	4804 dodecyl disulphide	no	yes		0,05		I

Status: Point in time view as at 19/05/2019.

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

450	24430	0002561588	Basic anhydride	no	yes	no			
451	66755	0002682220	4-methyl-4-isothiazolin-3-one	yes	no	no	0,5		Only to be used in aqueous polymer dispersions and emulsions
452	38885	0002725224	6-bis(2,4-dimethylphenyl)-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	no	5		I
453	26320	0002768007	Trimethoxysilane	no	yes	no	0,05		(10)
454	12670	0002855113	2-amino-3-aminomethyl-3,5,5-trimethylcyclohexane	no	yes	no	6		
455	20530	0002867471	Acrylic acid, 2-(dimethylamino)-ethyl ester	yes	yes	no	ND		
456	10810	0002998408	Acrylic acid, sec-butyl ester	no	yes	no		(22)	
457	20140	0002998187	Acrylic acid, sec-butyl ester	yes	yes	no		(23)	
458	36960	0003061754	Benamide	no	no	no			
459	46870	0003135318	4-tert-butyl-4-hydroxybenzylphosphonic acid,	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

			dioctadecyl ester						
460	14950	00031735	313-hexyl isocyanate	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
461	22420	00031734	75-6 naphthalene diisocyanate	no	yes	no	(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
462	26170	00031957	78-6 vinyl-N-methylacetamide	no	yes	no	0,02		[^{F9} (1)]
463	25840	00032904	92-4 trimethylolpropane trimethacrylate	no	yes	no	0,05		
464	61280	00032933	297-8 hydroxy-4-n-hexyloxybenzophenone	yes	no	yes	(8)		
465	68040	00033337	228-1 naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	yes	no	no			
466	50640	00036481	18-8 octyltin dilaurate	yes	no	no	(10)		
[^{F14} 467	14800	3724-650	40-0 tonic acid	yes	yes	no	(35)		
	45600]								
468	71960	00038252	261-0 fluorocorticoid acid, ammonium salt	yes	no	no		Only to be used in repeated use articles,	

Status: Point in time view as at 19/05/2019.

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

									sintered at high temperatures	
469	60480	0003864290-21	hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)		
470	60400	0003896210-25	hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)		
471	24888	000396555-7	sulphoisophthalic acid, monosodium salt, dimethyl ester	no	yes	no	0,05			
472	66560	0004066202-8	methylenebis(4-methyl-6-cyclohexylphenol)	yes	no	yes		(5)		
473	12265	0004074400-2	acid, divinyl ester	no	yes	no	ND		5 mg/kg in final product. Only to be used as co-monomer.	(1)
474	43600	0004080430-3	chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	yes	no	no	0,3			
475	19110	0004098471-9	isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)

Status: Point in time view as at 19/05/2019.

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

476	16570	00041288	473-8-4 diisocyanate	yes	no	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety	(10)
477	46720	00041302	46-di- tert- butyl-4- ethylphenol	yes	no	yes	4,8			(1)
478	60180	00041914	73-5 hydroxybenzoic acid, isopropyl ester	yes	no	no				
479	12970	00041962	6-6 anhydride	no	yes	no				
480	46790	00042213	80-di- tert- butyl-4- hydroxybenzoic acid, 2,4-di- tert- butylphenyl ester	yes	no	no				
481	13060	00044221	95-5- benzenetricarboxylic acid trichloride	no	yes	no	0,05		SML expressed as 1,3,5- benzenetricarboxylic acid	[^{F9} (1)]
482	21100	00046553	40- methacrylic acid, isopropyl ester	yes	no	no		(23)		
483	68860	00047244	48-5 octylphosphonic acid	yes	no	no	0,05			
484	13395	00047672	03-7 bis(hydroxymethyl)propionic acid	no	yes	no	0,05			(1)
485	13560 15700	00051243	01-1 diisocyanate	yes	no	no		(17)	1 mg/ kg in final product	(10)

Status: Point in time view as at 19/05/2019.

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

									expressed as isocyanate moiety
486	54005	0005136	44-7-1 N- palmitamide- N'- stearamide	yes	no	no			
487	45640	0005232	299-5 cyano-3,3- diphenylacrylic acid, ethyl ester	yes	no	no	0,05		
488	53440	0005518	81-3 ethylenebispalmitamide	yes	no	no			
489	41040	0005743	36-2 butyrate	yes	no	no			
490	16600	0005873	5-1 diisocyanate	no	no	no		(17)	1 mg/ kg in final product expressed as isocyanate moiety
491	82720	0006182	11-2 propyleneglycol distearate	yes	no	no			
492	45650	0006197	230-4 cyano-3,3- diphenylacrylic acid, 2- ethylhexyl ester	yes	no	no	0,05		
493	39200	0006200	41-2 hydroxyethyl)-2- hydroxypropyl-3- (dodecyloxy)methylammonium chloride	yes	no	no	1,8		
494	62140	0006303	7-6 phosphorous acid	no	no	no			
495	35160	0006642	261-5 amino-1,3- dimethyluracil	yes	no	no	5		

Status: Point in time view as at 19/05/2019.

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

496	71680	0006683	phenyltol tetrakis[3- (3,5- di-tert- butyl-4- hydroxyphenyl)- propionate]	no	no				
497	95020	0006846	250-4 trimethyl-1,3- pentanediol diisobutyrate	yes	no	no	5		Only to be used in single-use gloves
498	16210	0006864	337-5 dimethyl-4,4'- diaminodicyclohexylmethane	no	yes	no	0,05		Only to be used in polyamides (5)
499	19965 65020	0006915	1117 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	0007128	261-5 bis(5- tert- butyl-2- benzoxazolyl)thiophene	yes	no	yes	0,6		
501	34480	—	aluminium fibers, flakes and powders	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

511	91920	0007664	45019	peroxy acid	yes	no	no			
512	81680	0007681	16016	potassium iodide	yes	no	no	(6)		
513	86800	0007681	8215	potassium iodide	yes	no	no	(6)		
514	91840	0007704	45019	peroxy acid	yes	no	no			
515	26360	0007732	21805	water	yes	yes	no			In compliance with Directive 98/83/EC ^b
	95855									
516	86960	0007757	8217	sulphite	yes	no	no	(19)		
517	81520	0007758	9023	potassium bromide	yes	no	no			
518	35845	0007771	44010	peroxy acid	yes	no	no			
519	87120	0007772	9081	thiosulphate	yes	no	no	(19)		
520	65120	0007773	3001	manganese chloride	yes	no	no			
521	58320	0007782	4201	zinc white	yes	no	no			
522	14530	0007782	5101	zinc white	no	yes	no			
523	45195	0007787	7004	potassium bromide	yes	no	no			
524	24520	0008001	3017	oil	no	yes	no			
525	62640	0008001	1306	Japan wax	yes	no	no			
526	43440	0008001	1756	linseed oil	yes	no	no			
527	14411	0008001	1794	oil	yes	yes	no			
	42880									
528	63760	0008002	1415	linseed oil	yes	no	no			
529	67850	0008002	2507	non wax	yes	no	no			
530	41760	0008006	4148	beeswax	yes	no	no			
531	36880	0008012	2893	wax	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

532	88640	0008013	078	san yes oil, epoxidised	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 2006/125/EC, the SML is lowered to mg/30 kg. Oxirane < 8 %,
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Status: Point in time view as at 19/05/2019.

