

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

- (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.

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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

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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 **U.K.**

GENERAL PROVISIONS

Article 1 **U.K.**

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 **U.K.**

Scope

1 This Regulation shall apply to materials and articles which are placed on the ^{F1}... 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 ^{F1}... 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 ^{F2}... provisions applicable to printing inks, adhesives or coatings.

Textual Amendments

- F1** Word in Art. 2 omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **66(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Words in Art. 2(3) omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **66(a)**; 2020 c. 1, Sch. 5 para. 1(1)

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Article 3 **U.K.**

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;

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- (11) ‘overall migration limit’ (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants;
- (12) ‘food simulant’ means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials;
- (13) ‘specific migration limit’ (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants;
- (14) ‘total specific migration limit’ (SML(T)) means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated;
- (15) ‘functional barrier’ means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation;
- (16) [^{F3}‘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) [^{F3}‘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) [^{F4}‘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

- F3** 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 \(Text with EEA relevance\).](#)
- F4** 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 **U.K.**

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

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- (c) comply with the traceability requirements set out in Article 17 of Regulation (EC) No 1935/2004; and
- (d) are manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006⁽¹⁴⁾; and
- (e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation.

CHAPTER II **U.K.**

COMPOSITIONAL REQUIREMENTS

SECTION 1 **U.K.**

Authorised substances

Article 5 **U.K.**

^{F5} ... List of authorised substances

1 Only the substances included in the ^{F6}... list of authorised substances (hereinafter referred to as the ^{F6}... list) set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

- 2 The ^{F6}... 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.

[^{F73} The appropriate authority may prescribe amendments to the list.]

Textual Amendments

- F5** Word in *Art. 5* heading omitted (31.12.2020) by virtue of *The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704)*, regs. 1, **67(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Word in *Art. 5* omitted (31.12.2020) by virtue of *The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704)*, regs. 1, **67(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** *Art. 5(3)* substituted (31.12.2020) by *The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704)*, regs. 1, **67(b)**; 2020 c. 1, Sch. 5 para. 1(1)

^{F8}Article 5A **U.K.**

Regulations and devolved powers

1. Any power to make regulations under this Regulation—
- a so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;

Status: Point in time view as at 31/12/2020.

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 so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument.
2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).
3. Any power to make regulations under this Regulation includes power—
- a to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
 - b to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
4. Any statutory instrument or Scottish statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution—
- a in the case of England, of either House of Parliament;
 - b in the case of Wales, of Senedd Cymru;
 - c in the case of Scotland, of the Scottish Parliament.
5. In this Regulation, any power—
- a of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
 - b of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
 - c of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only.]

Textual Amendments

F8 Art. 5A inserted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **68**; 2020 c. 1, **Sch. 5 para. 1(1)** (as amended by S.I. 2020/1504, regs. 1(2), **16(7)**)

Article 6 **U.K.**

Derogations for substances not included in the ^{F9}... list

1 By way of derogation from Article 5, substances other than those included in the ^{F10}... list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to [^{F11}any relevant enactment].

[^{F12} By way of derogation from Article 5, colorants and solvents which were capable of lawful use in the manufacture of plastic layers in plastic materials and articles prior to adoption of the list may continue to be so used subject to any relevant enactment.]

3 The following substances not included in the ^{F10}... list are authorised subject to the rules set out in Articles 8, 9, 10, 11 and 12:

- [^{F13}a all salts of substances for which ‘ yes ’ is indicated in column 2 in Table 1 of Annex II of authorised acids, phenols or alcohols, and subject to the restrictions set out in column 3 and 4 of that table;]
- b mixtures obtained by mixing authorised substances without a chemical reaction of the components;

Status: Point in time view as at 31/12/2020.

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 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 ^{F10} ... list.
- 4 The following substances not included in the ^{F10} ... 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 ^{F10} ... 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 ^{F10} ... list provided they are included in the provisional list referred to in Article 7.

Textual Amendments

- F9** Word in Art. 6 heading omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **69(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Word in Art. 6 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **69(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Words in Art. 6(1) substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **69(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Art. 6(2) substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **69(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Substituted by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

^{F14}Article 7 **U.K.**

Establishment and management of the provisional list

1. The appropriate authority must regularly prescribe updates to the provisional list of additives that that was published by the European Commission in 2008.
2. An additive must be removed from the provisional list—
 - a when it is included in the list set out in Annex 1;
 - b when a decision is taken by the appropriate authority not to include it in the list; or
 - c if during the examination of the data, the appropriate authority calls for supplementary information and that information is not submitted within the time limits specified by the appropriate authority.]

Status: Point in time view as at 31/12/2020.

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

F14 Art. 7 substituted (31.12.2020) by [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **70**; 2020 c. 1, Sch. 5 para. 1(1)

SECTION 2 **U.K.**

General requirements, restrictions and specifications

Article 8 **U.K.**

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 **U.K.**

Specific requirements on substances

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

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

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

Article 10 **U.K.**

General restrictions on plastic materials and articles

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

Article 11 **U.K.**

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).

^{F15}₂

Status: Point in time view as at 31/12/2020.

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} 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.]

[^{F4} 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

- F3** 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).
- F4** 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).
- F15** 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 **U.K.**

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.

Status: Point in time view as at 31/12/2020.

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

CHAPTER III **U.K.**

SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES

Article 13 **U.K.**

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 ^{F16}... list or in the provisional list.

[^{F33} 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 ^{F16}... list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:

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

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

Textual Amendments

- F3** 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 \(Text with EEA relevance\)](#).
- F16** Word in Art. 13 omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **71**; 2020 c. 1, Sch. 5 para. 1(1)

Article 14 **U.K.**

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 ^{F17}... list or the provisional list.

Status: Point in time view as at 31/12/2020.

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 The substances not listed in the ^{F17}... 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.

^{F18}6

Textual Amendments

- F17** Word in Art. 14 omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **72(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F18** Art. 14(6) omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, **72(b)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER IV **U.K.**

DECLARATION OF COMPLIANCE AND DOCUMENTATION

Article 15 **U.K.**

Declaration of compliance

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

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

3 The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

Article 16 **U.K.**

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

Status: Point in time view as at 31/12/2020.

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

manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the ^{F19}... 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.

Textual Amendments

F19 Word in Art. 16 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 73; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER V **U.K.**

COMPLIANCE

Article 17 **U.K.**

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:

- [^{F3}a mg/kg using the actual content of the container for which the closure is intended applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2;]
- b mg/article if the intended use of the article is unknown.

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

- a mg/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.

Status: Point in time view as at 31/12/2020.

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

- F3** 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 **U.K.**

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.

[^{F34} 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.

[^{F37} 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

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

Status: Point in time view as at 31/12/2020.

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 **U.K.**

Assessment of substances not included in the ^{F20} ... 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.

Textual Amendments

F20 Word in [Art. 19](#) heading omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, 74; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER VI **U.K.**

FINAL PROVISIONS

Article 20 **U.K.**

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 **U.K.**

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 **U.K.**

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.

Status: Point in time view as at 31/12/2020.

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

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

- a the rules for migration testing set out in Article 18 of this Regulation; or
- b the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

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

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

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

Article 23 **U.K.**

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.

F21 ...

Textual Amendments

- F21** Words in [Signature](#) omitted (31.12.2020) by virtue of [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), regs. 1, 75; 2020 c. 1, Sch. 5 para. 1(1)

Status: Point in time view as at 31/12/2020.

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 U.K.

Substances

1. ^{F22}... List of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids U.K.

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).

[^{F3}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.

Status: Point in time view as at 31/12/2020.

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. | |

Status: Point in time view as at 31/12/2020.

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 31/12/2020.

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 | | |

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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)

| | | | | | | | | | |
|----|-------|---|---|-----------|----|----|-----|-----|---|
| | | | 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) |

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| | | | | | | | | | | |
|----|-------|---|--|-----|----|----|----|------|--|--|
| | | | 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) | | |

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| | | | | | | | | | | |
|----|-------|---|--|-----|----|----|--|------|--|--|
| 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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| | | | | | | | | | | |
|----|-------|---|---|-----|----|----|--|--|--|--|
| 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 | | | | |

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| | | | | | | | | | |
|----|-------|---|---|-----|----|----|--|--|--|
| | | | 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 | | | |

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| | | | | | | | | | | |
|----|-------|---|--|-----|----|----|--|--|--|--|
| 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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| | | | | | | | | | |
|----|-------|---|---|-----|----|-----|------|------|--|
| 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 | | |

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| | | | | | | | | | |
|----|-------|---|---|-----|----|-----|----|--------------|---|
| | | | 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 [^{F3} 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) | |

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| | | | | | | | | | |
|----|-------|---|---|-----|----|-----|------|--|---------------------|
| | | | 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 |

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| | | | | | | | | | |
|----|-------|---|--|-----|----|----|--|--|--|
| | | | ether of butyl-2- cyano-3- (4- hydroxyphenyl) acrylate | | | | | | |
| 78 | 77897 | — | polyethylene glycol (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 | | | |

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| | | | | | | | | | |
|--------------------|-------|---|---|-----|----|----|---|-----|--|
| | | | of asbestos) | | | | | | |
| 85 | 85610 | — | silicates, yes natural, silanated (with the exception of asbestos) | no | no | | | | |
| 86 | 86000 | — | silicic acid, silylated | yes | no | no | | | |
| [^{F3} 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) | |

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| | | | | | | | | | |
|----|-------|---|---|-----|----|-----|------|--|---|
| | | | 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 [F ³ simulant D1 and/or D2] is laid down. Average molecular weight not less than 350 Da. Viscosity at 100 °C not less than 2,5 cSt (2,5 × 10 ⁻⁶ m ² /s). |

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| | | | | | | | | | |
|----|-------|---|--|-----|----|----|--|--|---|
| | | | | | | | | | 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 |

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| | | | | | | | | | |
|----|----------|---|---|-----|----|----|--|--|--|
| | | | petroleum based hydrocarbon feedstocks | | | | | | 480 Da. Viscosity at 100 °C not less than 8,5 cSt ($8,5 \times 10^{-6} \text{ m}^2/\text{s}$). 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 |

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| | | | | | | | | | |
|-----|-------|---|-----|-----|----|----|-----|--|---|
| 110 | 93520 | 0000059e02-9 00101914e0pherol | yes | no | no | | | | |
| 111 | 53600 | 0000060e04-benediaminetetraacetic 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 | 0000075e21-1 oxide | no | yes | no | ND | | | 1 mg/ kg in final product (10) |

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| | | | | | | | | | |
|-----|-------|--------------|---|-----|-----|------|-----|---|-----------------------|
| 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 | chlorofluoromethane | 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 | phoryes | 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 | acid | yes | yes | no | | | |
| | 44160 | | | | | | | | |
| 140 | 44640 | 0000077930 | acid, triethyl ester | yes | no | no | | | (32) |
| 141 | 13380 | 0000077996 | trimethylolpropane | yes | yes | no | 6 | | |
| | 25600 | | | | | | | | |
| | 94960 | | | | | | | | |
| 142 | 26305 | 0000078087 | triethoxysilanes | yes | no | 0,05 | | Only to be | [^{F28} (1)] |

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| | | | | | | | | | | the 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 |

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| | | | | | | | | | | |
|----------------------|----------------|---------|--|-----|-----|------|------|------|---|---|
| | | | | | | | | | (c) | and young children as defined by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product. |
| 160 | 84800 | 0000087 | sa8-3 salicylic acid, 4-tert-butylphenyl ester | yes | no | yes | 12 | | | |
| [^{F29} 161 | 92160 | 000087 | 69(4)-tartaric acid | yes | no | no] | | | | |
| 162 | 65520 | 0000087 | 78-5 nitro | yes | no | no | | | | |
| 163 | 66400 | 0000088 | 22-4 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 | | | |

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| | | | | | | | | | | |
|-----|----------------|--------|--|-----|-----|----|------|------|---|-----------------------|
| 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 | 1276-9 diamino-6- phenyl-1,3,5- triazine | no | yes | no | 5 | | | [^{F28} (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 | 6237-6 acrylic acid, methyl ester | no | yes | no | | (22) | | |
| 177 | 16955 | 000009 | 6491-1 ethylene carbonate | no | yes | no | 30 | | SML expressed | |

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| | | | | | | | | | |
|----------------------|-------|--------|---|-----|-----|-----|------|------|---|
| | | | | | | | | | 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 | 000009 | 649-5 thiobis(6-tert-butyl-3-methylphenol) | yes | no | yes | 0,48 | | |
| 179 | 48800 | 000009 | 722-4 dihydroxy-5,5'-dichlorodiphenylmethane | yes | no | yes | 12 | | |
| [^{F30} 180 | 17160 | 000009 | 753-0 phenol | no | yes | no | | (33) | |
| 181 | 20890 | 000009 | 763-2 acrylic acid, ethyl ester | no | yes | no | | (23) | |
| 182 | 19270 | 000009 | 765-4 acetic acid | no | yes | no | | | |
| 183 | 21010 | 000009 | 784-9 acrylic acid, isobutyl ester | no | yes | no | | (23) | |
| 184 | 20110 | 000009 | 788-1 acrylic acid, butyl ester | no | yes | no | | (23) | |
| 185 | 20440 | 000009 | 790-5 acrylic acid, diester | no | yes | no | 0,05 | | |

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| | | | | | | | | | |
|-----|-------|--------------|-------------------------------------|-----|-----|----|------|------|--|
| | | | 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 | 00001016006 | 1,6-hexanediol diglycidyl ether | no | yes | no | ND | | Not to be used for articles (8) |

Status: Point in time view as at 31/12/2020.

