

## MEMORANDUM

To: Flustix GmbH

From: Dr. Thomas Dörmer, LL.M.

Date: 19 April 2021

Subject: European Union marking requirements for plastic products

### I. Facts of the case

The Flustix initiative (hereafter: Flustix) offers consumer seals checking goods and packaging for their plastic sustainability, verified according to their established Standard plastic content, recycled content as well as the recyclability of products, semi-products and raw materials. To this end, Flustix and its independent and accredited partners (e.g. DIN CERTCO / TÜV Rheinland / Wessling Group) examine, verify and certify products that are free of plastic. .

The European Union Directive 2019/904 of 5 June 2019 on the reduction of the impact of certain plastic products on the environment (please see attached as **Appendix 1**) and the Implementing Regulation 2020/2151 of 17 December 2020 (please see attached as **Appendix 2**) stipulate several marking requirements for certain single-use plastic products. The Implementing Regulation 2020/2151 shall apply from 3 July 2021.

The implementation in Germany shall take place through the Single-Use-Plastic-Marking-Regulation (*Einwegkunststoffkennzeichnungsverordnung*). Other EU countries are under the obligation to fully implement the EU regulation as well.

### II. Question

Do single-use products such as disposable food containers, cigarette filters and hygiene articles which meet the requirements for the certification as plastic free products according to Flustix's standards need to bear a marking of the presence of plastics and the appropriate waste management options according to the mentioned provisions of the European Union?

### III. Assumptions

We assume that the examination standard applied for the assessment whether a single-use product such as disposable food containers, cigarette filters and hygiene articles contain plastics or not is similar in essence within the meaning of the European Union provisions and Flustix's guidelines and schemes.

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We assume that the certification procedure by Flustix and its accredited partners is in general carried out according to Flustix's standards and therefore qualified to identify plastics according to European Union provisions.

We note however, unavoidable residues/secondary microplastics and minor adhesives are exempted under the Flustix's standard. These exemptions are part of the legal analysis below.

#### IV. Legal assessment

According to article 7 of the EU Directive 2019/904, member states shall ensure that each single-use plastic product listed in Part D (e.g number 4: dealing with beverage cups) of the Annex bears a conspicuous, clearly legible and indelible marking informing consumers of (i) appropriate waste management options or waste disposal means to be avoided in line with the waste hierarchy and (ii) the presence of plastic in the product and the impact of littering or inappropriate waste disposal. Any marking specifications shall be established by the European Commission.

Therefore, the European Commission has adopted the Implementing Regulation 2020/2151 of 17 December 2020. According to article 2 number 4 of the Implementing Regulation, harmonized marking specifications for beverage cups are laid down in Annex IV of the Implementing Regulation. According to Annex IV of the Implementing Regulation, beverage cups made partly from plastic or made wholly from plastic shall bear specific printed markings.

##### 1. Plastic definitions according to EU standards

According to the EU Directive 2019/904, a *Single-use plastic product* is defined as a product that is made wholly or partly from plastic and that is not conceived, designed or placed on the market to accomplish, within its life span, multiple trips or rotations by being returned to a producer for refill or re-used for the same purpose for which it was conceived.

*Plastic* according to the EU Directive 2019/904 means material consisting of a polymer (as defined in point 5 of Article 3 of Regulation (EC) No 1907/2006), to which additives or other substances may have been added, and which can function as a main structural component of final products, with the exception of natural polymers that have not been chemically modified.

Plastics manufactured with modified natural polymers, or plastics manufactured from bio-based, fossil or synthetic starting substances are not naturally occurring and are therefore addressed by the EU Directive 2019/904. The adapted definition of plastics therefore covers polymer-based rubber items and bio-based and biodegradable plastics regardless of whether they are derived from biomass or are intended to biodegrade over time.

Paints, inks and adhesives are explicitly excluded from and shall not be covered by the definition of plastics (Recital number 11 of the EU Directive 2019/904).