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

									iodine number < 6.
533	42720	0008015869	Sebacic wax	yes	no	no			
534	80720	0008017065	phosphoric acids	yes	no	no			
535	24100	0008050097		yes	yes	no			
	24130								
	24190								
	83840								
536	84320	0008050056	hydrogenated, ester with methanol	yes	no	no			
537	84080	0008050068	ester with pentaerythritol	yes	no	no			
538	84000	0008050036	ester with glycerol	yes	no	no			
539	24160	0008052106	tall oil	no	yes	no			
540	63940	0008062155	sulphonic acid	yes	no	no	0,24	Only to be used as dispersant for plastics dispersions	
541	58480	0009000015	arabic	yes	no	no			
542	42640	0009000017	cellulose	yes	no	no			
543	45920	0009000012	gum	yes	no	no			
544	58400	0009000020	gum	yes	no	no			
545	93680	0009000056	gum	yes	no	no			
546	71440	0009000060	gum	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

547	55440	00090002008	gum	yes	no	no			
548	42800	00090002111	resin	yes	no	no			
549	80000	00090002884	polyethylene wax	yes	no	no			
550	81060	00090003070	propylene wax	no	no	no			
551	79920	000900030106392	poly(ethylene terephthalate) glycol	no	no	no			
552	81500	00090003098	polypropylene	no	no	no			The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC ^c
553	14500	00090004311	rose	yes	yes	no			
	43280								
554	43300	00090004318	rose acetate butyrate	yes	no	no			
555	53280	00090004577	cellulose	no	no	no			
556	54260	00090004584	hydroxyethylcellulose	no	no	no			
557	66640	00090004591	ethylcellulose	no	no	no			
558	60560	00090004620	hydroxyethylcellulose	no	no	no			
559	61680	00090004642	propylcellulose	no	no	no			
560	66700	00090004653	hydroxypropylcellulose	no	no	no			
561	66240	00090004675	cellulose	no	no	no			
562	22450	00090004700	cellulose	yes	no	no			
563	78320	00090004807	ethylene glycol monoricinoleate	yes	no	yes	42		
564	24540	00090005258	starch, edible	yes	yes	no			
	88800								

Status: Point in time view as at 19/05/2019.

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

565	61120	0009005137-0	hydroxyethyl starch	no	no			
566	33350	0009005137-1	lactic acid	yes	no	no		
567	82080	0009005137-2	propyleneglycol alginate	yes	no	no		
568	79040	0009005615-5	sorbitan monolaurate	yes	no	no		
569	79120	0009005615-6	sorbitan monooleate	yes	no	no		
570	79200	0009005615-7	sorbitan monopalmitate	yes	no	no		
571	79280	0009005615-8	sorbitan monostearate	yes	no	no		
572	79360	0009005615-9	sorbitan trioleate	yes	no	no		
573	79440	0009005615-4	sorbitan tristearate	yes	no	no		
574	24250 84560	0009006016-6	chitosan, natural	yes	yes	no		
575	76721	0063148601-1	polydimethylsiloxane (Mw > 6 800 Da)	no	no	no		Viscosity at 25 °C not less than 100 cSt (100 × 10 ⁻⁶ m ² /s)
576	60880	0009032421-2	hydroxyethyl methylcellulose	yes	no	no		
577	62280	0009044157-1	isobutylene-butene copolymer	no	no	no		
578	79600	0009046019-0	polyethylenetridecyl	yes	no	no	5	For materials and

Status: Point in time view as at 19/05/2019.

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

			ether phosphate					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	00090491747	hydroxypropyl starch	no	no			
580	46070	00100166203	dextrin	yes	no	no		
581	36800	00100222118	nitrate	yes	no	no		
582	50240	0010039435	octyltin bis(2-ethylhexyl maleate)	yes	no	no	(10)	
583	40400	0010043615	nitride	yes	no	no	(16)	
584	13620 40320	0010043613	acid	yes	yes	no	(16)	
585	41120	0010043614	chloride	yes	no	no		
586	65280	0010043812	hypophosphite	yes	no	no		
587	68400	0010094458	recycled polyurethane	yes	yes	5		

Status: Point in time view as at 19/05/2019.

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

588	64320	0010377	LiH ₂ I ₂ iodide	yes	no	no	(6)		
589	52645	0010436	C ₂₀ H ₄₁ N eicosenamide	yes	no	no			
590	21370	0010595	C ₁₀ H ₁₀ O ₂ acrylic acid, 2-sulphoethyl ester	yes	no	ND			(1)
591	36160	0010605	C ₁₈ H ₃₄ O ₂ n-octyl stearate	yes	no	no			
592	34690	0011097	Mg ₃ (OH) ₂ (CO ₃) ₂ magnesium carbonate hydroxide	yes	no	no			
593	44960	0011104	Co ₃ O ₄ cobalt oxide	yes	no	no			
594	65360	0011129	Mn ₂ O ₃ manganese oxide	yes	no	no			
595	19510	0011132	C ₆ H ₁₀ O ₅ D-glucose	yes	no				
596	95935	0011138	C ₁₂ H ₂₂ O ₁₁ xanthan gum	yes	no	no			
597	67120	0012001	Ca ₂ SiO ₄ lithia	yes	no	no			
598	41600	0012004 0037293	Al ₂ O ₃ alumina Al ₂ (OH) ₂ SO ₄ aluminum sulfate	yes	no	no			
599	36840	0012007	B ₄ O ₇ tetraborate	yes	no	no	(16)		
600	60030	0012072	Mg ₂ SiO ₄ magnesian silicate	yes	no	no			
601	35440	0012124	AgBr silver bromide	yes	no	no			
602	70240	0012198	Ca ₂ SiO ₄ lithia	yes	no	no			
603	83460	0012269	C ₁₂ H ₁₀ N ₂ pyridazine	yes	no	no			
604	60080	0012304	Ca ₂ SiO ₄ lithia	yes	no	no			
605	11005	0012542	C ₁₀ H ₁₆ O ₂ adipic acid, dicyclopentenyl ester	no	yes	no	0,05		(1)
606	65200	0012626	Mn ₂ O ₃ manganese hydroxide	yes	no	no			
607	62245	0012751	P ₂ S ₅ phosphorus pentasulfide	yes	no	no			Only to be used

Status: Point in time view as at 19/05/2019.