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 [F ³ simulant D1 and/or D2] is laid down. For indirect food contact only, behind a PET layer. |
| 200 | 51680 | 000010220819 | diphenylthiourea | yes | no | yes | 3 | | |
| 201 | 16540 | 000010220910 | diphenyl carbonate | no | yes | no | 0,05 | | |
| 202 | 23070 | 000010221316 | phenylenedioxydiacetic acid | no | yes | no | 0,05 | | [F ²⁸ (1)] |
| 203 | 13323 | 000010221419 | bis(2-hydroxyethoxy)benzene | no | yes | no | 0,05 | | |
| 204 | 25180 | 000010226013 | '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. |

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| | | | | | | | | | 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 | | | |

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| | | | | | | | | | |
|-----|-------|--------------|--|-----|----|------|------|------------------------------------|------|
| 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 | 000010715-2 | no ethylenediamine | yes | no | 12 | | | |
| | 16960 | | | | | | | | |
| 227 | 16990 | 000010721-1 | 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 | | | | |

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| | | | | | | | | | | |
|-----------------------|--------|-------------|-------------------------------|-----|-----|----|------|------|--|-------|
| 234 | 19960 | 00001083166 | maleic anhydride | no | yes | no | | (3) | | |
| 235 | 14710 | 00001083794 | 2,4-cresol | no | yes | no | | | | |
| [^{F13} 236] | 23050 | 00001084452 | 4,4'-phenylenediamine | no | yes | no | ND | | | (28)] |
| 237 | 15910 | 00001084463 | 2,4-dihydroxybenzene | no | yes | no | 2,4 | | | |
| | 24072 | | | | | | | | | |
| 238 | 18070 | 00001085544 | glutaric anhydride | no | yes | no | | | | |
| [^{F31} 239] | 19975 | 00001082744 | 2,4,6-triamino-1,3,5-triazine | yes | yes | no | 2,5 | | | |
| | 25420 | | | | | | | | | |
| | 93720] | | | | | | | | | |
| 240 | 45760 | 00001089118 | hexamethylenediamine | no | no | no | | | | |
| [^{F29} 241] | 22960 | 00001089521 | phenol | no | yes | no | 3] | | | |
| 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 | 00001094904 | 2,5-dihydrofuran | yes | yes | no | 0,6 | | | |
| 247 | 24820 | 00001105564 | suberic acid | yes | yes | no | | | | |
| | 90960 | | | | | | | | | |
| 248 | 19540 | 00001104167 | maleic acid | yes | yes | no | | (3) | | |
| | 64800 | | | | | | | | | |
| 249 | 17290 | 00001104174 | 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 | 00001104414 | sebacic acid | yes | no | no | | | | |

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| | | | | | | | | | |
|----------------------|-------|--------------|------------------------------|-----|----|------|------|--|---|
| 253 | 15250 | 0000110160-1 | no | yes | no | | | | |
| | | | diaminobutane | | | | | | |
| 254 | 13720 | 0000110164-4 | yes | yes | no | | (30) | | |
| | 40580 | | butanediol | | | | | | |
| 255 | 25900 | 0000110188-3 | no | yes | no | 5 | | | |
| | | | hexane | | | | | | |
| 256 | 18010 | 0000110244-9 | yes | yes | no | | | | |
| | 55680 | | Malic acid | | | | | | |
| [^{F30} 257 | 13550 | 0000110288-5 | yes | yes | no | | | | |
| | 16660 | 0025265-71-8 | | | | | | | |
| | 51760 | | | | | | | | |
| | | | propylene glycol | | | | | | |
| 258 | 70480 | 0000111008-8 | yes | no | no | | | | |
| | | | Malic acid, butyl ester | | | | | | |
| 259 | 58720 | 0000111048-9 | yes | no | no | | | | |
| | | | heptanoic acid | | | | | | |
| 260 | 24280 | 0000111206-6 | no | yes | no | | | | |
| | | | sebacic acid | | | | | | |
| 261 | 15790 | 0000111400-0 | yes | yes | no | 5 | | | |
| | | | ethylene diamine | | | | | | |
| 262 | 35284 | 0000111412-1 | yes | no | no | 0,05 | | | |
| | | | N-(2-aminoethyl)ethanolamine | | | | | | Not to be used for articles in contact with fatty foods for which [^{F3} simulant D1 and/or D2] is laid down. For indirect food contact only, behind |

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| | | | | | | | | | | |
|-----|-------|----------|---|-----|----|-----|------|------|---------------------------------------|---|
| 280 | 73720 | 00001159 | Phosphoric acid, trichloroethyl ester | yes | no | no | ND | | | |
| 281 | 25120 | 00001166 | tetrafluoromethylene | yes | no | no | 0,05 | | | |
| 282 | 18430 | 00001166 | hexafluoropropylene | yes | no | no | ND | | | |
| 283 | 74640 | 00001178 | phthalic acid, bis(2-ethylhexyl) ester | yes | no | 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 | 00001193 | salicylic acid, methyl ester | yes | no | no | 30 | | | |
| 285 | 66480 | 00001192 | 4,4'-methylene bis(4-methyl-6-tert-butylphenol) | yes | no | yes | | (13) | | |
| 286 | 38240 | 00001196 | benzophenone | no | no | yes | 0,6 | | | |
| 287 | 60160 | 00001204 | 2-hydroxybenzoic acid, | yes | no | no | | | | |

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| | | | | | | | | | | |
|-----|-------------------------|----------|---|-----|-----|----|-----|------|--------------------------|-----|
| | | | ethyl ester | | | | | | | |
| 288 | 24970 | 00001206 | terephthalic acid, dimethyl ester | yes | no | | | | | |
| 289 | 15880 24051 | 00001204 | 1,3-dihydroxybenzene | no | yes | no | 6 | | | |
| 290 | 55360 | 00001219 | lignosulfonic acid, propyl ester | yes | no | no | | (20) | | |
| 291 | 19150 | 00001215 | isophthalic acid | yes | no | | | (27) | | |
| 292 | 94560 | 00001224 | 2,2,6,6-tetramethylpiperidine | no | yes | no | 5 | | | |
| 293 | 23175 | 00001225 | phosphonic acid, triethyl ester | yes | no | no | ND | | 1 mg/kg in final product | (1) |
| 294 | 93120 | 00001234 | 2,3-dipropionic acid, didodecyl ester | no | yes | | | (14) | | |
| 295 | 15940 18867 48620 | 00001234 | 1,4-dihydroxybenzene | yes | yes | no | 0,6 | | | |
| 296 | 23860 | 00001233 | 3,3,6,6-tetramethylcyclohexanone | yes | no | | | | | |
| 297 | 23950 | 00001236 | phthalic anhydride | no | yes | no | | | | |
| 298 | 14110 | 00001235 | 7,7-dialdehyde | yes | no | | | | | |
| 299 | 63840 | 00001235 | 7,7-dicyclopentadiene | yes | no | no | | | | |
| 300 | 30045 | 00001238 | 3,3,6,6-tetramethylcyclohexane carboxylic acid, butyl ester | yes | no | no | | | | |
| 301 | 89120 | 00001238 | 3,3,6,6-tetramethylcyclohexane carboxylic acid, butyl ester | yes | no | no | | | | |
| 302 | 12820 | 00001239 | 2,2,4,4-tetrahydrophthalic acid | no | yes | no | | | | |

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| | | | | | | | | | | |
|-----|-------|--------------|--------|-----------------------------------|-----|-----|-----|------|--|--|
| 303 | 12130 | 0000124011-0 | 4011-0 | yes | yes | no | | | | |
| | 31730 | | acid | | | | | | | |
| 304 | 14320 | 0000124017-2 | 4017-2 | yes | yes | no | | | | |
| | 41960 | | acid | | | | | | | |
| 305 | 15274 | 0000124024-4 | 4024-4 | ethylene diamine | no | no | 2,4 | | | |
| | 18460 | | | | | | | | | |
| 306 | 88960 | 0000124026-5 | 4026-5 | amides | yes | no | no | | | |
| 307 | 42160 | 0000124031-0 | 4031-0 | carbon dioxide | yes | no | no | | | |
| 308 | 91200 | 0000126513-6 | 6513-6 | acetate isobutyrate | yes | no | no | | | |
| 309 | 91360 | 0000126514-7 | 6514-7 | octaacetate | yes | no | no | | | |
| 310 | 16390 | 0000126232-7 | 6232-7 | dimethyl-1,3-propanediol | no | yes | no | 0,05 | | |
| | 22437 | | | | | | | | | |
| 311 | 16480 | 0000126558-9 | 6558-9 | erythritol | yes | yes | no | | | |
| | 51200 | | | | | | | | | |
| 312 | 21490 | 0000126981-5 | 6981-5 | acrylonitrile | yes | yes | no | ND | | |
| 313 | 16650 | 0000127463-0 | 7463-0 | phenylsulphone | yes | yes | no | 3 | | |
| | 51570 | | | | | | | | | |
| 314 | 23500 | 0000127891-3 | 7891-3 | pinene | no | yes | no | | | |
| 315 | 46640 | 0000128237-0 | 8237-0 | tert-butyl-p-cresol | yes | no | no | 3 | | |
| 316 | 23230 | 0000131171-0 | 1171-0 | phthalic acid, diallyl ester | no | yes | no | ND | | |
| 317 | 48880 | 0000131253-3 | 1253-3 | 4-dihydroxy-2-methoxybenzophenone | yes | no | yes | (8) | | |
| 318 | 48640 | 0000131256-6 | 1256-6 | 4-dihydroxybenzophenone | yes | no | no | (8) | | |
| 319 | 61360 | 0000131257-7 | 1257-7 | 4-hydroxy-2-methoxybenzophenone | yes | no | yes | (8) | | |

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| | | | | | | | | | |
|-----|----------------|-----------|-------------------------------------|-----|-----|-----|------|------|--|
| 320 | 37680 | 000013660 | 707 Sebacic acid, butyl ester | yes | no | no | | | |
| 321 | 36080 | 000013766 | 606 Caproic acid, butyl ester | yes | no | no | | | |
| 322 | 63040 | 000013812 | 217 Lactic acid, butyl ester | yes | no | no | | | |
| 323 | 11470 | 000014088 | 878 Fatty acid, ethyl ester | no | yes | no | | (22) | |
| 324 | 83700 | 000014123 | 5 Fatty acid | yes | no | yes | 42 | | |
| 325 | 10780 | 000014132 | 2 Lactic acid, n-butyl ester | no | yes | no | | (22) | |
| 326 | 12763 35170 | 000014124 | 3-5 aminoethanol | yes | yes | no | 0,05 | | Not to be used for articles in contact with fatty foods for which [F3simulant D1 and/ or D2] is laid down. For indirect food contact only, behind a PET layer. |
| 327 | 30140 | 000014178 | 6 Lactic acid, | yes | no | no | | | |

Status: Point in time view as at 31/12/2020.