##### 2. Plastic definitions according to Flustix's standards

According to the Flustix Certification Scheme (November 2020, please see attached as **Appendix 3**), *plastics* are organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or a similar process of molecules with a lower molecular weight or by chemical modification of natural molecules. Other substances or materials may also be added to these compounds. Polymers that occur naturally and have not been chemically modified are excluded from the certification scheme as well as bio degradable.

Consumer goods or packaging are plastic free according to Flustix's Certification Scheme if they consist of components, materials, ingredients and / or materials that do not contain plastics within the meaning of the definition of plastics above.

Exceptions exist for unavoidable residues (which for example can arise due to contamination through environmental influences, residues in materials used, manufacturing process, during transport, packaging) and technical unavoidability (such as plastic used in the production of recycled paper according to DIN EN 643 Papier, Karton und Pappe – Europäische Liste der Altpapier-Standardarten). Moreover, certain adhesives e.g. with less than 0.2 per cent by mass weight content are considered to be technically necessary plastics.

### 3. Legal Analysis and Conclusion

In our view, if the requirements are met that a single-use product and in particular disposable food containers, cigarette filters and hygiene articles is certified by Flustix as "plastic-free", there is no need for this product to bear a marking according to the provisions of the European Union informing consumers of the presence of plastic and appropriate waste management options.

The exceptions for unavoidable residues included in Flustix's Certification Scheme are not explicitly set out within the mentioned relevant EU Directive. However, the Union Guidelines on the EU Regulation No 10/2011 on plastic materials and articles intended to come into contact with food (please see attached as **Appendix 4**) lay down certain exceptions for substances that are for example used in minute amounts and hence are not regarded as being covered by the Plastics Regulation which applies to plastic materials and substances that are functional constituents of plastic. Those exceptions include non-intentionally added substances (impurities in the substances used or reaction intermediates formed during the process or reaction products) and paints, inks and adhesives are explicitly excluded from and shall not be covered by the definition of plastics (Recital number 11 of the EU Directive 2019/904).

Although the Plastic Regulation is a specific measure for plastic food contact materials and food safety, we note that in this regard, even higher standards in terms of health and consumer protection shall apply. We are therefore of the view that the standards for environment protection and sustainability within the EU Directive 2019/904 and the Implementing Regulation 2020/2151 are at least not intended to be stricter and that the exceptions of the Union Guidelines on the EU Regulation No 10/2011 may at least be used for interpretation, especially in case of disposable food containers, cigarette filters and hygiene articles which are intended to come into direct contact with beverages/human beings. Moreover, the European Union Directive 2019/904 explicitly states that the significant negative environmental, health and economic impact of certain plastic products calls for the setting up of a specific legal framework to effectively reduce those negative effects and therefore not only refers to environmental issues.



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Appendices:

1. European Union Directive 2019/904 of 5 June 2019
2. Implementing Regulation 2020/2151 of 17 December 2020
3. Flustix Certification Scheme
4. Union Guidelines on the EU Regulation No 10/2011