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

										in PET polymers and copolymers
608	40800	0013003412-8	butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	yes	no	yes	6			
609	83455	0013445562	pyrophosphoric acid	no	no	no				
610	93440	0013463677	dioxide	yes	no	no				
611	35120	0013560349-1	aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	yes	no	no				
612	16694	0013811502	divinyl-2-imidazolidinone	no	yes	no	0,05			(10)
613	95905	0013983710	styrene	yes	no	no				
614	45560	0014464616	calcite	yes	no	no				
615	92080	0014807106-6		yes	no	no				
616	83470	0014808607	carbazole	yes	no	no				
617	10660	0015214289-8	acrylamido-2-methylpropanesulphonic acid	no	yes	no	0,05			
618	51040	0015535179-2	octyltin mercaptoacetate	yes	no	no		(10)		
619	50320	0015571458-1	octyltin bis(2-ethylhexyl mercaptoacetate)	yes	no	no		(10)		

Status: Point in time view as at 19/05/2019.

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

620	50720	001557160-5	160-5 octyltin dimaleate	yes	no	no		(10)		
621	17110	0016219575-3	1575-3 ethylidenebicyclo[2,2,1]hept-2-ene	no	yes	no	0,05			(9)
622	69840	001626009-6	009-6 palmitamide	no	yes	yes	5			
623	52640	0016389488-1	488-1 nitro	yes	no	no				
624	18897	0016712664-4	2664-4 hydroxy-2-naphthalenecarboxylic acid	no	yes	no	0,05			
625	36720	0017194400-2	400-2 hydroxide	yes	no	no				
626	57800	0018641574-1	1574-1 glyceroltribehenate	yes	no	no				
627	59760	0019569211-2	211-2 zinc	yes	no	no				
628	96190	0020427581-1	581-1 zinc hydroxide	yes	no	no				
629	34560	0021645411-1	411-1 zinc hydroxide	yes	no	no				
630	82240	0022788112-8	112-8 propyleneglycol dilaurate	yes	no	no				
631	59120	0023128174-7	174-7 hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	yes	no	yes	45			
632	52880	0023676409-7	409-7 ethoxybenzoic acid, ethyl ester	yes	no	no	3,6			
633	53200	0023949266-8	266-8 ethoxy-2'-ethyloxanilide	yes	no	yes	30			
634	25910	0024800411-0	411-0 propyleneglycol	yes	no	no				
635	40720	0025013416-5	3416-5 butyl-4-hydroxyanisole	yes	no	no	30			

Status: Point in time view as at 19/05/2019.

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

636	31500	0025134	5-ethyl-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	0025151	1,2-bis(2-ethylhexyloxy)ethane	no	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	
638	23590	0025322	1,3-bis(2-ethylhexyloxy)propane	yes	yes	no				
	76960									
639	23651	0025322	1,3-bis(2-propyloxy)propane	yes	yes	no				
	80800									
640	54930	0025359	Formaldehyde-1-naphthol, copolymer	no	no	no	0,05			
[F1] 641	22331	0025513	3,4-bis(4-(35-45 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65 % w/w) 1,6-diamino-2,4,4-trimethylhexane)	no	yes	no	0,05			I
642	64990	0025736	maleic anhydride-	yes	no	no			The fraction	

Status: Point in time view as at 19/05/2019.

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

			styrene, copolymer, sodium salt						with molecular weight below 1 000 Da [^{F1} shall] not exceed 0,05 % (w/w)	
643	87760	0026266577-9	monopalmitate	yes	no	no				
644	88080	0026266580-1	trioleate	yes	no	no				
645	67760	002640186-5	n-octyltin tris(isooctyl mercaptoacetate)	yes	no	no	(11)			
646	50480	002640187-8	octyltin bis(isooctyl mercaptoacetate)	yes	no	no	(10)			
647	56720	002640223-3	monohexanoate	yes	no	no				
648	56880	002640226-6	monooctanoate	yes	no	no				
649	47210	002642740-6	ethylthiostannonic acid polymer	no	no	no			Molecular unit = (C ₈ H ₁₈ S ₃ Sn ₂) _n (n = 1,5-2)	
650	49600	002663640-1	dimethylbis(isooctyl mercaptoacetate)	yes	no	no	(9)			
651	88240	002665805-7	tristearate	yes	no	no				
652	38820	002674153-2	di-tert-butylphenyl pentaerythritol diphosphite	yes	no	yes	0,6			
653	25270	002674729-0	toluene diisocyanate dimer	no	yes	no	(17)	1 mg/ kg in final product	(10)	

Status: Point in time view as at 19/05/2019.

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

									expressed as isocyanate moiety
654	88600	0026836	47-101 sebitol monostearate	yes	no	no			
655	25450	0026896	48-010 1,4-bis(4-chlorophenyl)ethane	no	no	no	0,05		
656	24760	0026914	43-201 4-sulphonic acid	yes	no	no	0,05		
657	67680	0027107	80-7 n- octyltin tris(2- ethylhexyl mercaptoacetate)	yes	no	no		(11)	
658	52000	0027176	87-40 4-ethylbenzenesulphonic acid	no	no	no	30		
659	82800	0027194	72-7 propyleneglycol monolaurate	yes	no	no			
660	47540	0027458	90-8 dodecyl disulphide	yes	no	yes	0,05		
661	95360	0027676	62-5 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	14-8 tris(4- hydroxyphenyl)ethane	no	yes	no	0,005		Only to be used in polycarbonates
663	64150	0028290	70-11 7-phenic acid	yes	no	no			
664	95000	0028931	67-4 1,6-hexylpropyl trimethacrylate- methyl methacrylate copolymer	no	no	no			
665	83120	0029013	28-3 propyleneglycol monopalmitate	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

666	87280	00291165081	sorbitan diolate	yes	no	no			
667	55190	0029204012	oleic acid	yes	no	no			
668	80240	0029894357	polyglycerol ricinolate	yes	no	no			
669	56610	0030233548	glycerol monobehenate	yes	no	no			
670	56800	0030899528	glycerol monolaurate diacetate	yes	no	no	(32)		
671	74240	0031570044	phosphoric acid, tris(2,4-di-tert-butylphenyl)ester	yes	no	no			
672	76845	0031831515	polyesters of 1,4-butanediol with caprolactone	yes	no	no	(29) (30)	The fraction with molecular weight below 1 000 Da [F ¹ shall] not exceed 0,5 % (w/w)	
673	53670	0032509661	polyethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	yes	no	yes	6		
674	46480	0032647670	benzylidene sorbitol	yes	no	no			
675	38800	0032687788	bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	yes	no	yes	15		
676	50400	0033568999	octyltin	yes	no	no	(10)		

Status: Point in time view as at 19/05/2019.