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| | | | | | | | | | | |
|----------------------|--------|-------------|----------------------|-----|-----|----|------|----------|--|------|
| | | | ethyl ester | | | | | | | |
| 328 | 65040 | 000014182-1 | 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 | 000014462-1 | acetic acid | yes | yes | no | 6 | | | |
| | 69920 | | | | | | | | | |
| 334 | 17005 | 000015156-4 | ethyleneimine | yes | yes | no | ND | | | |
| 335 | 68960 | 000030102-0 | acetamide | yes | no | no | | | | |
| 336 | 15095 | 000033448-5 | decanoic acid | yes | yes | no | | | | |
| | 45940 | | | | | | | | | |
| 337 | 15820 | 000034542-6 | difluorobenzophenone | no | yes | no | 0,05 | | | |
| 338 | 71020 | 000037340-5 | acetic acid | yes | no | no | | | | |
| 339 | 86160 | 000040951-2 | silicon carbide | yes | no | no | | | | |
| [^{F32} 340 | 47440 | 000046158-5 | cyanogen chloride | no | no | no | 60] | | | |
| 341 | 13180 | 000049866-8 | [2,2,1]hept-2-ene | | | no | 0,05 | | | |
| | 22550 | | | | | | | | | |
| 342 | 14260 | 000050244-3 | lactone | yes | yes | no | | (29) | | |
| 343 | 23770 | 000050416-2 | propanediol | no | yes | no | 0,05 | | | |
| [^{F29} 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 | 000051410-6 | acetic acid | no | yes | no | | | | |
| 347 | 13050 | 000052844-0 | acetic acid | no | yes | no | | (21) | | |

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| | | | | | | | | | | |
|-----|-------|-------------|-----------------------------------|-----|-----|----|------|------|---|------|
| | 25540 | | | | | | | | | |
| 348 | 22350 | 000054463-8 | no phthalic acid | yes | yes | no | | | | |
| | 67891 | | | | | | | | | |
| 349 | 25550 | 000055210-7 | no phthalic anhydride | yes | yes | no | | (21) | | |
| 350 | 63920 | 000055715-5 | no sebacic acid | yes | no | no | | | | |
| 351 | 21730 | 000056334-1 | no methyl-1-butene | yes | yes | no | ND | | Only to be used in polypropylene | (1) |
| 352 | 16360 | 000057622-6 | no dimethylphenol | yes | yes | no | 0,05 | | | |
| 353 | 42480 | 000058400-8 | no succinic acid, rubidium salt | yes | no | no | 12 | | | |
| 354 | 25210 | 000058428-9 | no toluene diisocyanate | yes | yes | no | | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 355 | 20170 | 000058506-9 | no acrylic acid, tert-butyl ester | yes | yes | no | | (23) | | |
| 356 | 18820 | 000059214-1 | no hexene | yes | yes | no | 3 | | | |
| 357 | 13932 | 000059832-3 | 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 | 000059946-4 | no cumylphenol | yes | yes | no | 0,05 | | | |

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| | | | | | | | | |
|----------------------|-------|----------------|------------------------|-----|----|------|--|---|
| 359 | 15970 | 000061149-4 | yes | yes | no | (8) | | |
| | 48720 | | 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 | | | | | |
| [^{F29} 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 |

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| | | | | | | | | | |
|----------------------|-------|--------------|---|-----|-----|----|------|---|------|
| 372 | 18640 | 0000822406-0 | hexamethylene diisocyanate | yes | no | | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 373 | 22390 | 0000840266-3 | 2-naphthalenedicarboxylic acid, dimethyl ester | no | yes | no | 0,05 | | |
| 374 | 21190 | 0000868771-9 | methacrylic acid, monoester with ethyleneglycol | yes | no | | (23) | | |
| 375 | 15130 | 0000872105-9 | decene | no | yes | no | 0,05 | | |
| [^{F31} 376 | 66905 | 0000872150-4 | 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 | |

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| | | | | | | | | | | treatment of materials and articles. |
|-----|-------|---------|--|-----|-----|-----|------|------|--|---|
| 378 | 21970 | 0000923 | 102-4 methylmethacrylamide | no | yes | no | 0,05 | | | |
| 379 | 21940 | 0000924 | 142-5 methylolacrylamide | no | yes | no | ND | | | |
| 380 | 11980 | 0000925 | 60-1 acrylic acid, propyl ester | no | yes | no | | (22) | | |
| 381 | 15030 | 0000931 | 81-4 1,8-dioxane | yes | no | no | 0,05 | | | Only to be used in polymers contacting foods for which simulant A is laid down |
| 382 | 19490 | 0000947 | 104-6 lactam | yes | no | no | 5 | | | |
| 383 | 72160 | 0000948 | 265-2 phenylindole | yes | no | yes | 15 | | | |
| 384 | 40000 | 0000991 | 1284-4 bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine | yes | no | yes | 30 | | | |
| 385 | 11530 | 0000999 | 60-1 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, |

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| | | | | | | | | | | |
|---------------------|-------|---------|--|-----|-----|----|------|------|--|---|
| | | | | | | | | | 2-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 acetic acid, octyl ester | yes | no | no | | (20) | | |
| 387 | 26155 | 0001072 | 2463-5 vinylimidazole | no | yes | no | 0,05 | | | [^{F28} (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 acetic acid, dodecyl ester | yes | no | no | | (20) | | |
| [^{F3} 391 | 22932 | 0001187 | 2355 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 |

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| | | | | | | | | | ratio 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 | 2,2,4,4-tetranitro | yes | no | no | | | |
| 394 | 41280 | 0001305 | 5,6,10-trimethylhydroxide | yes | no | no | | | |
| 395 | 41520 | 0001305 | 5,7,8-trimethyl oxide | yes | no | no | | | |
| 396 | 64640 | 0001309 | 4,8-bisphenol hydroxide | yes | no | no | | | |
| 397 | 64720 | 0001309 | 4,8-bisphenol oxide | yes | no | no | | | |
| [^{F13} 398 | 35760 | 0001309 | antimony trioxide | yes | no | no | | | (6)] |
| 399 | 81600 | 0001310 | 5,8-bisphenol hydroxide | yes | no | no | | | |
| 400 | 86720 | 0001310 | 5,7,12-trimethyl hydroxide | yes | no | no | | | |
| 401 | 24475 | 0001313 | 8,12-dithiolane sulphide | no | yes | no | | | |
| 402 | 96240 | 0001314 | zinc 2-oxide | yes | no | no | | | |
| 403 | 96320 | 0001314 | zinc 3-sulphide | yes | no | no | | | |
| 404 | 67200 | 0001317 | 1,3,5-benzenedisulphide | yes | no | no | | | |
| 405 | 16690 | 0001321 | 1,4-dioxolane | yes | no | ND | | SML (1) expressed | |

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| | | | | | | | | | |
|----------------------|-------|--------------|---|-----|----|----|------|--|--|
| | | | | | | | | | as the 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 | | | |
| I ^{F29} 410 | 62720 | 0001332158-7 | ethylene vinyl alcohol copolymer (EVOH) | 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 |

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| | | | | | | | | |
|-----|-------|---------|--------------|-----|----|----|--|--|
| | | | | | | | | layer 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 |

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| | | | | | | | | | |
|-----|-------|---------|----------------------------|-----|----|----|-----|--|---|
| | | | | | | | | | of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w. |
| 412 | 45200 | 0001335 | 5235 copper iodide | yes | no | no | (6) | | |
| 413 | 35600 | 0001336 | 2116 antimony hydroxide | yes | no | no | | | |
| 414 | 87600 | 0001338 | 5012 sorbitan monolaurate | yes | no | no | | | |
| 415 | 87840 | 0001338 | 5011 sorbitan monostearate | yes | no | no | | | |
| 416 | 87680 | 0001338 | 5011 sorbitan monooleate | yes | no | no | | | |

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| | | | | | | | | | |
|----------------------|----------------|---------|--|-----|-----|-----|------|--------|---|
| 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 | | |
| [^{F32} 421 | 13000 | 0001477 | 55-0 benzenedimethanamine | no | yes | no | | (34)] | |
| 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 | 06-4 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 | | |

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| | | | | | | | | | |
|----------------------|-------|------------------|---|-----|-----|-----|------|------|--|
| 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 | 0002082817-1 | 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 | acrylic acid, dodecyl ester | no | yes | no | 0,05 | | (2) |
| [^{F31} 438 | 13303 | 0002162574(25-6) | diisopropylphenyl carbodiimide | no | yes | no | 0,05 | | Expressed as the sum of bis(2,6-diisopropylphenyl)carbodiimide and its hydrolysis product 2,6-diisopropylaniline I |
| 439 | 21280 | 0002177701-1 | acrylic acid, | yes | yes | no | | (23) | |

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| | | | | | | | | | |
|-----|-------|---------|---|-----|-----|----|--------|------|--|
| | | | 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 epoxy group. 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 | 4801 dodecyl disulphide | no | yes | | 0,05] | | |

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| | | | | | | | | | |
|----------------------|-------|------------|---|-----|-----|----|------|------|--|
| 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 |
| [^{F31} 452 | 38885 | 0002725224 | 6-bis(2,4-dimethylphenyl)-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine | yes | no | no | 5] | | |
| 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 | | | |

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| | | | | | | | | | |
|----------------------|--------|----------|---|-----|-----|-----|------|---|-----------------------|
| | | | dioctadecyl ester | | | | | | |
| 460 | 14950 | 00031735 | 1,3-bis(3-hydroxyisocyanate) | yes | no | | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 461 | 22420 | 00031734 | 7,6-naphthalene diisocyanate | no | yes | no | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 462 | 26170 | 00031957 | 8-6 vinyl-N-methylacetamide | no | yes | no | 0,02 | | [^{F28} (1)] |
| 463 | 25840 | 00032904 | 2,4-trimethylolpropane trimethacrylate | no | yes | no | 0,05 | | |
| 464 | 61280 | 00032933 | 297-8 hydroxy-4-n-hexyloxybenzophenone | yes | no | yes | (8) | | |
| 465 | 68040 | 00033337 | 281-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin | yes | no | no | | | |
| 466 | 50640 | 00036481 | 1,8-octyltin dilaurate | yes | no | no | (10) | | |
| [^{F33} 467 | 14800 | 3724-650 | 4-trotonic acid | yes | yes | no | (35) | | |
| | 45600] | | | | | | | | |
| 468 | 71960 | 00038252 | 26-fluorocortic acid, ammonium salt | yes | no | no | | Only to be used in repeated use articles, | |

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| | | | | | | | | | | |
|-----|-------|---------------|--|-----|-----|-----|------|------|--|------|
| | | | | | | | | | sintered at high temperatures | |
| 469 | 60480 | 000386429(21) | hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole | yes | no | yes | | (12) | | |
| 470 | 60400 | 000389621(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 | 000406620(8) | methylenebis(4-methyl-6-cyclohexylphenol) | yes | no | yes | | (5) | | |
| 473 | 12265 | 000407440(1) | acid, divinyl ester | no | yes | no | ND | | 5 mg/kg in final product. Only to be used as co-monomer. | (1) |
| 474 | 43600 | 000408043(3) | chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride | yes | no | no | 0,3 | | | |
| 475 | 19110 | 000409847-9 | isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane | no | yes | no | | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |

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| | | | | | | | | | | |
|-----|----------------|----------|--|-----|-----|-----|------|------|---|-----------------------|
| 476 | 16570 | 00041288 | 1738-4-4 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 | 25-6 succinic 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 | [^{F28} (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 | 01-4 diisocyanate | yes | no | no | | (17) | 1 mg/ kg in final product | (10) |

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| | | | | | | | | | | expressed as isocyanate moiety |
|-----|-------|---------|--|-----|----|----|------|------|---|---|
| 486 | 54005 | 0005136 | 44-7- 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 | 18-3 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 | (10) |
| 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 | 40-2 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 | | | |

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| | | | | | | | | | |
|-----|----------------|---------|--|-----|-----|-----|------|--|---|
| 496 | 71680 | 0006683 | phenylacrylate 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 | | | |

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| | | | | | | | | | | |
|-----|-------|---------|-------|--------------------|-----|-----|----|--|------|--|
| 511 | 91920 | 0007664 | 45019 | peroxy acid | yes | no | no | | | |
| 512 | 81680 | 0007681 | 16016 | potassium iodide | yes | no | no | | (6) | |
| 513 | 86800 | 0007681 | 8215 | 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 | iodic 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 | lanolin oil | no | yes | no | | | |
| 525 | 62640 | 0008001 | 1306 | Japan wax | yes | no | no | | | |
| 526 | 43440 | 0008001 | 1750 | linseed oil | yes | no | no | | | |
| 527 | 14411 | 0008001 | 1790 | ster oil | yes | yes | no | | | |
| | 42880 | | | | | | | | | |
| 528 | 63760 | 0008002 | 1431 | linseed oil | yes | no | no | | | |
| 529 | 67850 | 0008002 | 2507 | lanolin wax | yes | no | no | | | |
| 530 | 41760 | 0008006 | 4148 | beeswax | yes | no | no | | | |
| 531 | 36880 | 0008012 | 2893 | beeswax | yes | no | no | | | |

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| | | | | | | | | | | |
|-----|-------|---------|------|-------------------------------|----|----|-------------|------|-----|---|
| 532 | 88640 | 0008013 | 0718 | 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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| | | | | | | | | | iodine number < 6. |
|-----|-------|------------|-----------------------------------|-----|-----|----|------|--|--|
| 533 | 42720 | 0008015869 | Sebacic wax | yes | no | no | | | |
| 534 | 80720 | 0008017065 | phosphoric acids | yes | no | no | | | |
| 535 | 24100 | 0008050091 | | yes | yes | no | | | |
| | 24130 | | | | | | | | |
| | 24190 | | | | | | | | |
| | 83840 | | | | | | | | |
| 536 | 84320 | 0008050045 | hydrogenated, ester with methanol | yes | no | no | | | |
| 537 | 84080 | 0008050026 | ester with pentaerythritol | yes | no | no | | | |
| 538 | 84000 | 0008050031 | 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 | xylose | yes | no | no | | | |
| 543 | 45920 | 0009000012 | mar | yes | no | no | | | |
| 544 | 58400 | 0009000020 | gum | yes | no | no | | | |
| 545 | 93680 | 0009000015 | gum | yes | no | no | | | |
| 546 | 71440 | 0009000017 | xylose | yes | no | no | | | |