## I

*(Legislative acts)*

## DIRECTIVES

**DIRECTIVE (EU) 2019/904 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 5 June 2019****on the reduction of the impact of certain plastic products on the environment****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) The high functionality and relatively low cost of plastic means that this material is increasingly ubiquitous in everyday life. While plastic plays a useful role in the economy and provides essential applications in many sectors, its growing use in short-lived applications, which are not designed for re-use or cost-effective recycling, means that related production and consumption patterns have become increasingly inefficient and linear. Therefore, in the context of the Circular Economy Action Plan laid down in the Communication of the Commission of 2 December 2015 entitled 'Closing the loop – An EU action plan for the Circular Economy', the Commission concluded in the European Strategy for Plastics laid down in its Communication of 16 January 2018 entitled 'A European Strategy for Plastics in a Circular Economy' that the steady increase in plastic waste generation and the leakage of plastic waste into the environment, in particular into the marine environment, must be tackled in order to achieve a circular life cycle for plastics. The European Strategy for Plastics is a step towards establishing a circular economy in which the design and production of plastics and plastic products fully respect re-use, repair and recycling needs and in which more sustainable materials are developed and promoted. The significant negative environmental, health and economic impact of certain plastic products calls for the setting up of a specific legal framework to effectively reduce those negative effects.
- (2) This Directive promotes circular approaches that give priority to sustainable and non-toxic re-usable products and re-use systems rather than to single-use products, aiming first and foremost to reduce the quantity of waste generated. Such waste prevention is at the pinnacle of the waste hierarchy enshrined in Directive 2008/98/EC of the European Parliament and of the Council <sup>(4)</sup>. This Directive will contribute to the achievement of United Nations (UN) Sustainable Development Goal 12 to ensure sustainable consumption and production patterns, which

<sup>(1)</sup> OJ C 62, 15.2.2019, p. 207.

<sup>(2)</sup> OJ C 461, 21.12.2018, p. 210.

<sup>(3)</sup> Position of the European Parliament of 27 March 2019 (not yet published in the Official Journal) and decision of the Council of 21 May 2019.

<sup>(4)</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

is part of the 2030 Agenda for Sustainable Development adopted by the UN General Assembly on 25 September 2015. By retaining the value of products and materials for as long as possible and generating less waste, the economy of the Union can become more competitive and more resilient, while reducing pressure on precious resources and the environment.

- (3) Marine litter is transboundary in nature and is recognised as a growing global problem. Reducing marine litter is a key action for the achievement of UN Sustainable Development Goal 14 which calls to conserve and sustainably use the oceans, seas and marine resources for sustainable development. The Union must play its part in preventing and tackling marine litter and aim to be a standard setter for the world. In that context, the Union is working with partners in many international fora such as G20, G7 and the UN to promote concerted action and this Directive is part of the Union's efforts in that regard. In order for those efforts to be effective, it is also important that exports of plastic waste from the Union do not result in increased marine litter elsewhere.
- (4) In accordance with the United Nations Convention on the Law of the Sea of 10 December 1982 (UNCLOS) <sup>(5)</sup>, the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter of 29 December 1972 ('London Convention') and its 1996 Protocol ('London Protocol'), Annex V to the International Convention for the Prevention of Pollution from Ships 1973 (MARPOL), as modified by the Protocol of 1978 relating thereto, and the Basel Convention on the control of transboundary movements of hazardous wastes and their disposal of 22 March 1989 <sup>(6)</sup> and with Union waste legislation, namely Directive 2008/98/EC and Directive 2000/59/EC of the European Parliament and of the Council <sup>(7)</sup>, Member States are required to ensure environmentally sound waste management to prevent and reduce marine litter from both sea and land sources. In accordance with Union water legislation, namely Directives 2000/60/EC <sup>(8)</sup> and 2008/56/EC <sup>(9)</sup> of the European Parliament and of the Council, Member States are also required to tackle marine litter where it undermines the attainment of good environmental status of their marine waters, including as a contribution to UN Sustainable Development Goal 14.
- (5) In the Union, 80 to 85 % of marine litter, measured as beach litter counts, is plastic, with single-use plastic items representing 50 % and fishing-related items representing 27 % of the total. Single-use plastic products include a diverse range of commonly used fast-moving consumer products that are discarded after having been used once for the purpose for which they were provided, are rarely recycled, and are prone to becoming litter. A significant proportion of the fishing gear placed on the market is not collected for treatment. Single-use plastic products and fishing gear containing plastic are therefore a particularly serious problem in the context of marine litter, pose a severe risk to marine ecosystems, to biodiversity and to human health and damage activities such as tourism, fisheries and shipping.
- (6) Proper waste management remains essential for the prevention of all litter, including marine litter. Existing Union legislation, namely Directives 2008/98/EC, 2000/59/EC, 2000/60/EC and 2008/56/EC and Council Regulation (EC) No 1224/2009 <sup>(10)</sup>, and policy instruments provide some regulatory responses to address marine litter. In particular, plastic waste is subject to overall Union waste management measures and targets, such as the recycling target for plastic packaging waste laid down in European Parliament and Council Directive 94/62/EC <sup>(11)</sup> and the objective in the European Strategy for Plastics to ensure that by 2030 all plastic packaging placed on the Union market is re-usable or easily recycled. However, the impact of those measures on marine litter is not sufficient and there are differences in the scope and the level of ambition amongst national measures to prevent and reduce marine litter. In addition, some of those measures, in particular marketing restrictions for single-use plastic products, could create barriers to trade and distort competition in the Union.