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

			bis(isooctyl maleate)							
677	82560	0033587120-1	propyleneglycol dipalmitate	yes	no	no				
678	59200	0035074176-2	hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	yes	no	yes	6			
679	39060	0035958130-6	bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	yes	no	yes	5			
680	94400	0036443668-2	bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate]	yes	no	no	9			
681	18310	0036653182-4	hexadecanol	no	yes	no				
682	53270	003720599-5	ethylcarboxymethylcellulose	yes	yes	no				
683	66200	003720600-2	butylcarboxymethylcellulose	yes	yes	no				
684	68125	0037244061-2	neophylite	yes	no	no				
685	85950	0037296172-2	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

Status: Point in time view as at 19/05/2019.

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

										with food.
686	61390	0037353	5906	hydroxyethylcellulose	no					
687	13530	0038103	206-9	bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	no	yes	no	0,05		
	13614									
688	92560	0038613	6774	bis(3,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	yes	no	yes	18		
689	95280	0040601	176-5	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	0041484	435-0	Diethyl bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	no	yes	yes	2,4		
691	13600	0047465	397-4	bis(3-methyl-4-hydroxyphenyl)-2-indolinone	no	yes	no	1,8		
692	52320	0052047	250-3	dodecylphenylindole	yes	no	yes	0,06		
693	88160	0054140	306-4	sorbitan tripalmitate	yes	yes	no			
694	21400	0054276	356-6	methacrylic acid, sulphopropyl ester	yes	no	yes	0,05		(1)
695	67520	0054849	386-6	tris(isooctyl mercaptoacetate)	no	no	yes		(9)	

Status: Point in time view as at 19/05/2019.

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

696	92205	00575694	40-phthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)	no	no				
697	67515	00575833	3,3'-methyltris(ethylhexyl mercaptoacetate)	no	no		(9)		
698	49595	00575836	3,6-methylbis(ethylhexyl mercaptoacetate)	no	no		(9)		
699	90720	00584466	2,9-bis(2-oxo-1-phenylethyl)ethane	no	no				
700	31520	00611675	58-fatty acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	yes	no	yes	6		
701	40160	00612696	N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	yes	no	no	2,4		
702	87920	00617526	8-0-tan yes tetrastearate	yes	no	no			
703	17170	00617884	74 fatty acids, coco	no	yes	no			
704	77600	00617885	85-0 polyethyleneglycol ester of hydrogenated castor oil	yes	no	no			
705	10599/90	00617888	84 fatty, unsaturated (C ₁₈), dimers,	no	yes	no		(18)	(1)
	10599/91								

Status: Point in time view as at 19/05/2019.

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

			non hydrogenated, distilled and non-distilled							
706	17230	0061790	Fatty acids, tall oil	no	yes	no				
707	46375	0061790	Diatomaceous earth	no	no	no				
708	77520	0061791	polyethylene glycol ester of castor oil	no	no	no	42			
709	87520	0062568	sofiban monobenenate	yes	no	no				
710	38700	0063397	2-(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	yes	no	yes	18			
711	42000	0063438	2-(2-carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)	yes	no	yes	30			
712	42960	0064147	leard oil, dehydrated	yes	no	no				
F ¹⁰ 713	43480	0064365	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
		0007440	[44-0]							

Status: Point in time view as at 19/05/2019.

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

									Regulation (EU) No 231/2012 ^d with exception of ash content which can be up to 10 % (w/w).
714	84400	0064365	0579 hydrogenated, ester with pentaerythritol	yes	no	no			
715	46880	0065140	391-01 tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	yes	no	no	6		
716	60800	0065447	717(20) hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	yes	no	no	30		
717	84210	0065997	0611 hydrogenated	yes	no	no			
718	84240	0065997	0319 hydrogenated, ester with glycerol	yes	no	no			
719	65920	0066822	260-4 methacryloyloxyethyl-N,N-dimethyl-N-	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

			carboxymethylammonium chloride, sodium salt - octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers						
720	67360	0067649	965-4- n-dodecyltin tris(isooctyl mercaptoacetate)	yes	no	no	(25)		
721	46800	0067845	965-6- tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	yes	no	no			
722	17200	0068308	965-2- fatty acids, soya	no	yes	no			
723	88880	0068412	965-3- starch, hydrolysed	yes	no	no			
724	24903	0068425	965-3- starch, hydrolysed starch, hydrogenated	yes	no	yes			In compliance with the purity criteria for maltitol syrup E 965(ii) as laid down in Commission Directive 2008/60/EC ^e

Status: Point in time view as at 19/05/2019.

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

[^{F15}]										
726	83599	0068442	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	yes	no	yes		(9)		
727	43360	0068442	Fluorescent regenerated	yes	no	no				
728	75100	0068515 0028553	Aliphatic 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

Status: Point in time view as at 19/05/2019.

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

										2006/141/EC or processed cereal-based foods and 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.
729	75105	0068515 0026761	Phthalic diesters with primary, saturated C ₉ -C ₁₁ alcohols more than 90 % C ₁₀	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	

Status: Point in time view as at 19/05/2019.

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

										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; technical support agent in concentrations up to 0,1 % in the final product.
730	66930	0068554	4701	methylsilsesquioxane	no					Residual monomer in methylsilsesquioxane:

Status: Point in time view as at 19/05/2019.

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

									< 1 mg methyltrimethoxysilane/ kg of methylsilsesquioxane	
731	18220	0068564	488-5 heptylamino undecanoic acid	no	yes	no	0,05			(2)
732	45450	0068610	051-5 cresol- dicyclopentadiene- isobutylene, copolymer	yes	no	yes	5			
733	10599/92 10599/93	0068783	415-5 fatty, unsaturated (C ₁₈), dimers, hydrogenated, distilled and non- distilled	no	yes	no		(18)		(1)
734	46380	0068855	540-9 diatomaceous earth, soda ash flux- calcined	no	no	no				
735	40120	0068951	501-8 polyethylene glycol hydroxymethylphosphonate	no	no	no				
736	50960	0069226	44-4 octyltin ethyleneglycol bis(mercaptoacetate)	yes	no	no		(10)		
737	77370	0070142	204-6 polyethyleneglycol-30 dipolyhydroxystearate	yes	no	no				
738	60320	0070321	282-7 hydroxy-3,5- bis(1,1- dimethylbenzyl)phenyl]benzotriazole	yes	no	yes	1,5			
739	70000	0070331	292-1 oxamidobis[ethyl-3- (3,5- di-tert- butyl-4- hydroxyphenyl)- propionate]	yes	no	no				

Status: Point in time view as at 19/05/2019.

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

740	81200	0071878	81096- [(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	0073138	8316 acids and rosin acids	yes	yes	no				
	83610									
742	92700	0078301	2444- tetramethyl-20- (2,3- epoxypropyl)-7- oxa-3,20- diazadispiro- [5.1.11.2]- heneicosan-21- one, polymer	yes	no	yes	5			
743	38950	0079072	2964- ethylbenzylidene)sorbitol	yes	no	no				
[^{F14} 744	18888	080181-3	1-3 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.	