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| | | | | | | | | |
|-----|----------------|--------------|--------------------------------------|-----|-----|----|---|---|
| 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 | cellulose, 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 | polyethylene tridecyl | yes | no | no | 5 | For materials 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)

| | | | | | | | | |
|-----|----------------|-------------|------------------------------------|-----|-----|----|------|---|
| | | | 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 | 001001620-3 | dextrin | yes | no | no | | |
| 581 | 36800 | 00100222118 | nitrate | yes | no | no | | |
| 582 | 50240 | 001003933-5 | octyltin bis(2-ethylhexyl maleate) | yes | no | no | (10) | |
| 583 | 40400 | 00100433615 | nitride | yes | no | no | (16) | |
| 584 | 13620 40320 | 00100433613 | acid | yes | yes | no | (16) | |
| 585 | 41120 | 00100433124 | chloride | yes | no | no | | |
| 586 | 65280 | 00100433812 | hypophosphite | yes | no | no | | |
| 587 | 68400 | 001009445-8 | recycled polyurethane | yes | yes | 5 | | |

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| | | | | | | | | | |
|-----|-------|--------------------|--|-----|-----|----|------|--|-----------------|
| 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 ethyl 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 ₁₀ 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 (OH) ₂ Si ₂ O ₇ magnesian talc | yes | no | no | | | |
| 601 | 35440 | 0012124 | AgBr silver bromide | yes | no | no | | | |
| 602 | 70240 | 0012198 | Ca ₂ (Mg) ₂ (OH) ₂ (CO ₃) ₂ kerolite | yes | no | no | | | |
| 603 | 83460 | 0012269 | C ₁₂ H ₁₀ N ₂ pyridazine | yes | no | no | | | |
| 604 | 60080 | 0012304 | Ca ₂ (Mg) ₂ (OH) ₂ (CO ₃) ₂ hyalite | 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 ₃ phosphide | yes | no | no | | | Only to be used |

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| | | | | | | | | | | in PET polymers and copolymers |
|-----|-------|--------------|--|-----|-----|-----|------|------|--|---|
| 608 | 40800 | 0013003414-8 | butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite) | yes | no | yes | 6 | | | |
| 609 | 83455 | 0013445562 | pyrophosphoric acid | no | no | no | | | | |
| 610 | 93440 | 0013463677 | tin 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 | calcite | yes | no | no | | | | |
| 616 | 83470 | 0014808607 | calcite | 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) | | |

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| | | | | | | | | | | |
|-----|-------|--------------|---|-----|-----|-----|------|------|--|-----|
| 620 | 50720 | 001557160-5 | 160-5 octyltin dimalate | 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 | 6409-7 ethoxybenzoic acid, ethyl ester | yes | no | no | 3,6 | | | |
| 633 | 53200 | 0023949266-8 | 9266-8 ethoxy-2'-ethyloxanilide | yes | no | yes | 30 | | | |
| 634 | 25910 | 0024800410-1 | 410-1 propyleneglycol | yes | no | no | | | | |
| 635 | 40720 | 0025013416-5 | 3416-5 butyl-4-hydroxyanisole | yes | no | no | 30 | | | |

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| | | | | | | | | | | |
|---------------------|-------|---------|--|-----|-----|----|--------|------|---|--|
| 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 [^{F3} 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 | | | |
| [^{F3} 641 | 22331 | 0025513 | 3,6-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] | | | |
| 642 | 64990 | 0025736 | maleic anhydride- | yes | no | no | | | The fraction | |

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| | | | styrene, copolymer, sodium salt | | | | | | with molecular weight below 1 000 Da [^{F3} shall] not exceed 0,05 % (w/w) | |
|-----|-------|-------------|---|-----|-----|-----|------|------|--|------|
| 643 | 87760 | 00262665719 | stearic monopalmitate | yes | no | no | | | | |
| 644 | 88080 | 00262665811 | stearic trioleate | yes | no | no | | | | |
| 645 | 67760 | 00264018615 | n- octyltin tris(isooctyl mercaptoacetate) | yes | no | no | (11) | | | |
| 646 | 50480 | 00264018718 | octyltin bis(isooctyl mercaptoacetate) | yes | no | no | (10) | | | |
| 647 | 56720 | 00264022313 | hexyl monohexanoate | yes | no | no | | | | |
| 648 | 56880 | 00264022616 | hexyl monooctanoate | yes | no | no | | | | |
| 649 | 47210 | 00264274016 | butyltin diethyltin stannonic acid polymer | no | no | no | | | Molecular unit = (C ₈ H ₁₈ S ₃ Sn ₂) _n (n = 1,5-2) | |
| 650 | 49600 | 00266364011 | dimethyltin bis(isooctyl mercaptoacetate) | yes | no | no | (9) | | | |
| 651 | 88240 | 00266580517 | stearic tristearate | yes | no | no | | | | |
| 652 | 38820 | 00267415317 | (2,4- di-tert- butylphenyl) pentaerythritol diphosphite | yes | no | yes | 0,6 | | | |
| 653 | 25270 | 00267472910 | toluene diisocyanate dimer | no | yes | no | | (17) | 1 mg/ kg in final product | (10) |

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| | | | | | | | | | expressed as isocyanate moiety |
|-----|-------|---------|---|-----|-----|-----|-------|------|---|
| 654 | 88600 | 0026836 | 47-101 sebitol monostearate | yes | no | no | | | |
| 655 | 25450 | 0026896 | 48-010 dioctyl dicaprylate | no | no | no | 0,05 | | |
| 656 | 24760 | 0026914 | 43-201 styrene sulfonic 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 dodecylbenzene sulfonic 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 maleic acid | yes | no | no | | | |
| 664 | 95000 | 0028931 | 67-4 trimethylolpropane trimethacrylate- methyl methacrylate copolymer | no | no | no | | | |
| 665 | 83120 | 0029013 | 28-3 propyleneglycol monopalmitate | yes | no | no | | | |

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| | | | | | | | | | |
|-----|-------|-------------|--|-----|----|-----|--------------|---|--|
| 666 | 87280 | 00291165081 | orbitan 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 ₃ 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 | 0032647679 | dibenzylidene 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) | | |

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| | | | | | | | | | | |
|-----|-------|--------------|--|-----|-----|-----|------|--|--|--|
| | | | 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 | 0037206012-2 | butylcarboxymethylcellulose | yes | yes | no | | | | |
| 684 | 68125 | 0037244206-1 | 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 |

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| | | | | | | | | | | 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) | |

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| | | | | | | | | | |
|-----|----------|----------|--|-----|-----|-----|-----|------|-----|
| 696 | 92205 | 00575694 | 40-phthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol) | no | no | | | | |
| 697 | 67515 | 00575833 | 3,3'-dimethyltris(ethylhexyl mercaptoacetate) | no | no | | (9) | | |
| 698 | 49595 | 00575833 | 3,5-dimethylbis(ethylhexyl mercaptoacetate) | no | no | | (9) | | |
| 699 | 90720 | 00584466 | 2,2-bis(4-phenylbenzoyl)propane | 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 polyethylene glycol 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 | | | | | | | | |

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| | | | | | | | | | | |
|---------------------|-------|---------|--|-----|-----|-----|----|--|--|--|
| | | | 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 | Diethyl sebacate ester of castor oil | no | no | no | 42 | | | |
| 709 | 87520 | 0062568 | Sorbitan monobehenate | yes | no | no | | | | |
| 710 | 38700 | 0063397 | Di(2-carboethoxyethyl)tin-bis(isooctyl mercaptoacetate) | yes | no | yes | 18 | | | |
| 711 | 42000 | 0063438 | Di(2-carboethoxyethyl)tin-tris(isooctyl mercaptoacetate) | yes | no | yes | 30 | | | |
| 712 | 42960 | 0064147 | Castor oil, dehydrated | yes | no | no | | | | |
| F ²⁹ 713 | 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] | | | | | | | |

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| | | | | | | | | | Regulation (EU) No 231/2012 ^d with exception of ash content which can be up to 10 % (w/w). |
|-----|-------|---------|---|-----|----|----|----|--|---|
| 714 | 84400 | 0064365 | F0510 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 | 720 hydroxyethyl)-4- hydroxy-2,2,6,6- tetramethyl piperidine- succinic acid, dimethyl ester, copolymer | yes | no | no | 30 | | |
| 717 | 84210 | 0065997 | F0610 hydrogenated | yes | no | no | | | |
| 718 | 84240 | 0065997 | F0310 hydrogenated, ester with glycerol | yes | no | no | | | |
| 719 | 65920 | 0066822 | N60-4 methacryloyloxyethyl- N,N- dimethyl- N- | yes | no | no | | | |

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| | | | | | | | | | |
|-----|-------|---------|---|-----|-----|----|------|--|--|
| | | | carboxymethylammonium chloride, sodium salt - octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers | | | | | | |
| 720 | 67360 | 0067649 | n- dodecyltin tris(isooctyl mercaptoacetate) | yes | no | no | (25) | | |
| 721 | 46800 | 0067845 | tert-butyl-4-hydroxybenzoic acid, hexadecyl ester | yes | no | no | | | |
| 722 | 17200 | 0068308 | faty2 acids, soya | no | yes | no | | | |
| 723 | 88880 | 0068412 | starch, hydrolysed | yes | no | no | | | |
| 724 | 24903 | 0068425 | syrups, hydrolysed starch, hydrogenated | no | yes | no | | | In compliance with the purity criteria for maltitol syrup E 965(ii) as laid down in Commission Directive 2008/60/EC ^e |

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| | | | | | | | | | |
|-----|-------|--------------------|---|-----|----|-----|--------------|---------------------------------------|--|
| 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 |

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| | | | | | | | | | | |
|-----|-------|--------------------|---|-----|----|----|--------------|---------------------------------------|--|--|
| | | | | | | | | | | 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 | |

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| | | | | | | | | | | |
|-----|-------|---------|------|---------------------|----|--|--|--|--|--|
| | | | | | | | | | | 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 | methylsilsequioxane | no | | | | | Residual monomer in methylsilsequioxane: |

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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)

| | | | | | | | | | < 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 fatty, unsaturated (C ₁₈), dimers, hydrogenated, distilled and non- distilled | no | yes | no | | (18) | | (1) |
| 734 | 46380 | 0068855 | 540 diatomaceous earth, soda ash flux- calcined | no | no | no | | | | |
| 735 | 40120 | 0068951 | 5018 bis[2-(2-hydroxyethyl)phosphonate] | no | no | no | | | | |
| 736 | 50960 | 0069226 | 44-4 octyltin ethyleneglycol bis(mercaptoacetate) | yes | no | no | | (10) | | |
| 737 | 77370 | 0070142 | 2046 polyethyleneglycol-30 dipolyhydroxystearate | yes | no | no | | | | |
| 738 | 60320 | 0070321 | 2827 hydroxy-3,5- bis(1,1- dimethylbenzyl)phenyl]benzotriazole | yes | no | yes | 1,5 | | | |
| 739 | 70000 | 0070331 | 2921 oxamidobis[ethyl-3- (3,5- di-tert- butyl-4- hydroxyphenyl)- propionate] | yes | no | no | | | | |

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| | | | | | | | | | | |
|----------------------|----------------|----------|---|-----|-----|-----|---|------|--|--|
| 740 | 81200 | 0071878 | 81086- [(1,1,3,3- tetramethylbutyl)amino]-1,3,5- triazine-2,4- diyl]- [(2,2,6,6- tetramethyl-4- piperidyl)- imino]hexamethylene[(2,2,6,6- tetramethyl-4- piperidyl) imino] | yes | no | yes | 3 | | | |
| 741 | 24070 83610 | 0073138 | 8316 acids and rosin acids | yes | yes | no | | | | |
| 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 | 2944 ethylbenzylidene)sorbitol | yes | no | no | | | | |
| [^{F33} 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.] | |

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| | | | | | | | | | |
|---------------------|-------|---|---|-----|-----|-----|------|------|---|
| 745 | 68145 | 0080410232-9 | 2,2'-nitri(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)pentacerythritol 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 | 0085209221-4 | methylenebis(4,6-di-tert-butylphenyl) lithium phosphate | yes | no | no | 5 | | |
| 751 | 81515 | 0087189251-2 | poly(zinc glycerolate) | yes | no | no | | | |
| [^{F3} 752 | 39890 | 008782641-3 0069158-41-4 0054686-97-4 0081541-12-0 | bis(methylbenzylidene)sorbitol | yes | no | no | | | |
| 753 | 62800 | 0092704401-1 | calcined kaolin | 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)

| | | | | | | | | | |
|-----|-------|-------------|---|-----|-----|-----|------|------|---|
| 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 |

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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)

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | 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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| | | | | | | | | | (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 | 6 | | | | | |
| 762 | 31530 | 0123968 | 2,5-Dic acid, 2,4-di-tert-pentyl-6-(1-(3,5-di-tert- | yes | no | yes | 5 | | | | |

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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)

| | | | | | | | | | | |
|-----|-------|------------|--|-----|-----|-----|------|--|---|-----|
| | | | 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 | 0134701245 | 20-5 dimethyl-6-(1-methylpentadecyl)phenol | yes | no | yes | 1 | | | |
| 766 | 38879 | 0135861563 | 56-3 dimethylbenzylidene)sorbitol | yes | no | no | | | | |
| 767 | 38510 | 0136504196 | 76-6 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 | 0143925602 | 60-2 bis(hydrogenated tallow alkyl) oxidised | yes | no | no | | | Not to be used for articles in contact with fatty foods | (1) |

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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)

| | | | | | | | | | for which [^{F3} 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 | 2504-2-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol | yes | no | no | 0,05 | | | |
| 771 | 34650 | 0151841 | 165-1-1-hydroxybis[2,2'-methylenebis(4,6-di-tert-butylphenyl) phosphate] | yes | no | no | 5 | | | |
| 772 | 47500 | 0153250 | 05243-dicyclohexyl-2,6- | yes | no | no | 5 | | | |

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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)

| | | | | | | | | | |
|-----|-------|-----------|--|-----|----|-----|---|------|--|
| | | | naphthalene dicarboxamide | | | | | | |
| 773 | 38840 | 015486254 | 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 | 01617172 | 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 | 01664121 | cyclohexanedicarboxylic acid, diisononyl ester | yes | no | no | | (32) | |
| 776 | 76723 | 0167883 | polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4'-diisocyanate | yes | no | no | | | The fraction with molecular weight below 1 000 Da [^{F3} shall] not exceed 1,5 % (w/w) |

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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)

| | | | | | | | | | | |
|----------------------|-------|---------|---|-----|----|-----|------|--|------------------------|-----------------------|
| 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 | Isoterebutyl tetrakis (2-cyano-3,3-diphenylacrylate) | no | no | yes | 0,05 | | | |
| [^{F3} 779] | 39815 | 0182121 | 1,2-bis(methoxymethyl)fluorene | yes | no | yes | 0,05 | | | [^{F28} (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 31/12/2020.