<sup>(5)</sup> OJ L 179, 23.6.1998, p. 3.

<sup>(6)</sup> OJ L 39, 16.2.1993, p. 3.

<sup>(7)</sup> Directive 2000/59/EC of the European Parliament and of the Council of 27 November 2000 on port reception facilities for ship-generated waste and cargo residues (OJ L 332, 28.12.2000, p. 81).

<sup>(8)</sup> Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

<sup>(9)</sup> Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

<sup>(10)</sup> Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 (OJ L 343, 22.12.2009, p. 1).

<sup>(11)</sup> European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10).

- (7) To focus efforts where they are most needed, this Directive should cover only those single-use plastic products that are found the most on beaches in the Union as well as fishing gear containing plastic and products made from oxo-degradable plastic. The single-use plastic products covered by measures under this Directive are estimated to represent around 86 % of the single-use plastics found, in counts, on beaches in the Union. Glass and metal beverage containers should not be covered by this Directive as they are not among the single-use plastic products that are found the most on beaches in the Union.
- (8) Microplastics do not fall directly within the scope of this Directive, yet they contribute to marine litter and the Union should therefore adopt a comprehensive approach to that problem. The Union should encourage all producers to strictly limit microplastics in their formulations.
- (9) Terrestrial pollution and contamination of soil by larger items of plastic and resulting fragments or microplastics can be significant and such plastic can leak into the marine environment.
- (10) This Directive is a *lex specialis* in relation to Directives 94/62/EC and 2008/98/EC. In the event of a conflict between those Directives and this Directive, this Directive should prevail within the scope of its application. That is the case for restrictions on placing on the market. In particular with regard to consumption reduction measures, product requirements, marking requirements and extended producer responsibility, this Directive supplements Directives 94/62/EC and 2008/98/EC and Directive 2014/40/EU of the European Parliament and of the Council <sup>(12)</sup>.
- (11) Single-use plastic products can be manufactured from a wide range of plastics. Plastics are usually defined as polymeric materials to which additives may have been added. However, that definition would cover certain natural polymers. Unmodified natural polymers, within the meaning of the definition of 'not chemically modified substances' in point 40 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(13)</sup>, should not be covered by this Directive as they occur naturally in the environment. Therefore, for the purposes of this Directive, the definition of polymer in point 5 of Article 3 of Regulation (EC) No 1907/2006 should be adapted and a separate definition should be introduced. Plastics manufactured with modified natural polymers, or plastics manufactured from bio-based, fossil or synthetic starting substances are not naturally occurring and should therefore be addressed by this Directive. The adapted definition of plastics should therefore cover polymer-based rubber items and bio-based and biodegradable plastics regardless of whether they are derived from biomass or are intended to biodegrade over time. Paints, inks and adhesives should not be addressed by this Directive and therefore these polymeric materials should not be covered by the definition.
- (12) In order to clearly define the scope of this Directive, the term 'single-use plastic product' should be defined. The definition should exclude plastic products that are conceived, designed and placed on the market to accomplish within their life span multiple trips or rotations by being refilled or re-used for the same purpose for which they are conceived. Single-use plastic products are typically intended to be used just once or for a short period of time before being disposed of. Wet wipes for personal care and domestic use should also be within the scope of this Directive, whereas industrial wet wipes should be excluded. To further clarify whether a product is to be considered a single-use plastic product for the purposes of this Directive, the Commission should develop guidelines on single-use plastic products. In view of the criteria set out in this Directive, examples of food containers to be considered as single-use plastic products for the purposes of this Directive are fast-food containers or meal, sandwich, wrap and salad boxes with cold or hot food, or food containers of fresh or processed food that does not need further preparation, such as fruits, vegetables or desserts. Examples of food containers that are not to be considered as single-use plastic products for the purposes of this Directive are food containers with dried food or food that is sold cold requiring further preparation, containers containing food in more than single-serve portions or single-serve portion-sized food containers sold in more than one unit.