Status: Point in time view as at 19/05/2019.

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

745	68145	0080410232-9	2,2',9'-nitriolo(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	0080693601-6	di-tert-butyl-4-methylphenyl)diphosphite	yes	no	yes	5		SML expressed as sum of phosphite and phosphate	
747	47600	008403061-5	dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes		(25)		
748	12765	00844341-28	aminoethyl)-β-alanine, sodium salt	no	yes	no	0,05			
749	66360	0085209221-2	methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	yes	no	yes	5			
750	66350	0085209223-4	methylenebis(4,6-di-tert-butylphenyl) lithium phosphate	yes	no	no	5			
751	81515	0087189251-2	poly(zinc glycerolate)	yes	no	no				
[^F 752	39890	008782641-3 0069158-41-4 0054686-97-4 0081541-12-0	bis(methylbenzylidene)sorbitol	yes	no	no				1
753	62800	0092704401-1	calcined	yes	no	no				

Status: Point in time view as at 19/05/2019.

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

754	56020	009988064-6	octyl-6-rol dibehenate	yes	no	no			
755	21765	010624643-7	methylenebis(3-chloro-2,6-diethylaniline)	no	yes	no	0,05		(1)
756	40020	011055327-0	bis(octylthiomethyl)-6-methylphenol	yes	no	yes		(24)	
757	95725	011063871-6	ethylene glycol reaction product with citric acid, lithium salt	yes	no	no			
758	38940	011067524-8	bis(dodecylthiomethyl)-6-methylphenol	yes	no	yes		(24)	
759	54300	011833720-0	ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	yes	no	yes	6		
760	83595	01193451-0	reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	yes	no	no	18		Composition: — 4,4'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3) (36-46 % w/w (*)), — 4,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No

Status: Point in time view as at 19/05/2019.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)*

									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
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Status: Point in time view as at 19/05/2019.

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

									(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	0120218	Diethylbis(methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	no	no	yes	6		
762	31530	0123968	2,4-di-tert-pentyl-6-(1-(3,5-di-tert-	yes	no	yes	5		

Status: Point in time view as at 19/05/2019.

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

			pentyl-2-hydroxyphenyl)ethyl)phenyl ester							
763	39925	0129228323	21-3 bis(methoxymethyl)-2,5-dimethylhexane	yes	no	yes	0,05			
764	13317	0132459542	54-2 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	0134701220	20-5 dimethyl-6-(1-methylpentadecyl)phenol	yes	no	yes	1			
766	38879	0135861563	56-3 dimethylbenzylidene)sorbitol	yes	no	no				
767	38510	0136504195	49-6 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	0143925022	02-2 bis(hydrogenated tallow alkyl) oxidised	yes	no	no			Not to be used for articles in contact with fatty foods	(1)

Status: Point in time view as at 19/05/2019.

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

									for which [^{F1} simulant D1 and/ or D2] is laid down. Only to be used in: (a) polyolefins at 0,1 % (w/ w) concentration and in PET at 0,25 % (w/ w) concentration.
769	74010	0145650	010-8-phosphoric 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	0147315	012-4-bis(2,4-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	yes	no	no	0,05		
771	34650	0151841	015-1-hydroxybis[2,2'-methylenebis(4,6-di-tert-butylphenyl) phosphate]	yes	no	no	5		
772	47500	0153250	015-2-1,3-dicyclohexyl-2,6-	yes	no	no	5		

Status: Point in time view as at 19/05/2019.

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

			naphthalene dicarboxamide						
773	38840	0154862543(2)	bis(2,4-dicumylphenyl)phosphite	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	0161717232(4)	tris(tert-butylphenyl)-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	0166412178(8)	cyclohexanedicarboxylic acid, diisononyl ester	yes	no	no		(32)	
776	76723	0167883061(2)	polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4'-diisocyanate	yes	no	no			The fraction with molecular weight below 1 000 Da [F ¹ shall] not exceed 1,5 % (w/w)

Status: Point in time view as at 19/05/2019.

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

777	31542	0174254	acrylic acid, methyl ester, telomer with 1-dodecanethiol, C ₁₆ -C ₁₈ alkyl esters	yes	no	no			0,5 % in final product	(1)
778	71670	0178671	isocyanate tetrakis (2-cyano-3,3-diphenylacrylate)	no	no	yes	0,05			
[^{F1} 779]	39815	0182121	bis(methoxymethyl)fluorene	yes	no	yes	0,05			[^{F9} (2)]
780	81220	0192268	poly[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediy][(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]-	yes	no	no	5			

Status: Point in time view as at 19/05/2019.

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

			ω-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]							
781	95265	02270994	0,5-tris(4-benzoylphenyl)benzene	yes	no	no	0,05			
782	76725	0661476	polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane			no			The fraction with molecular weight below 1 000 Da [F ¹ shall not exceed 1 % (w/w)	
783	55910	0736150	glycerides of castor-oil mono-, hydrogenated, acetates		no	no		(32)		
[F ¹⁰ 784	95420	0745070	1,5-tris(2,2-dimethylpropanamido)benzene	yes	no	no	5]
785	24910	0000100	terephthalic acid		yes	no		(28)		
786	14627	0000117	3,5-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 3-chlorophthalic acid	
787	14628	0000118	4,5-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 4-chlorophthalic acid	

Status: Point in time view as at 19/05/2019.

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

788	21498	0002530	135-0 (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: 440–12 000)	yes	no	no			Average molecular weight not less than 440 Da. Viscosity at 100 °C not less than 3,8 cSt (3,8 × 10 ⁻⁶ m ² /s).	(2)
790	80480	0090751 0082451	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	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-	(16)

Status: Point in time view as at 19/05/2019.

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

										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	0106990	N,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	0203255	3,3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid	yes	no	yes	5			SML expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products
793	94000	0000102	triethanolamine	yes	no	no	0,05			SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed

Status: Point in time view as at 19/05/2019.

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

									as triethanolamine	
[^{F12} 794	18117	0000079	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	0124172	N,N-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N'-diformylhexamethylenediamine	yes	no	no	0,05			(2) (12)
796	72141	0018600	(1,4-phenylene)bis[4H-3,1-	yes	no	yes	0,05		SML including the sum	

Status: Point in time view as at 19/05/2019.

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

			benzoxazin-4-one]					of its hydrolysis products		
[F12]	797	76807	0073018	2055	esters of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	no	yes		(31) (32)	I
	798	92200	0006422	2661	terephthalic acid, bis(2-ethylhexyl)ester	no	no	60	(32)	
[F10]	799	77708			polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C ₈ -C ₂₂) alcohols	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	0000867	1130	ethyl phosphonoacetate	yes	no	no		Only for use in PET
	801	30607	—		acids, C ₂ -C ₂₄ , aliphatic, linear, monocarboxylic,	yes	no	no		

Status: Point in time view as at 19/05/2019.