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 ³ shall] not exceed 1 % (w/w) | |
| 783 | 55910 | 0736150 | glycerides of castor-oil mono-, hydrogenated, acetates | | no | no | | (32) | |
| [F ²⁹ 784 | 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-dichlorophthalic anhydride | no | yes | no | 0,05 | | SML expressed as 3-chlorophthalic acid |
| 787 | 14628 | 0000118 | 4-chlorophthalic anhydride | no | yes | no | 0,05 | | SML expressed as 4-chlorophthalic acid |

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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)

| | | | | | | | | | | |
|-----|-------|--------------------|--|-----|-----|----|------|--|--|-------------|
| 788 | 21498 | 0002530 | 135-0 (methacryloxy)propyltrimethoxysilane | 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 ($3,8 \times 10^{-6}$ m ² /s). | (2) |
| 790 | 80480 | 0090751 0082451 | 1487 1487 morpholino-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 \leq 30 mg/kg, of N,N'-bis(2,2,6,6-tetramethylpiperidin-4- | (16) |

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| | | | | | | | | | | |
|-----|-------|---------|--|-----|----|-----|------|--|--|--|
| | | | | | | | | | | 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 |

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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)

| | | | | | | | | | |
|---------|-------|---------|--|-----|-----|-----|------|--|---|
| | | | | | | | | | as triethanolamine |
| [F31794 | 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 |

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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)

| | | | | | | | | | |
|----------------------|-------|---------|--|-----|-----|-----|----------------|---|--|
| | | | benzoxazin-4-one] | | | | | of its hydrolysis products | |
| [^{F31} 797 | 76807 | 0073018 | 2,5-diethyl-1,6-hexanedioic acid diethyl ester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol | no | yes | | (31) (32)] | | |
| 798 | 92200 | 0006422 | terephthalic acid, bis(2-ethylhexyl)ester | no | no | 60 | (32) | | |
| [^{F29} 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 | triethyl phosphonoacetate | yes | no | no | | Only for use in PET | |
| 801 | 30607 | — | acids, C ₂ -C ₂₄ , aliphatic, linear, | 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)

| | | | | | | | | | |
|-----|-------|---------|---|-----|----|----|---|--|------|
| | | | monocarboxylic, 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 [^{F3} 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- thiopropene-1,3- diyl)- block- poly(x- oleyl-7- hydroxy-1,5- diiminoctane-1,8- | yes | no | no | | Only to be used as polymer production aid in polyethylene (PE), polypropylene | |

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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)

| | | | | | | | | | |
|----------------------|-------|--------------|---|-----|-----|----|---|--|--|
| | | | diyl), process mixture with x = 1 and/ or 5, neutralised with dodecylbenzenesulfonic acid | | | | | | (PP) and polystyrene (PS) |
| 805 | 93450 | — | titanium dioxide, coated with a copolymer of n- octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt] | yes | no | no | | | The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/ w |
| 806 | 14876 | 0001076197-7 | cyclohexanedicarboxylic acid | no | yes | no | 5 | | Only to be used for manufacture of polyesters |
| [^{F30} 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 |

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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)

| | | | | | | | | | |
|-----|-------|---------|--|-----|----|-----|------|------|--|
| | | | | | | | | | agglomerates have a diameter of 100-500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm. |
| 808 | 38550 | 0882073 | 14(4) propylbenzylidene)propylsorbitol | yes | no | no | 5 | | SML including the sum of its hydrolysis products |
| 809 | 49080 | 0852282 | 189-4 (2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3-dione | yes | no | yes | 0,05 | | Only (6) for use (14) in PET (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 [^{F3} simulant D1 and/or D2] |

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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)

| | | | | | | | | | |
|----------------------|-------|---------|--|----|----|----|------|--|---|
| | | | | | | | | | is laid down. |
| 811 | 80077 | 006844 | polyethylene waxes, oxidised | no | no | 60 | | | |
| [^{F31} 812 | 80350 | 0124578 | poly(12-hydroxystearic acid)-polyethyleneimine copolymer | no | no | | | | Only to be used in plastics up to 0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine. |
| 813 | 91530 | — | sulphosuccinic acid alkyl (C ₄ -C ₂₀) or cyclohexyl diesters, salts | no | no | 5 | | | |
| 814 | 91815 | — | sulphosuccinic acid monoalkyl (C ₁₀ -C ₁₆) polyethyleneglycol esters, salts | no | no | 2 | | | |
| 815 | 94985 | — | trimethylolpropane mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid | no | no | 5 | (32) | | Not to be used for articles in contact with fatty foods for |

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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)

| | | | | | | | | | | which [^{F3} simulant D1 and/ or D2] is laid down |
|-----|-------|---|---|-----|----|----|------|--|--|---|
| 816 | 45704 | — | cis-1,2-cyclohexanedicarboxylic acid, salts | yes | no | no | 5 | | | |
| 817 | 38507 | — | cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts | yes | no | no | 5 | | | Not to be used with polyethylene in contact with acidic foods. Purity ≥ 96 %. |
| 818 | 21530 | — | methallylsulphonic acid, salts | yes | 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 [^{F3} simulant D1 and/ |

Status: Point in time view as at 31/12/2020.

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 D2] is laid down. SML expressed as neodecanoic acid. | |
| 820 | 76420 | — | pimelic acid, salts | yes | no | no | | | | |
| 821 | 90810 | — | stearoyl-lactylic acid, salts | yes | no | no | | | | |
| [^{F35} 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 | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | | |
|----------------------|-------|----------|---|-----|----|----|--|--|--|---|
| I ^{F36} 855 | 40560 | | (butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate | yes | no | no | | | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below. | |
| I ^{F37} 856 | 40563 | 25101-28 | (butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate | yes | 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) |

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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)

| | | | | | | | | | |
|-----|-------|---------|---|-----|----|----|--|--|--|
| | | | | | | | | | repeat-use articles at room temperature or below, and when either in contact only with aqueous, acidic and/or low alcoholic (< 20 %) foodstuffs for less than 1 day, or when in contact only with dry foodstuffs for any duration of time. |
| 857 | 66765 | 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 |

Status: Point in time view as at 31/12/2020.

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 2 % at room temperature or below.] |
|----------------------------|---|-----|----|-----|------|--|--|---|---|
| [^{F26} X18588565 | 0090498390-1 | 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)propionyloxy)-1,1- dimethylethyl]-2,4,8,10- tetraoxaspiro[5,5]undecane | 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. |
| [^{F23} 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 | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | |
|-----|-------|---------|---|----|----|--|--|--|---|
| | | | | | | | | | it shall be > 40 nm. I |
| 860 | 71980 | 0051798 | pe335 [2- (poly(n- propoxy))propanoic acid] | no | no | | | | Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles |
| 861 | 71990 | 0013252 | pe336 [2- (n- propoxy)propanoic acid] | no | no | | | | Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | |
|----------------------|-------|--------------|------------------------------|-----|----|------|--|---|
| [^{F31} 862 | 15180 | 0018085302-4 | no diacetoxy-1- butene | yes | no | 0,05 | | SML (17) including (19)] the hydrolysis product 3,4-dihydroxy-1-butene Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers. |
| [^{F36} 863 | 15260 | 000064612503 | no decanediamine | 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.] |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | | |
|--------------------|-------|---------------|---|-----|----|----|---|--|--|---|
| 864 | 46330 | 0000056206-4 | 206-4 diamino-6- hydroxypyrimidine | yes | no | no | 5 | | Only to be used in rigid poly(vinyl chloride) (PVC) in contact with non-acidic and non-alcoholic aqueous food | |
| ^{F30} 865 | 40619 | 0025322(99-0) | (99-0) acrylate, methyl methacrylate, butyl methacrylate) copolymer | yes | no | no | | | Only to be used in: (a) rigid poly(vinyl chloride) (PVC) at a maximum level of 1 % w/w; (b) polylactic acid (PLA) at a maximum level of 5 % w/w. |] |
| 866 | 40620 | — | (butyl acrylate, methyl methacrylate) copolymer, | yes | no | no | | | Only to be used in rigid | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | | |
|--------------------|-------|---------|--|----|----|--|--|--|---|---|
| | | | cross-linked with allyl methacrylate | | | | | | poly(vinyl chloride) (PVC) at a maximum level of 7 % | |
| 867 | 40815 | 0040471 | (0040471) 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 % | |
| ^{F30} 868 | 53245 | 0009010 | (0009010) yes acrylate, methyl methacrylate) copolymer | no | no | | | | Only to be used in: | |
| | | | | | | | | | (a) | rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % w/w; |
| | | | | | | | | | (b) | polylactic acid (PLA) at a maximum level of 5 % w/w; |
| | | | | | | | | | (c) | polyethylene terephthalate (PET) at a maximum |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | | level of 5 % w/w. I |
|---------|-------|--------------|--|-----|----|----|---|--|--|--|
| 869 | 66763 | 002713645181 | (oxo) 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 | 0160535406 | N,N'-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide | yes | no | no | 5 | | | |
| [F4]871 | | 0287916863 | Sebacic 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 |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | |
|----------------------|-------|--------------|--|-----|----|------|--|--|-------|
| | | | | | | | | assigns food simulant E, at ambient temperature or below, and when migration of the total oligomeric fraction of less than 1 000 Da does not exceed 50 µg/kg food. | |
| [^{F38} 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)] |
| [^{F36} 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. |]] |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | | |
|----------------------|-------|----------|--|-----|-----|-----|------|------|---|--|
| I ^{F26} 874 | 16265 | 01560656 | 00-8 dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyloxy, ω-3-dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyl polydimethylsiloxane | no | yes | no | 0,05 | (33) | Only to be used as comonomer in siloxane modified polycarbonate. The oligomeric mixture shall be characterised by the formula $C_{24}H_{38}Si_2O_5(SiOC_2H_6)_n$ ($50 > n \geq 26$).] | |
| 875 | 80345 | 0058128 | 21-612 poly(12-hydroxystearic acid) stearate | yes | no | yes | 5 | | | |
| 878 | 31335 | — | acids, fatty (C ₈ -C ₂₂) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary | yes | no | no | | | | |

Status: Point in time view as at 31/12/2020.