<sup>(12)</sup> Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1).

<sup>(13)</sup> 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).

Examples of beverage containers to be considered as single-use plastic products are beverage bottles or composite beverage packaging used for beer, wine, water, liquid refreshments, juices and nectars, instant beverages or milk, but not cups for beverages as these are a separate category of single-use plastic products for the purposes of this Directive. As they are not among the single-use plastic products that are found the most on beaches in the Union, glass and metal beverage containers should not be covered by this Directive. However, the Commission should, in the context of the review of this Directive, evaluate, inter alia, caps and lids made of plastic used for glass and metal beverage containers.

- (13) Single-use plastic products covered by this Directive should be addressed by one or several measures, depending on various factors, such as the availability of suitable and more sustainable alternatives, the feasibility of changing consumption patterns, and the extent to which they are already covered by existing Union legislation.
- (14) For certain single-use plastic products, suitable and more sustainable alternatives are not yet readily available and the consumption of most such single-use plastic products is expected to increase. To reverse that trend and to promote efforts towards more sustainable solutions, Member States should be required to take the necessary measures, for example by setting national consumption reduction targets, to achieve an ambitious and sustained reduction in the consumption of those products, without compromising food hygiene, food safety, good hygiene practices, good manufacturing practices, consumer information, or traceability requirements set out in Regulations (EC) No 178/2002 <sup>(14)</sup>, (EC) No 852/2004 <sup>(15)</sup> and (EC) No 1935/2004 <sup>(16)</sup> of the European Parliament and of the Council and other relevant legislation related to food safety, hygiene and labelling. Member States should have the highest possible ambition for those measures, which should induce a substantial reversal of increasing consumption trends and lead to a measurable quantitative reduction. Those measures should take into account the impact of products throughout their life cycle, including when they are found in the marine environment, and should respect the waste hierarchy.

Where Member States decide to implement that obligation through marketing restrictions, they should ensure that such restrictions are proportionate and non-discriminatory. Member States should encourage the use of products that are suitable for multiple use and that are, after having become waste, suitable for preparing for re-use and recycling.

- (15) For other single-use plastic products, suitable and more sustainable alternatives that are also affordable are readily available. In order to limit the adverse impact of such single-use plastic products on the environment, Member States should be required to prohibit their placing on the market. By doing so, the use of those readily available and more sustainable alternatives as well as of innovative solutions towards more sustainable business models, re-use alternatives and substitution of materials would be promoted. The restrictions on placing on the market introduced in this Directive should also cover products made from oxo-degradable plastic, as that type of plastic does not properly biodegrade and thus contributes to microplastic pollution in the environment, is not compostable, negatively affects the recycling of conventional plastic and fails to deliver a proven environmental benefit. Furthermore, in view of the high prevalence of expanded polystyrene litter in the marine environment and the availability of alternatives, single-use food and beverage containers and cups for beverages made of expanded polystyrene should also be restricted.
- (16) Tobacco product filters containing plastic are the second most found single-use plastic items on beaches in the Union. The huge environmental impact caused by post-consumption waste of tobacco products with filters containing plastic, discarded directly into the environment, needs to be reduced. Innovation and product development are expected to provide viable alternatives to filters containing plastic and need to be accelerated. Extended producer responsibility schemes for tobacco products with filters containing plastic should also encourage innovation leading to the development of sustainable alternatives to tobacco product filters containing plastic. Member States should promote a wide range of measures to reduce litter from post-consumption waste of tobacco products with filters containing plastic.