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

			from natural oils and fats, lithium salt						
802	33105	0146340	alcohols, C ₁₂ -C ₁₄ secondary, β-(2-hydroxyethoxy), ethoxylated	yes	no	no	5		(12)
803	33535	0152261	3-1 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. Not to be used in contact with alcoholic foods.	(13)
804	80510	1010121	80-73-nonyl-1,1-dioxo-1-thiopropyl-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl),	yes	no	no		Only to be used as polymer production aid in polyethylene (PE), polypropylene (PP)	

Status: Point in time view as at 19/05/2019.

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

			process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid						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	0001076197-7	cyclohexanedicarboxylic acid	no	yes	no	5		Only to be used for manufacture of polyesters
[F11]807	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

Status: Point in time view as at 19/05/2019.

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

									have a diameter of 100-500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.
808	38550	0882073	4-4 bis(4-propylbenzylidene)propylsorbitol	yes	no	no	5		SML including the sum of its hydrolysis products
809	49080	0852282	289-4 (2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione	yes	no	yes	0,05		Only (6) for use in PET (14) (15)
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 [F1 simulant D1 and/ or D2] is laid down.

Status: Point in time view as at 19/05/2019.

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

811	80077	006844	polyethylene waxes, oxidised	yes	no	no	60		
[^{F12} 812	80350	0124578	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	—	sulphosulphonic acid alkyl (C ₄ -C ₂₀) or cyclohexyl diesters, salts	yes	no	no	5		
814	91815	—	sulphosulphonic acid monoalkyl (C ₁₀ -C ₁₆) polyethyleneglycol esters, salts	yes	no	no	2		
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

Status: Point in time view as at 19/05/2019.

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

									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 \geq 96 %.
818	21530	—	methallylsulphonic acid, salts	yes	no	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 ^{F1} simulant D1 and/or D2] is laid down.

Status: Point in time view as at 19/05/2019.

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

									SML expressed as neodecanoic acid.	
820	76420	—	pimelic acid, salts	yes	no	no				
821	90810	—	stearoyl-lactylic acid, salts	yes	no	no				
[^{F16} 822]	71938		Perchloric acid, salts	yes	no	no	0,002			(4)]
823	24889	—	5-Sulphoisophthalic acid, salts	no	yes	no	5			
854	71943	0329238p24f6	perfluoroacetic acid, α -substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropoxy groups	yes	no	no			Only to be used in concentrations up to 0,5 % w/w in the polymerisation of 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	yes	no	no			Only to be used	

Status: Point in time view as at 19/05/2019.

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

			methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate					in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below.
[^{F18} 856	40563	25101-28	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

Status: Point in time view as at 19/05/2019.

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

									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	0037953	(methyl 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

Status: Point in time view as at 19/05/2019.

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

								or below.
[F7] [X1] 858	38565	0090498390	1 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 (2)] 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 methid tautomer.
[F4] 859			(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform	yes	no	no		Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at

Status: Point in time view as at 19/05/2019.

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

860	71980	0051798	2p3F6orof2- (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	0013252	2p3F6orof2- (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	0018085	302-4 diacetoxy-1- butene	no	yes	no	0,05	SML (17) including (19)] the hydrolysis product

Status: Point in time view as at 19/05/2019.

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

									3,4-dihydroxy-1-butene Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers.
[^{F17} 863	15260	000064642503	no 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	0000056206-4	yes diamino-6-hydroxypyrimidine	no	no	no	5		Only to be used in rigid poly(vinyl chloride)

Status: Point in time view as at 19/05/2019.

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

									(PVC) in contact with non-acidic and non-alcoholic aqueous food	
1865	40619	0025322	(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.	1
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 %	

Status: Point in time view as at 19/05/2019.

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

867	40815	0040471	03-21	yes methacrylate, ethyl acrylate, methyl methacrylate) copolymer	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %	
[F11]868	53245	0009010	08-21	yes acrylate, methyl methacrylate) copolymer	no	no			Only to be used in: (a) (b) (c)] rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % w/ w; polylactic acid (PLA) at a maximum level of 5 % w/ w; polyethylene terephthalate (PET) at a maximum level of 5 % w/ w.

Status: Point in time view as at 19/05/2019.

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

869	66763	0027136	66763 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	0160535	95500 'N"-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide	yes	no	no	5			
[^{F2} 871		0287916	871 succinic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene	yes	no	no			Only to be used in polyolefins at levels of up to 20 weight %. These polyolefins shall only be used in contact with foods for which Table 2 of Annex III assigns food simulant E, at ambient temperature	(23)]

Status: Point in time view as at 19/05/2019.

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

									or below, and when migration of the total oligomeric fraction of less than 1 000 Da does not exceed 50 µg/kg food.
[^{F19} 872		0006607241-6	no phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine	yes	no	0,05			To be used only as a co-monomer in polycarbonate copolymers (20)]
[^{F17} 873	93460		titanium dioxide reacted with octyltriethoxysilane	yes	no	no			Reaction] product of titanium dioxide with up to 2 % w/w surface treatment substance octyltriethoxysilane, processed at high temperatures.
[^{F7} 874	16265	0156065600-8	no dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyloxy, ω-3-dimethyl-3-	yes	no	0,05	(33)		Only to be used as comonomer in siloxane

Status: Point in time view as at 19/05/2019.

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

			(4'-hydroxy-3'-methoxyphenyl)propylsilyl polydimethylsiloxane						modified polycarbonate. The oligomeric mixture shall be characterised by the formula $C_{24}H_{38}Si_2O_5(SiOC_2H_6)_n$ ($50 > n \geq 26$).
875	80345	0058128p02y612	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, aliphatic, monohydric, saturated, primary (C ₃ -C ₂₂)	yes	no	no			
879	31336	—	acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats and oils, esters	yes	no	no			

Status: Point in time view as at 19/05/2019.

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

			with alcohols, linear, aliphatic, monohydric, saturated, primary (C ₁ -C ₂₂)						
1 ^{F10} 880	31348		acids, fatty (C ₈ -C ₂₂), esters with pentaerythritol'	yes	no	no			
881	25187	000301029644	no 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

Status: Point in time view as at 19/05/2019.

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

										single use materials and articles.
882	25872	00024162936	2936-trimethylphenol	no	yes	no	0,05			
883	22074	0004457371-0	371-0-methyl-1,5-pentenediol	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	0091082alkyl(C ₁₀ -C ₂₁)sulphonic acid, esters with phenol	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 [F ¹ simulant D1 and/or D2] is laid down.	
885	45676	02632445418	5418-oligomers of (butylene terephthalate)	yes	no	no			Only to be used in poly(ethylene terephthalate) (PET),	

Status: Point in time view as at 19/05/2019.