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 III does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles. I |
| 882 | 25872 | 0002416293,6 | 293,6-trimethylphenol | no | yes | no | 0,05 | | | |
| 883 | 22074 | 0004457371-0 | 1,5-pentanediol | no | yes | no | 0,05 | | Only to be used in materials in contact with food at a surface to mass ratio up to 0,5 dm ² /kg | |
| 884 | 34240 | 009108217,6 | alkyl(C ₂₁)sulphonic acid, esters with phenol | yes | no | no | 0,05 | | Not to be used for articles in contact with fatty foods for | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | which [^{F3} simulant D1 and/ or D2] is laid down. |
|----------------------|-------|---------|---|-----|----|----|--|------|---|
| 885 | 45676 | 0263244 | 45418 oligomers of (butylene terephthalate) | yes | no | no | | | Only to be used in poly(ethylene terephthalate) (PET), poly(butylene terephthalate) (PBT), polycarbonate (PC), polystyrene (PS) and rigid poly(vinyl chloride) (PVC) plastics in concentrations up to 1 % w/ w, in contact with aqueous, acidic and alcoholic foods, for long term storage at room temperature. |
| [^{F36} 894 | 93360 | 0016545 | 5163 propionic acid, ditetradecyl ester | no | no | | | (14) | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | |
|-----|-------|--------------|--|-----|----|----|------|--|--|
| 895 | 47060 | 017109039635 | 3,5-di-tert-butyl-4-hydroxyphenyl)propanoic acid, esters with C13-C15 branched and linear alcohols | yes | no | no | 0,05 | | Only to be used in polyolefins in contact with foods other than fatty/high-alcoholic and dairy products. |
| 896 | 71958 | 09584453418 | 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 |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | |
|----------------------|--|-------------|--|-----|----|----|--|--|--|
| | | | | | | | | | polyoxymethylene polymers and intended for repeated use articles. |
| [^{F26} 902 | | 000012842-9 | benzothiazol-3-one 1,1-dioxide, sodium salt | yes | no | no | | | The substance shall comply with the specific purity criteria as set out in Commission Regulation (EU) No 231/2012 ¹ .] |
| [^{F23} 903 | | 37486-624- | perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] | yes | no | no | | | Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for: (a) repeated and single use materials and articles when sintered or processed (non-sintered) at |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | | |
|-----|-------|---------|-------------------------------------|-----|----|----|---|--|-----|---|
| | | | | | | | | | | temperatures at or above 360 °C for at least 10 minutes or at higher temperatures for equivalent shorter times; repeated use materials and articles when processed (non-sintered) at temperatures from 300 °C and up to 360 °C for at least 10 minutes. |
| 923 | 39150 | 0000120 | NON-bis(2-hydroxyethyl)dodecanamide | yes | no | no | 5 | | (b) | The residual amount of diethanolamine in plastics, as an impurity and decomposition |

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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)

| | | | | | | | | |
|-----|-------|---------|---|------------|----|------|--|--|
| | | | | | | | | product of the substance, [F ³ shall] not result in a migration of diethanolamine higher than 0,3 mg/kg food. |
| 924 | 94987 | | trimethyl mixed triesters and diesters with n-octanoic and n-decanoic acids | isopropane | no | 0,05 | | Only for use in PET in contact with all types of foods other than fatty, high-alcoholic and dairy products. |
| 926 | 71955 | 0908020 | 2-fluoro(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 |

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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)

| | | | | | | | | | |
|---------|-------|----------|--------------------------------------|-----|----|--|--|---|------|
| | | | | | | | | 10 minutes. | |
| [F23969 | | 24937-78 | 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 below 1 000 Da shall not exceed 5 mg/kg food.] | |
| 971 | 25885 | 0002459 | triphthaloyl trimellitate | yes | no | | | Only 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 | (17) |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | |
|--------------------|-------|---------|---|-----|----|-----|----|--|--|
| | | | | | | | | | fat at the surface. |
| 972 | 45197 | 0012158 | 87466 hydroxide phosphate | yes | no | no | | | |
| 973 | 22931 | 0019430 | (93-Fluoro)butyl ethylene | no | no | no | | | Only to be used as a co-monomer up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures. |
| ^{F35} 974 | 74050 | 939402 | 025-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. II |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | |
|----------------------|-------|--------------|--|-----|-----|----|------|---|
| [^{F26} 979 | 79987 | — | (polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer | no | no | | | Only to be used in polyethylene terephthalate (PET) at a maximum level of 5 % w/w.] |
| [^{F38} 988 | | 3634-83-113- | 1,3-bis(isocyanatomethyl)benzene | no | yes | no | (34) | SML(T) applies to the migration of its hydrolysis product, 1,3-benzenedimethanamine To be used only as co-monomer in the manufacture of a middle layer coating on a poly(ethylene terephthalate) polymer film in a multilayer film.] |
| [^{F23} 998 | | | (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, | yes | no | no | | Only to be used as particles in non-plasticised PVC up to 10 % |

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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)

| | | | | | | | | by number it shall be > 40 nm. | |
|-----------------------|---------|---|-----|----|--|--|--|---|--|
| [^{F39} 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 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. The final material shall be used at room temperature or | |

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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)

| | | | | | | | | |
|-----------------------|--|---------|--|----|----|--|--|--|
| | | | | | | | | below. I |
| 1017 | | 25618-5 | polyglycerol | no | no | | | To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275 °C. |
| [^{F39} 1030 | | | montmorillonite clay modified by dimethyldialkyl(C16-C18)ammonium chloride | no | no | | | Only to be used up to 12 % (w/w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room temperature or below. The sum of the specific migration of 1-chlorohexadecane and 1- |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | |
|----------------------|-----------|-----------------------------|----|-----|----|---|--|---|
| | | | | | | | | chlorooctadecane shall not exceed 0,05 mg/kg food. Can contain platelets in the nanoform that are only in one dimension thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer. |
| [^{F4} 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 |

Status: Point in time view as at 31/12/2020.

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 less than 1 000 Da shall not exceed 50 µg/kg food (expressed as furan-2,5-dicarboxylic acid). |
| 1034 | | 3710-30-37- | no octadiene | yes | no | 0,05 | | Only to be used as a crosslinking co-monomer in the manufacture of polyolefins for contact with any type of foods for long term storage at room temperature, including when packaged under hot-fill conditions. |
| 1043 | | | (butadiene, ethyl acrylate, methyl methacrylate, styrene) | yes | no | no | | Only to be used as particles in |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | |
|--|--|---|--|--|--|---|
| | | copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform | | | | non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 998, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > |
|--|--|---|--|--|--|---|

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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)

| | | | | | | | | | |
|------|------|--------|--|-----|----|----|--|--|--|
| | | | | | | | | | 20 nm, and for at least 95 % by number it shall be > 40 nm.] |
| [F4 | 1045 | 119093 | 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 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. |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | | |
|------|--|----------|--|-----|-----|----|---|-----|--|--------------|
| 1048 | | 624-03-3 | ethylene glycol dipalmitate | yes | no | no | | (2) | Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils. | |
| 1050 | | | zinc oxide, nanoparticles, uncoated | yes | no | no | | | Only to be used in unplasticised polymers. | |
| 1051 | | 42774-1 | N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl) isophthalamide | yes | no | no | 5 | | | |
| 1052 | | 1455-42 | 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 | (22) (23) |

Status: Point in time view as at 31/12/2020.

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 SPG). |
| 1053 | | | fatty acids, C16– 18 saturated, esters with dipentaerythritol | yes | no | no | | | Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils] |
| [^{F39} 1055 | 7695-91 58-95-7 | 2- tocopherol acetate | yes | no | no | | | | Only (24) to be used as antioxidant in polyolefins. |
| [^{F40} 1059 | 147398- 30- 10 | Poly((R)-3- hydroxybutyrate- co- (R)-3- hydroxyhexanoate) | yes | no | no | | (35) | | Only (23)] to be used either alone or blended with other polymers in contact with all foods under contact conditions of up to 6 months and/or 6 months and more, at room |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | |
|------|--|--|-----------------------------|-----|----|----|--|--|
| | | | | | | | | temperature or below, including hot fill or a short heating up phase. The migration of all oligomers with a molecular weight below 1 000 Da shall not exceed 5,0 mg/kg food. |
| 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 |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | |
|-----------------------|---------------|---|----|-----|----|--|--|--|
| | | | | | | | | sunflower seeds that are fit for human consumption. The processing temperature of the plastic containing the additive shall not exceed 240 °C. |
| [^{F41} 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. |
| 1062 | | mixture composed of 97 % tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3 % hexamethyldisilazane | no | yes | no | | | Only to be used for the production of recycled PET and at up to 0,12 % (w/w). |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | | |
|-----------|------------|--------------------------------------|-----|----|----|------|--|--|---|
| | | (HMDS) with CAS No 999-97-3 | | | | | | | |
| [F41]1063 | 1547-26-2 | 3,3,3,4,4,5-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 | yes | no | no | 5 | | | Only to be (26)] |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | |
|-----------------------|---------|---|--|-----|----|------|--|---|
| | | | methyl-branched and linear C ₁₄ - C ₁₈ alkanamides, derived from fatty acids | | | | | used in the manufacture of articles made of polyolefins, and which do not come into contact with foods for which food simulant D2 is assigned in Table 2 of Annex III. |
| [^{F33} 1066 | 23985-7 | 1,2,3,4- | 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 |
| | | tetrahydronaphthalene-2,6-dicarboxylic acid, dimethyl ester | | | | | | |

Status: Point in time view as at 31/12/2020.

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 food simulants A, B, C and/ or D1 are assigned in Table 2 of Annex III. The specific migration limit in column 8 refers to the sum of the substance and of its dimers (cyclic and open chain). I | |
|-----------------------|---------|----------------------|-----|----|--|--|--|---|---|
| [^{F42} 1067 | 616-38- | dimethylno carbonate | yes | no | | | | Only to be used: a) | (27)] with 1,6-hexanediol in the manufacture of polycarbonate pre-polymers that are used at up |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | | |
|-----------------------|-------------|--|----|-----|----|--|--|--|
| [^{F33} 1068 | 2530-83-18- | (2,3-epoxypropoxy)propyl]trimethoxy silane | no | yes | no | | | Only to be used as a component of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for the |
|-----------------------|-------------|--|----|-----|----|--|--|--|

Status: Point in time view as at 31/12/2020.

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 and 0,06 mg/kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer). I |
| [^{F42} 1069 | 75-28-5 | isobutane | yes | no | no | | | Only to be used as a blowing agent. I |
| [^{F43} 1075 | | Montmorillonite clay modified with hexadecyltrimethylammonium bromide | no | no | | | | Only to be used as additive at up to 4,0 % w/w in polylactic acid plastics intended for long-term storage of water at ambient temperature or below. Can form |

Status: Point in time view as at 31/12/2020.

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 in the nanoform that are in one or two dimensions thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer. |
| 1076 | 1227937 | Phosphoric acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl ester | no | no | 0,05 | | Only to be used as an additive at up to 0,2 % w/w in high impact polystyrene materials and articles intended contact with food at room temperature and below, including hot-fill | |

Status: Point in time view as at 31/12/2020.

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 heating up to 100 °C for up to 2 hours. It shall not be used in contact with foods for which simulant C and/or D1 is assigned in Annex III. | |
| 1077 | | | Titanium dioxide surface-treated with fluoride-modified alumina | yes | no | no | | Only to be used at up to 25,0 % w/w, including in the nanoform. | 29] |
| 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 | [^{F23} 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 | [^{F24} [^{F25} 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 | [^{F26} OJ L 83, 22.3.2012, p. 1 .] | | | | | | | | |
| i | [^{F27} 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.] | | | | | | | | |

Status: Point in time view as at 31/12/2020.

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

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

- F23** 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).
- F24** 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).
- F25** 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).
- F26** 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).
- F27** 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).
- F28** 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).
- F29** 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).
- F30** 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).
- F31** 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).
- F32** 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).
- F33** 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).
- F34** 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).
- F35** 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).
- F36** 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).
- F37** 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).

Status: Point in time view as at 31/12/2020.

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

- F38** 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).
- F39** 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).
- F40** Substituted by Commission Regulation (EU) 2019/1338 of 8 August 2019 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F41** 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).
- F42** 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).
- F43** Inserted by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Textual Amendments

- F22** Word in Annex 1 point 1 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 76; 2020 c. 1, Sch. 5 para. 1(1)

2. Group restriction of substances **U.K.**

Table 2 on Group restrictions contains the following information:

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

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

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

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

TABLE 2

| (1) | (2) | (3) | (4) |
|----------------------|------------------|----------------|---------------------------------|
| Group Restriction No | FCM substance No | SML (T)[mg/kg] | Group restriction specification |
| 1 | 128 211 | 6 | expressed as acetaldehyde |
| [^{F32} | 89 227 | 30 | expressed as ethyleneglycol] |

Status: Point in time view as at 31/12/2020.

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 1048 | | |
| 3 | 234 248 | 30 | expressed as maleic acid |
| 4 | 212 435 | 15 | expressed as caprolactam |
| 5 | 137 472 | 3 | expressed as the sum of the substances |
| 6 | 412 512 513 588 | 1 | expressed as iodine |
| 7 | 19 20 | 1,2 | expressed as tertiary amine |
| 8 | 317 318 319 359 431 464 | 6 | expressed as the sum of the substances |
| 9 | 650 695 697 698 726 | 0,18 | expressed as tin |
| 10 | 28 29 30 31 32 33 466 582 618 619 620 646 676 736 | 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 |

Status: Point in time view as at 31/12/2020.