<sup>(14)</sup> 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 (OJ L 31, 1.2.2002, p. 1).

<sup>(15)</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

<sup>(16)</sup> 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 (OJ L 338, 13.11.2004, p. 4).

- (17) Caps and lids made of plastic which are used for beverage containers are among the single-use plastic items that are found the most on beaches in the Union. Therefore, beverage containers that are single-use plastic products should only be allowed to be placed on the market if they fulfil specific product design requirements that significantly reduce the dispersal into the environment of beverage container caps and lids made of plastic. For beverage containers that are both single-use plastic products and packaging, that requirement is in addition to the essential requirements on the composition and the re-usable and recoverable, including recyclable, nature of packaging set out in Annex II to Directive 94/62/EC.

In order to facilitate conformity with the product design requirement and to ensure the smooth functioning of the internal market, it is necessary to develop a harmonised standard adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>(17)</sup>, and compliance with that standard should give rise to a presumption of conformity with those requirements. Therefore, the timely development of a harmonised standard is of the highest priority in ensuring effective implementation of this Directive. Sufficient time should be envisaged for the development of a harmonised standard and to allow the producers to adapt their production chains in relation to the implementation of the product design requirement. In order to ensure the circular use of plastics, the market uptake of recycled materials needs to be promoted. It is therefore appropriate to introduce requirements for a mandatory minimum content of recycled plastic in beverage bottles.

- (18) Plastic products should be manufactured taking into account their entire life span. The design of plastic products should always take into account the production and use phase and the reusability and recyclability of the product. In the context of the review to be undertaken pursuant to Article 9(5) of Directive 94/62/EC, the Commission should take into account the relative properties of different packaging materials, including composite materials, on the basis of life cycle assessments, addressing in particular waste prevention and design for circularity.
- (19) The presence of hazardous chemical substances in sanitary towels, tampons and tampon applicators should be avoided in the interest of women's health. In the framework of the restrictions process under Regulation (EC) No 1907/2006, it is appropriate for the Commission to assess further restrictions on such substances.
- (20) Certain single-use plastic products end up in the environment as a result of inappropriate disposal through the sewer system or other inappropriate release into the environment. Disposal through the sewer system can in addition cause substantial economic damage to sewer networks by clogging pumps and blocking pipes. For those products, there is frequently a significant lack of information about the material characteristics of the product or the appropriate means of waste disposal. Therefore, single-use plastic products that are frequently disposed of through the sewer system or otherwise inappropriately disposed of should be subject to marking requirements. The marking should inform consumers about appropriate waste management options for the product or which waste disposal means are to be avoided for the product in line with the waste hierarchy, and about the presence of plastics in the product as well as the resulting negative environmental impact of littering or of other inappropriate means of disposal of the product. The marking should, as appropriate, be either on the packaging of the product or directly on the product itself. The Commission should be empowered to establish harmonised specifications for the marking and when doing so should, where appropriate, test the perception of the proposed marking with representative groups of consumers to ensure that it is effective and easily understandable. Marking requirements are already required for fishing gear pursuant to Regulation (EC) No 1224/2009.
- (21) With regard to single-use plastic products for which no suitable and more sustainable alternatives are readily available, Member States should, in line with the polluter-pays principle, also introduce extended producer responsibility schemes to cover the necessary costs of waste management and clean-up of litter as well as the costs of awareness raising measures to prevent and reduce such litter. Those costs should not exceed the costs that are necessary to provide those services in a cost-efficient way and should be established in a transparent way between the actors concerned.