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

									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.
[F17]	894	93360	0016545516	5-hydroxypropanoic acid, ditetradecyl ester	no	no		(14)	
	895	47060	0171090396	3,5-di-tert-butyl-4-hydroxyphenylpropanoic 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

Status: Point in time view as at 19/05/2019.

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

									dairy products.
896	71958	0958445344-8	perfluoro-3-[(3-methoxypropoxy)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.
[F7]902		0000128442-9	benzothiazol-3(2H)-one 1,1-dioxide, sodium salt	yes	no	no			The substance shall comply with the specific

Status: Point in time view as at 19/05/2019.

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

[F ⁴ 903	37486-624-	perfluoro- [(5,8,11,14- tetramethyl)- tetraethyleneglycol ethyl propyl ether]	yes	no	no	purity criteria as set out in Commission Regulation (EU) No 231/2012 ^a .
						<p>Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for:</p> <p>(a) repeated and single use materials and articles when sintered or processed (non-sintered) at temperatures at or above 360 °C for at least 10 minutes or at higher temperatures for equivalent</p>

Status: Point in time view as at 19/05/2019.

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

									(b)	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	0000120	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, [F1 shall] not result in a migration of diethanolamine higher than 0,3 mg/kg food.	(18)
924	94987		trimethyl mixed isopropane	no	no	no	0,05		Only for	

Status: Point in time view as at 19/05/2019.

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

			triesters and diesters with n-octanoic and n-decanoic acids					use in PET in contact with all types of foods other than fatty, high-alcoholic and dairy products.
926	71955	0908020	05290 [(2-ethoxyethoxy)acetic acid], ammonium salt	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.
[F4]969		24937-78	8181 ethylene vinyl acetate copolymer wax	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

Status: Point in time view as at 19/05/2019.

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

									below 1 000 Da shall not exceed 5 mg/ kg food.
971	25885	0002459	trifluoromethyl trimellitate	yes	no				Only (17) to be used as a co- monomer up to 0,35 % w/w to produce modified polyesters intended to be used in contact with aqueous and dry foodstuffs containing no free fat at the surface.
972	45197	0012158	8-cyclohexyl hydroxide phosphate	yes	no	no			
973	22931	0019430	(perfluorobutyl) ethylene	no	no				Only to be used as a co- monomer up to 0,1 % w/w in the polymerisation of

Status: Point in time view as at 19/05/2019.

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

									fluoropolymers, sintered at high temperatures.
[F16974	74050	939402-	02-5-phosphoric 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.
[F7979	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.
[F19988		3634-83-	1,3-bis(isocyanatomethyl)benzene	no	yes	no		(34)	SML(T) applies to the migration of its hydrolysis product,

Status: Point in time view as at 19/05/2019.

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

									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
[F4998		(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform	yes	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

Status: Point in time view as at 19/05/2019.

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

								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-	diethyl[1,5- 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

Status: Point in time view as at 19/05/2019.

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

								to manufacture poly(ethylene terephthalate) (PET).	
1016			(methacrylic acid, ethyl acrylate, n- butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform	no	no			Only to be used up to: (a) 10 % w/ w in non- plasticised PVC; (b) 15 % w/ w in non- plasticised PLA.	I
1017		25618-55-7	polyglycerol	no	no			The final material shall be used at room temperature or below.	
								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	no	no			Only to be used	I

Status: Point in time view as at 19/05/2019.

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

		by dimethylalkyl(C16- C18)ammonium chloride				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
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Status: Point in time view as at 19/05/2019.

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

								platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer.	
[F ² 1031	3238-40-2	furan-2,5-dicarboxylic acid	no	yes	no	5		Only to be used as a monomer in the production 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).	(22) (23)
1034	3710-30-3	7-octadiene	no	yes	no	0,05		Only to be used as a crosslinking co-monomer	1

Status: Point in time view as at 19/05/2019.

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

										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

Status: Point in time view as at 19/05/2019.

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

								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.
[F ² 1045	1190931	perfluoroacetic 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

Status: Point in time view as at 19/05/2019.

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

									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-	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		42774-1-	N,N'-bis(2,2,6,6-tetramethyl-4-	yes	no	no	5		

Status: Point in time view as at 19/05/2019.

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

			piperidinyl isophthalamide							
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 50 µg/kg food (expressed as SPG).	(22) (23)
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		7695-91-6 58-95-7	α-tocopherol acetate	yes	no	no			Only to be used as antioxidant in polyolefins.	(24)

Status: Point in time view as at 19/05/2019.

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

F ²¹ 1059	147398-310	(R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate	no	yes	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.	I
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	

Status: Point in time view as at 19/05/2019.

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

									that are fit for human consumption. The processing temperature of the plastic containing the additive shall not exceed 240 °C.	
[^{F22} 1061		80512-44-3,4'-	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.	I
1062			mixture composed of 97 % tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3 % hexamethyldisilazane (HMDS) with	no	yes	no			Only to be used for the production of recycled PET and at up to 0,12 % (w/w).	I

Status: Point in time view as at 19/05/2019.

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

			CAS No 999-97-3						
[^{F22} 1063		1547-26-2	2,3,3,4,4,5- heptafluoro-1- pentene	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	Stibogen oxide	yes	no	no	0,05		Stoichiometry: WO _n , n = 2,72-2,90
1065		85711-28-0	Mixture of methyl- branched and	yes	no	no	5		Only to be used in the manufacture (26)]

Status: Point in time view as at 19/05/2019.

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

			linear C ₁₄ - C ₁₈ alkanamides, derived from fatty acids						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.
[^{F14} 1066	23985-7	3,3,4-	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

Status: Point in time view as at 19/05/2019.

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

								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-	dimethylno carbonate	yes	no				Only to be used: a) with 1,6- hexanediol in the manufacture of polycarbonate pre- polymers that are used at up to 30 % to manufacture

Status: Point in time view as at 19/05/2019.

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

									b)	III; or 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- (2,3-	no	yes	no				Only to be used	

Status: Point in time view as at 19/05/2019.

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

		epoxypropoxy)propyl]trimethoxy silane					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/
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Status: Point in time view as at 19/05/2019.

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

									kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer).
[^{F21} 1069		75-28-5	isobutanoyes	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	[^{F4} Commission 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} [^{F6} Infant 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	[^{F7} OJ L 83, 22.3.2012, p. 1.]								
i	[^{F8} Infant 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 \(Text with EEA relevance\)](#).

Status: Point in time view as at 19/05/2019.

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

- 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).

Status: Point in time view as at 19/05/2019.

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

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) Group Restriction No	(2) FCM substance No	(3) SML (T)[mg/kg]	(4) 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	6	expressed as the sum of the substances

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

	431 464		
9	650 695 697 698 726	0,18	expressed as tin
10	28 29 30 31 32 33 466 582 618 619 620 646 676 736	0,006	expressed as tin
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	5	expressed as the sum of the substances and their oxidation products
	368		
	894]		
[^{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	ND	expressed as isocyanate moiety

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

	461 475 476 485 490 653		
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	70 147 176 218 323 325 365 371 380 425 446 448 456 636	6	expressed as acrylic acid
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),

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

			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]

Status: Point in time view as at 19/05/2019.