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

| | | | |
|---------------------|------|------|---|
| [^{F31} 14 | 294 | 5 | expressed as the sum of the substances and their oxidation products |
| | 368 | | |
| | 894] | | |
| [^{F29} 15 | 98 | 15 | expressed as formaldehyde] |
| | 196 | | |
| | 344 | | |
| 16 | 407 | 6 | expressed as boron Without prejudice to the provisions of Directive 98/83/EC |
| | 583 | | |
| | 584 | | |
| | 599 | | |
| 17 | 4 | ND | expressed as isocyanate moiety |
| | 167 | | |
| | 169 | | |
| | 198 | | |
| | 274 | | |
| | 354 | | |
| | 372 | | |
| | 460 | | |
| | 461 | | |
| | 475 | | |
| | 476 | | |
| | 485 | | |
| | 490 | | |
| 653 | | | |
| 18 | 705 | 0,05 | expressed as the sum of the substances |
| | 733 | | |
| 19 | 505 | 10 | expressed as SO ₂ |
| | 516 | | |
| | 519 | | |
| 20 | 290 | 30 | expressed as the sum of the substances |
| | 386 | | |
| | 390 | | |
| 21 | 347 | 5 | expressed as trimellitic acid |
| | 349 | | |
| 22 | 70 | 6 | expressed as acrylic acid |
| | 147 | | |
| | 176 | | |
| | 218 | | |
| | 323 | | |
| | 325 | | |
| | 365 | | |
| | 371 | | |
| | 380 | | |
| | 425 | | |
| | 446 | | |
| | 448 | | |
| | 456 | | |

Status: Point in time view as at 31/12/2020.

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 | | |
| 23 | 150 156 181 183 184 355 370 374 439 440 447 457 482 | 6 | expressed as methacrylic acid |
| 24 | 756 758 | 5 | expressed as the sum of the substances |
| 25 | 720 747 | 0,05 | sum of mono-n-dodecyltin tris(isooctylmercaptoacetate), di-n-dodecyltin bis(isooctylmercaptoacetate), 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 |
| [^{F29} 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 | 60 | expressed as the sum of the substances |

Status: Point in time view as at 31/12/2020.

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

| | | | |
|---------------------|--|------|--|
| | 140 157 159 207 242 283 532 670 728 729 775 783 797 798 810 815 | | |
| [^{F26} 33 | 180 874 | ND | expressed as eugenol] |
| [^{F38} 34 | 421 988 | 0,05 | Expressed as 1,3-benzenedimethanamine] |
| [^{F42} 35 | 467 744 1059 | 0,05 | expressed as crotonic acid] |

3. Notes on verification of compliance **U.K.**

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 |

Status: Point in time view as at 31/12/2020.

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 Article 3(1) c of the Framework Regulation (EC) No 1935/2004. |
| [^{F30} (4) | Compliance testing when there is a fat contact [^{F3} shall] be performed using saturated fatty food simulants as simulant D2.] |
| (5) | Compliance testing when there is a fat contact [^{F3} 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) 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 |

Status: Point in time view as at 31/12/2020.

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

| | |
|-----------------------|--|
| (17) | Only a method for determination of the residual content of the substance in the polymer is available |
| [^{F36} (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] |
| [^{F38} (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] |
| [^{F23} (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.] |
| [^{F4} (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.] |
| [^{F39} (24) | The substance or its hydrolysis products are authorised food additives and compliance with Article 11(3) shall be verified.] |
| [^{F41} (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 |

Status: Point in time view as at 31/12/2020.

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

| | |
|-----------------------|---|
| | 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.] |
| [^{F42} (27) | When a final material or article containing this substance and produced under conditions other than those described in point (a) column 10 of Table 1 is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in point (b) column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.] |
| [^{F43} (28) | A detection limit of 0,002 mg/kg food or food simulant applies |
| (29) | In polar polymers which swell in contact with foods for which simulant B is assigned in Annex III, there is a risk that under severe contact conditions the migration limits for aluminium and fluoride are exceeded. Under contact conditions above 4 hours at 100 °C this exceedance can be high.] |

4. Detailed specification on substances U.K.

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.

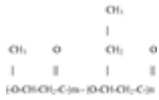
Column 2 (Detailed specification on the substance): contains the specification on the substance.

TABLE 4

| (1) | (2) |
|-------------------------|--|
| FCM substance No | Detailed specification on the substance |

Status: Point in time view as at 31/12/2020.

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

| | | |
|-----|--------------------|---|
| 744 | Definition | <p>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 additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications</p> |
| | 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> |

Status: Point in time view as at 31/12/2020.

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

| | | |
|--|------------------------------|---|
| | 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 |
| | [^{F33} 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 |
| | — 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 |

Status: Point in time view as at 31/12/2020.

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 II U.K.

Restrictions on plastic materials and articles

The following restrictions on plastic materials and articles apply:

1. Plastic materials and articles shall not release the substances in Table 1 below in quantities exceeding the specific migration limits expressed in mg/kg food or simulant specified in column (3), and subject to the remarks in Column (4).

Substances listed in Table 1 shall only be used in accordance with the compositional requirements set out in Chapter II. If Chapter II does not provide a basis for the authorised use of such a substance, that substance may only be present as an impurity subject to the restrictions specified in Table 1.

Table 1

General list of migration limits for substances migrating from plastic materials and articles

| (1) | (2) | (3) | (4) |
|------------|--|-----------------------------------|--------|
| Name | Salts allowed in accordance with Article 6(3)(a) | SML [mg/kg food or food simulant] | Remark |
| Aluminium | yes | 1 | |
| Ammonium | yes | | (1) |
| Antimony | no | 0,04 | (2) |
| Arsenic | no | ND | |
| Barium | yes | 1 | |
| Cadmium | no | ND (LOD 0,002) | |
| Calcium | yes | | (1) |
| Chromium | no | ND | (3) |
| Cobalt | yes | 0,05 | |
| Copper | yes | 5 | |
| Europium | yes | 0,05 | (4) |
| Gadolinium | yes | 0,05 | (4) |
| Iron | yes | 48 | |
| Lanthanum | yes | 0,05 | (4) |
| Lead | no | ND | |
| Lithium | yes | 0,6 | |
| Magnesium | yes | | (1) |
| Manganese | yes | 0,6 | |
| Mercury | no | ND | |

Status: Point in time view as at 31/12/2020.

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

General list of migration limits for substances migrating from plastic materials and articles

| | | | |
|-----------|-----|------|-----|
| Nickel | no | 0,02 | |
| Potassium | yes | | (1) |
| Sodium | yes | | (1) |
| Terbium | yes | 0,05 | (4) |
| Zinc | yes | 5 | |

ND:Not Detectable; detection limit assigned in accordance with second subparagraph of Article 11(4); LOD: specified Limit of Detection.

Remarks

(1)The migration is subject to Article 11(3) and Article 12

(2)The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature

(3)To verify compliance with the Regulation, the detection limit of 0,01 mg/kg shall apply for total chromium. However if the operator that placed the material on the market can prove on the basis of pre-existing documentary evidence that the presence of hexavalent chromium in the material is excluded because it is not used or formed or during the entire production process, a limit for the total chromium of 3,6 mg/kg food shall apply.

(4)The lanthanide substances europium, gadolinium, lanthanum, and/or terbium can be used in accordance with Article 6(3)(a) provided that:

- (a) The sum of all lanthanide substances migrating to the food or food simulant does not exceed the specific migration limit of 0,05 mg/kg; and
- (b) analytical evidence using a well described methodology demonstrating that the lanthanide substance(s) used are present in dissociated ionic form in the food or the food simulant, forms part of the documentation referred to in Article 16.

2. Primary aromatic amines ('PAAs') listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁽¹⁹⁾ and for which no migration limit is specified 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. They shall not be detectable using analytical equipment with a limit of detection of 0,002 mg/kg food or food simulant applied to each individual primary aromatic amine ('PAA'), in accordance with Article 11(4).

For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, but for which no specific migration limit is specified in Annex I, compliance with Article 3 of Regulation (EC) No 1935/2004 shall be verified in accordance with Article 19. The sum of those PAAs shall however not exceed 0,01 mg/kg in food or food simulant.]

ANNEX III **U.K.**

Food simulants

1. Food simulants **U.K.**

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.

Status: Point in time view as at 31/12/2020.

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}TABLE 1

List of food simulants

| Food simulant | Abbreviation |
|--|------------------|
| Ethanol 10 % (v/v) | Food simulant A |
| Acetic acid 3 % (w/v) | Food simulant B |
| Ethanol 20 % (v/v) | Food simulant C |
| Ethanol 50 % (v/v) | Food simulant D1 |
| Any vegetable oil containing less than 1 % unsaponifiable matter | Food simulant D2 |
| poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm | Food simulant E] |

2. General assignment of food simulants to foods **U.K.**

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.

^{F3}3. Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food **U.K.**

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

Status: Point in time view as at 31/12/2020.

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

test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

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

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

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

TABLE 2

food category specific assignment of food simulants

| (1) 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, | | X(*) | X | | | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-------|---|------|--|---|---|-------------------------|--|
| | tea, beers, soft drinks, energy drinks 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 | | | | | | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-------|---|--|--|--|--|-----|---|
| | products, pastry, biscuits, cakes and other bakers' wares | | | | | | |
| 02.01 | Starches | | | | | | X |
| 02.02 | Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like) | | | | | | X |
| 02.03 | Cereal flour and meal | | | | | | X |
| 02.04 | Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta | | | | | | X |
| 02.05 | Pastry, biscuits, cakes, bread, and other bakers' wares, dry: | | | | | | |
| | A. With fatty substances on the surface | | | | | X/3 | |
| | B. Other | | | | | | X |
| 02.06 | Pastry, cakes, | | | | | | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-------|--|---|--|--|--|-----|---|
| | bread, dough and other bakers' wares, fresh: | | | | | | |
| | A. | With fatty substances on the surface | | | | X/3 | |
| | B. | Other | | | | | X |
| 03 | Chocolate, sugar and products thereof Confectionery products | | | | | | |
| 03.01 | Chocolate, chocolate- coated products, substitutes and products coated with substitutes | | | | | X/3 | |
| 03.02 | Confectionery products: | | | | | | |
| | A. | In solid form: | | | | | |
| | I. | With fatty substances on the surface | | | | X/3 | |
| | II. | Other | | | | | X |

Status: Point in time view as at 31/12/2020.

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. | In paste form: | | | | | |
| | I. | With fatty substances on the surface | | | | X/2 | |
| | II. | Moist | | X | | | |
| 03.03 | | Sugar and sugar products | | | | | |
| | A. | In solid form: crystal or powder | | | | | X |
| | B. | X Molasses, sugar syrops, honey and the like | | | | | |
| 04 | | Fruit, vegetables and products thereof | | | | | |
| [^{F3} 04.01 | | Fruit, fresh or chilled: | | | | | |
| | A. | unpeeled and uncut | | | | | X/10 |
| | B. | X peeled and/ or cut | X (*) | | | | I |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-------|------------------|---|------|---|---|---|---|
| 04.02 | Processed fruit: | | | | | | |
| | A. | Dried or dehydrated fruits, whole, sliced, flour or powder | | | | | X |
| | B. | Fruit in the form of purée, preserves, pastes or in 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 | | | X | | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-----------------------|---|---|-------|--|--|---|------|
| | | alcoholic medium | | | | | |
| 04.03 | Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others): | | | | | | |
| | A. | Shelled, dried, flaked or powdered | | | | | X |
| | B. | Shelled and roasted | | | | | X |
| | C. | X In paste or cream form | | | | X | |
| [^{F3} 04.04 | Vegetables, fresh or chilled: | | | | | | |
| | A. | unpeeled and uncut | | | | | X/10 |
| | B. | X peeled and/ or cut | X (*) | | | | I |
| [^{F3} 04.05 | Processed vegetables: | | | | | | |
| | A. | Dried or dehydrated vegetables whole, sliced or in | | | | | X |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | |
|-------|---|-------|---|---|---|---|
| | the form of flour or powder. | | | | | |
| | B. (obsolete) | | | | | |
| | 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. X In an oily medium | | | | 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 | | | | X | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-------|--|---|------|---|--|---------|--|
| | cocoa butter, lard, resolidified butter) | | | | | | |
| 05.02 | Margarine, butter and other fats and oils made from water emulsions in oil | | | | | X/2 | |
| 06 | Animal products and eggs | | | | | | |
| 06.01 | Fish: | | | | | | |
| | A. Fresh, chilled, processed, salted or smoked including fish eggs | X | | | | X/3(**) | |
| | B. Preserved fish: | | | | | | |
| | I. In an oily medium | X | | | | X | |
| | II. In an aqueous medium | | X(*) | X | | | |
| 06.02 | Crustaceans and molluscs (including oysters, mussels, snails) | | | | | | |

Status: Point in time view as at 31/12/2020.

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. | Fresh within the shell | | | | | |
| | B. | Shell removed, processed, preserved 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 | | | | X/4(**) | |

Status: Point in time view as at 31/12/2020.