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

[^{F21} 35]	467 744 1059	0,05	expressed as crotonic acid]
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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) Note No	(2) 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 [^{F1} shall] be performed using saturated fatty food simulants as simulant D2.]
(5)	Compliance testing when there is a fat contact [^{F1} shall] 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)

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

	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.]

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

[^{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

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

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 <i>Alcaligenes eutrophus</i> 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 <i>Alcaligenes eutrophus</i> 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

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

		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	 <p>where n/(m + n) greater than 0 and less or equal to 0,25</p>
	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-hydroxy-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
	[^{F14} Restriction	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

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

	— 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

[^{F20}Nickel = 0,02 mg/kg food or food simulant]

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

[^{F12}. 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

Status: Point in time view as at 19/05/2019.

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

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.

[^{F13} **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.

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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) Reference number	(2) Description of food	(3) 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		X(*)	X			

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

	and the like, flavoured water, liquid coffee extract						
	B. cloudy drinks: juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate	X(*)			X		
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						

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

	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'						

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

	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				X/2	

Status: Point in time view as at 19/05/2019.

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

		substances on the surface					
	II.	Moist		X			
03.03		Sugar and sugar products					
	A.	In solid form: crystal or powder					X
	B.	X Molasses, sugar syrops, honey and the like					
04		Fruit, vegetables and products thereof					
[^{F1} 04.01		Fruit, fresh or chilled:					
	A.	unpeeled and uncut					X/10
	B.	X peeled and/ or cut	X (*)				I
04.02		Processed fruit:					
	A.	Dried or dehydrated fruits, whole,					X

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

		sliced, flour or powder					
	B.	Fruit in the form of purée, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products)	X(*)	X			
	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					

Status: Point in time view as at 19/05/2019.

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

	kernels and others):						
	A.	Shelled, dried, flaked or powdered					X
	B.	Shelled and roasted					X
	C.	X In paste or cream form				X	
[^{F1} 04.04	Vegetables, fresh or chilled:						
	A.	unpeeled and uncut					X/10
	B.	X peeled and/or cut	X (*)				I
[^{F1} 04.05	Processed vegetables:						X
	A.	Dried or dehydrated vegetables whole, sliced or in the form of flour or powder.					
	B.	(<i>obsolete</i>)					

Status: Point in time view as at 19/05/2019.

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

	C.	Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine).	X (*)	X			
	D.	Preserved vegetables:					
	I.	In an oily medium	X			X	
	II.	In an alcoholic medium			X		I
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					X/2	

Status: Point in time view as at 19/05/2019.

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

	fats and oils made from water emulsions in oil						
06	Animal products and eggs						
06.01	Fish:						
	A.	X Fresh, chilled, processed, salted or smoked including fish eggs				X/3(**)	
	B.	Preserved fish:					
	I.	X In an oily medium				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					

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

		or cooked with the shell					
	I.	X In an oily medium				X	
	II.	In an aqueous medium	X(*)	X			
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				X	

Status: Point in time view as at 19/05/2019.

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

		in an oily medium					
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		

Status: Point in time view as at 19/05/2019.

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

	B.	Milk powder including infant formula (based on whole milk powder)					X
07.02		Fermented milk such as yoghurt, buttermilk and similar products	X(*)		X		
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,	X(*)		X		

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

		cottage cheese and similar)					
	D.	Preserved cheese:					
	I.	X In an oily medium				X	
	II.	In an aqueous medium (feta, mozzarella, and similar)	X(*)		X		
08	Miscellaneous products						
08.01	Vinegar		X				
08.02	Fried or roasted foods:						
	A.	X Fried potatoes, fritters and the like				X/5	
	B.	X Of animal origin				X/4	
08.03	Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite						

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

	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. X With fatty character	X(*)			X/3		
	II. Other	X(*)	X				
08.04	Sauces:						
	A. With aqueous character	X(*)	X				
	B. X With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other	X(*)			X		

Status: Point in time view as at 19/05/2019.

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

		oil/ water mixtures e.g. coconut based sauces					
08.05	Mustard (except powdered mustard under heading 08.14)	X	X(*)			X/3(**)	
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff						
	A.	X With fatty substances on the surface				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

Status: Point in time view as at 19/05/2019.

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

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						X

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

	in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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 \geq 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]

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

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 \(Text with EEA relevance\).](#)

[^{F25} **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;

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

- (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) [F23the 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.

[F11.4. **Account of substances originating from other sources**

Status: Point in time view as at 19/05/2019.

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

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 its 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

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

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

[^{F1}Selection of test time]

Contact time in worst foreseeable use	[^{F1}Time to be selected for testing]
$t \leq 5 \text{ min}$	5 min
$5 \text{ min} < t \leq 0,5 \text{ hour}$	0,5 hour
$0,5 \text{ hours} < t \leq 1 \text{ hour}$	1 hour
$1 \text{ hour} < t \leq 2 \text{ hours}$	2 hours
$2 \text{ hours} < t \leq 6 \text{ hours}$	6 hours
$6 \text{ hours} < t \leq 24 \text{ hours}$	24 hours
$1 \text{ day} < t \leq 3 \text{ days}$	3 days
$3 \text{ days} < t \leq 30 \text{ days}$	10 days
Above 30 days	See specific conditions

[^{F1}TABLE 2

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
$T \leq 5 \text{ °C}$	5 °C
$5 \text{ °C} < T \leq 20 \text{ °C}$	20 °C
$20 \text{ °C} < T \leq 40 \text{ °C}$	40 °C
$40 \text{ °C} < T \leq 70 \text{ °C}$	70 °C
$70 \text{ °C} < T \leq 100 \text{ °C}$	100 °C or reflux temperature
$100 \text{ °C} < T \leq 121 \text{ °C}$	121 °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.]

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121 °C < T ≤ 130 °C	130 °C ^a
130 °C < T ≤ 150 °C	150 °C ^a
150 °C < T < 175 °C	175 °C ^a
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:

$$t_2 = t_1 * \text{Exp} (9627 * (1/T_2 - 1/T_1))$$

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

Status: Point in time view as at 19/05/2019.

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

[^{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 dm² 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 dm² 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

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

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.

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

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**

Status: Point in time view as at 19/05/2019.

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

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]

[^F13.3. **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.

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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 $FRF = (g \text{ fat in food/kg of food})/200 = (\% \text{ fat} \times 5)/100$.

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 dm²/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

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factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.]

F³4.2. Correction of migration into food simulant D2

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F³4.3. 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

Status: Point in time view as at 19/05/2019.

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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

Status: Point in time view as at 19/05/2019.

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

- (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).

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