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 form of paste, creams | | | | | |
| | C. | X Marinated meat products in an oily medium | | | | X | |
| 06.04 | Preserved meat: | | | | | | |
| | A. | X In an fatty or oily medium | | | | X/3 | |
| | B. | In an aqueous medium | X(*) | | X | | |
| 06.05 | Whole eggs, egg yolk, egg white | | | | | | |
| | A. | Powdered or dried or frozen | | | | | X |
| | B. | Liquid and cooked | | | X | | |
| 07 | Milk products | | | | | | |
| 07.01 | Milk | | | | | | |
| | A. | Milk and milk | | | X | | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-------|----|--|------|--|---|---------|---|
| | | based drinks whole, partly dried and skimmed or partly skimmed | | | | | |
| | 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 | | | | X/3(**) | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-------|-------------------------------|--|------|--|---|-----|--|
| | | the like) and melting cheese | | | | | |
| | C. | Processed cheese (soft cheese, cottage cheese and similar) | X(*) | | X | | |
| | 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 | |

Status: Point in time view as at 31/12/2020.

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

| | | | | | | | |
|-------|---|------|---|--|-----|-----|--|
| 08.03 | Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents | | | | | | |
| | A. Powdered or dried: | | | | | | |
| | I. With fatty character | | | | X/5 | | |
| | II. Other | | | | | X | |
| | B. any other form than powdered or dried: | | | | | | |
| | I. ^X With fatty character | X(*) | | | | X/3 | |
| | II. Other | X(*) | X | | | | |
| 08.04 | Sauces: | | | | | | |
| | A. With aqueous character | X(*) | X | | | | |

Status: Point in time view as at 31/12/2020.

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. | X With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/ water mixtures e.g. coconut based sauces | X(*) | | | X | |
| 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: | | | | | | |

Status: Point in time view as at 31/12/2020.

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. | With fatty substances on the surface | | | | X/5 | |
| | B. | Other | | | | | X |
| 08.09 | | Frozen or deep-frozen foods | | | | | X |
| 08.10 | | Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol. | X(*) | | X | | |
| 08.11 | | Cocoa: | | | | | |
| | A. | Cocoa powder, including fat-reduced and highly fat reduced | | | | | X |
| | B. | Cocoa paste | | | | X/3 | |
| 08.12 | | Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered | | | | | X |
| 08.13 | | Aromatic herbs | | | | | 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 other herbs such as camomile, mallow, mint, tea, lime blossom and others | | | | | | |
| 08.14 | Spices and seasonings in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and other | | | | | | X |
| 08.15 | Spices and seasoning in oily medium such as pesto, curry paste | | | | | X | |

[^{F44}4. **Food simulant assignment for testing overall migration** U.K.]

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

TABLE 3

Food simulant assignment for demonstrating compliance with the overall migration limit

| Foods covered | Food simulants in which testing shall be performed |
|----------------------|---|
| all types of food | 1. distilled water or water of equivalent quality or food simulant A; |

Status: Point in time view as at 31/12/2020.

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

| | |
|--|---|
| | 2. food simulant B; and 3. food simulant D2. |
| all types of food except for acidic foods | 1. distilled water or water of equivalent quality or food simulant A; and 2. food simulant D2. |
| [^{F33} all aqueous and alcoholic foods and milk products with a pH ≥ 4,5 | food simulant D1 |
| all aqueous and alcoholic foods and milk products with a pH < 4,5 | food simulant D1 and food simulant B] |
| all aqueous foods and alcoholic foods up to an alcohol content of 20 % | food simulant C |
| all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 % | 1. food simulant C; and 2. food simulant B.] |

Textual Amendments

F44 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 \(Text with EEA relevance\).](#)

[^{F45} **General derogation to the assignment of food simulants** U.K.]

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 U.K.

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

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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)

- 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) [^{F3}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) [^{F13}adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.
- At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,
- that are subject to restrictions in Annex II, or
 - for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant;]
- (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 ^{F45}... 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) [^{F44}the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information;]
- (9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

Textual Amendments

F45 Words in Annex 4 para. 7 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 77; 2020 c. 1, **Sch. 5 para. 1(1)**

Status: Point in time view as at 31/12/2020.

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 V U.K.

COMPLIANCE TESTING

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

CHAPTER 1 U.K.

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

1.1. Sample preparation U.K.

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 U.K.

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 U.K.

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.

[^{F3}1.4. Account of substances originating from other sources U.K.]

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 U.K.

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

2.1. Verification method U.K.

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 U.K.

Status: Point in time view as at 31/12/2020.

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

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 **U.K.**

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 **U.K.**

^[F3]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 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.
- (iv) ^[F43]if the plastic material or article intended to come into contact with food of which the compliance must be verified becomes in its final application part of a food processing equipment or an appliance, or a part thereof, the migration tests may be carried out by determining the specific migration into the food or food simulant produced or processed by the whole equipment or appliance, or the part thereof, as appropriate, subject to the following conditions:
 - the food or food simulant is processed during testing by the equipment or part thereof in accordance with the worst foreseeable conditions that can be achieved if the equipment or its part is operated in accordance with its operating instructions, and
 - the migration from parts used for storage such as from reservoirs, containers, or capsules or pads which are part of the equipment during the processing of

Status: Point in time view as at 31/12/2020.

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

the food, is determined using conditions representative for their use, unless the applied testing conditions for the whole tested equipment or appliance are representative also of their use.

When migration testing is done under the above conditions, and the transfer of constituents from the equipment or appliance as a whole does not exceed the migration limits, the plastic parts or materials present in the equipment or appliance shall be considered to comply with Article 11(1).

The testing of the parts used for storage or supply such as reservoirs, containers, capsules or pads shall be under conditions representative of their use, and shall include the foreseeable storage conditions of the food in these parts.

The supporting documentation referred to in Article 16 shall clearly document the testing on the whole food processing and/or food producing equipment or appliance, or on parts thereof. It shall demonstrate that the testing was representative of its foreseeable use, and shall indicate for which substances migration testing was carried out and provide all testing results. The manufacturer of individual plastic parts shall ensure the absence of migration for substances for which the Regulation specifies that their migration shall not be detectable at a specified level of detection in accordance with Article 11(4).

Compliance documentation supplied in accordance with the Regulation to the producer of the final equipment or appliance, or part thereof, shall list all substances subject to migration limits that might be exceeded under the foreseeable use of the supplied part or material.

When the result is not in compliance with the Regulation it shall be determined whether the source of the non-compliance is a plastic part subject to the Regulation or a part made from another material not subject to the Regulation on the basis of documentary evidence or analytical testing. Without prejudice to Article 3 of Regulation (EU) No 1935/2004, non-compliance to the Regulation shall only be established if the migration originates from a plastic part.]

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

[^{F3}Selection of test time]

| Contact time in worst foreseeable use | [^{F3}Time to be selected for testing] |
|--|---|
| t ≤ 5 min | 5 min |
| 5 min < t ≤ 0,5 hour | 0,5 hour |
| 0,5 hours < t ≤ 1 hour | 1 hour |
| 1 hour < t ≤ 2 hours | 2 hours |
| 2 hours < t ≤ 6 hours | 6 hours |
| 6 hours < t ≤ 24 hours | 24 hours |

Status: Point in time view as at 31/12/2020.

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 day < t ≤ 3 days | 3 days |
| 3 days < t ≤ 30 days | 10 days |
| Above 30 days | See specific conditions |

^{F3}TABLE 2

Selection of test temperature

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

^{F3}2.1.4. *Specific conditions for contact times above 30 days at room temperature and below U.K.*

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⁽²⁰⁾.

- (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.

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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)

- (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 U.K.

[^{F3}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.

[^{F13}2.1.6. *Repeated use materials and articles* U.K.

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. The specific migration in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test.

Compliance of the material or article shall then be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. The stability of the material shall be considered insufficient if migration is observed above the level of detection in any of the three migration tests, and increases from the first migration test to the third migration test. In case of insufficient stability, compliance of the material shall not be established even in case the specific migration limit is not exceeded in any of the three tests.

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

Irrespective of the above rules, a material or article shall never be considered to comply with this Regulation if in the first test a substance that is prohibited from migrating or from being released in detectable quantities under Article 11(4) is detected.]

2.1.7. Analysis of migrating substances U.K.

Status: Point in time view as at 31/12/2020.

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 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) **U.K.**

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 **U.K.**

[^{F3}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 **U.K.**

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 **U.K.**

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.

[^{F3}2.2.3. *Migration modelling* **U.K.**

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.]

[^{F3}2.2.4. *Food simulant substitutes* **U.K.**

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.]

[^{F4}2.2.5. *Single test for successive combinations of time and temperature* **U.K.**

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.]

Status: Point in time view as at 31/12/2020.

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

CHAPTER 3 **U.K.**

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 **U.K.**

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.

¹³TABLE 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 |
| OM0 | 30 min at 40 °C | Any food contact at cold or ambient temperatures and for a short duration (≤ 30 minutes). |
| OM1 | 10 d at 20 °C | Any food contact at frozen and refrigerated conditions |
| OM2 | 10 d at 40 °C | Any long-term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of $t = 120/2^{(T-70)/10}$ minutes. |
| OM3 | 2 h at 70 °C | Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of $t = 120/2^{(T-70)/10}$ minutes, which are not followed by |

Status: Point in time view as at 31/12/2020.

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

| | | |
|-----|---|--|
| | | long-term room temperature or refrigerated storage. |
| OM4 | 1 h at 100 °C or at reflux | 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. |

Test OM 7 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants 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 paragraph 3.2.

Test OM 6 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

Test OM 5 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM 2 covers also food contact conditions described for OM0, OM1 and OM3.]

[^{F3}3.2. Substitute overall migration tests for tests with food simulant D2 U.K.]

[^{F13}If it is not technically feasible to perform one or more of the tests OM0 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 overall migration shall be used to establish compliance with the Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2, either test OM8 or test OM9 shall be selected as a replacement test by selecting the most appropriate of these two tests on the basis of the intended and the foreseeable use of the material or article that is being tested. Subsequently, a migration test shall be done at each of the two test conditions specified for the selected test, using a new test sample for each test condition. The test condition that results in the higher overall migration shall be used to establish compliance with the Regulation.]

| Test number | Test conditions | Intended food contact conditions | Covers the intended food contact conditions described in |
|-------------|-----------------|----------------------------------|--|
|-------------|-----------------|----------------------------------|--|

Status: Point in time view as at 31/12/2020.

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

| | | | |
|-----|--|---|----------------------------------|
| 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] |

[^{F3}3.3. Verification of compliance U.K.]

3.3.1. Single use articles and materials U.K.]

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.

[^{F13}3.3.2. Repeated use articles and materials U.K.]

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 34 of Regulation (EU) 2017/625 of the European Parliament and of the Council⁽²¹⁾. 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 vegetable 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, the difference between the second and the first test results shall be lower than the first test results and the difference between the third and the second test results shall be lower than the difference between the second and the first test results.

By derogation from the first paragraph, if, on the basis of scientific evidence, it is established that for the material or article being tested the overall migration decreases 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 U.K.]

[^{F3}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 U.K.]

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.

[^{F3}3.4.2. Food simulant substitutes U.K.]

Status: Point in time view as at 31/12/2020.

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 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 U.K.

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) U.K.

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.

[^{F3}The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.]

[^{F4}When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table 2 of Annex III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.]

^{F15}4.2. Correction of migration into food simulant D2 U.K.

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^{F15}4.3. Combination of correction factors 4.1 and 4.2. U.K.

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ANNEX VI U.K.

Correlation tables

Directive 2002/72/EC

This Regulation

Status: Point in time view as at 31/12/2020.

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 1(1) | Article 1 |
| Article 1(2), (3) and (4) | Article 2 |
| Article 1a | Article 3 |
| Article 3(1), Article 4(1) and Article 5 | Article 5 |
| Article 4(2), Article 4a(1) and (4), Article 4d, Annex II (2) and (3) and Annex III (2) and (3) | Article 6 |
| Article 4a(3) and (6) | Article 7 |
| Annex II (4) and Annex III (4) | Article 8 |
| Article 3(1) and Article 4(1) | Article 9 |
| Article 6 | Article 10 |
| Article 5a(1) and Annex I (8) | Article 11 |
| Article 2 | Article 12 |
| Article 7a | Article 13 |
| Article 9(1) and (2) | Article 15 |
| Article 9(3) | Article 16 |
| Article 7 and Annex I (5a) | Article 17 |
| Article 8 | Article 18 |
| Annex II (3) and Annex III (3) | Article 19 |
| Annex I, Annex II, Annex IV, Annex IVa, Annex V Part B, and Annex VI | Annex I |
| Annex II (2), Annex III (2) and Annex V, Part A | Annex II |
| Article 8(5) and Annex VIa | Annex IV |
| Annex I | Annex V |
| Directive 93/8/EEC | This Regulation |
| Article 1 | Article 11 |
| Article 1 | Article 12 |
| Article 1 | Article 18 |
| Annex | Annex III |
| Annex | Annex V |
| Directive 97/48/EC | This Regulation |
| Annex | Annex III |
| Annex | Annex V |

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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)

Status: Point in time view as at 31/12/2020.

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) [^{F13}Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).:]
- (20) [^{F3}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.]
- (21) [^{F3}[^{F13}Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).]]

Textual Amendments

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

Status: Point in time view as at 31/12/2020.

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

F13 Substituted by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Status:

Point in time view as at 31/12/2020.

Changes to legislation:

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