<sup>(17)</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

- (22) Directive 2008/98/EC lays down general minimum requirements for extended producer responsibility schemes. Those requirements should apply to the extended producer responsibility schemes established by this Directive, irrespective of whether their mode of implementation is by legislative act or by means of agreements under this Directive. The relevance of some requirements depends on the characteristics of the product. Separate collection is not required to ensure proper treatment in line with the waste hierarchy for tobacco products with filters containing plastic, wet wipes and balloons. Therefore setting up separate collection for those products should not be mandatory. This Directive should establish extended producer responsibility requirements in addition to those laid down by Directive 2008/98/EC, for example, the requirement for producers of certain single-use plastic products to cover the costs of cleaning up litter. It should also be possible to cover the costs of the setting up of specific infrastructure for collection of post-consumption waste of tobacco products, such as appropriate waste receptacles in common litter hotspots. The calculation methodology for the costs of cleaning up litter should take into account considerations of proportionality. To minimise administrative costs, Member States should be able to determine financial contributions towards the costs of cleaning up litter by setting appropriate multiannual fixed amounts.
- (23) The large percentage of plastic stemming from discarded fishing gear, including abandoned and lost fishing gear, in marine litter indicates that the existing legal requirements laid down in Regulation (EC) No 1224/2009, Directive 2000/59/EC and Directive 2008/98/EC do not provide sufficient incentives to return such fishing gear to shore for collection and treatment. The indirect fee system set up under Directive (EU) 2019/883 of the European Parliament and of the Council <sup>(18)</sup> provides a system for removing the incentive for ships to discharge their waste at sea, and ensures a right of delivery. That system should, however, be supplemented by further financial incentives for fishermen to bring their waste fishing gear on shore to avoid any potential increase in the indirect waste fee to be paid. As plastic components of fishing gear have high recycling potential, Member States should, in line with the polluter-pays principle, introduce extended producer responsibility for fishing gear and components of fishing gear containing plastic to ensure separate collection of waste fishing gear and to finance environmentally sound waste management of waste fishing gear, in particular recycling.
- (24) In the framework of an extended producer responsibility for fishing gear containing plastic, Member States should monitor and assess, in line with the reporting obligations laid down in this Directive, fishing gear containing plastic.
- (25) While all marine litter containing plastic poses a risk to the environment and to human health and should be tackled, proportionality considerations should also be taken into account. Therefore, the fishermen themselves and artisanal makers of fishing gear containing plastic should not be considered as producers and should not be held responsible for fulfilling the obligations of the producer related to the extended producer responsibility.
- (26) Economic and other incentives to support sustainable consumer choices and promote responsible consumer behaviour can be an effective tool for achieving the objectives of this Directive.
- (27) Beverage bottles that are single-use plastic products are one of the marine litter items that are found the most on beaches in the Union. This is due to ineffective separate collection systems and low participation in those systems by consumers. It is necessary to promote more effective separate collection systems. Therefore, a minimum separate collection target should be established for beverage bottles that are single-use plastic products. While the obligation to separately collect waste requires that waste be kept separate by type and nature, it should be possible to collect certain types of waste together provided that this does not impede high-quality recycling in line with the waste hierarchy in accordance with Article 10(2) and point (a) of Article 10(3) of Directive 2008/98/EC. The setting of the separate collection target should be based on the amount of single-use plastic beverage bottles placed on the market in a Member State or alternatively on the amount of waste single-use plastic beverage bottles generated in a Member State. The calculation of the amount of waste generated in a Member State should take due account of all waste single-use plastic beverage bottles generated, including those which become litter instead of being disposed of through waste collection systems. Member States should be able to achieve that minimum target by setting separate collection targets for beverage bottles that are single-use plastic products in the framework of the extended producer responsibility schemes, by establishing deposit-refund schemes or by any other measure that

<sup>(18)</sup> Directive (EU) 2019/883 of the European Parliament and of the Council of 17 April 2019 on port reception facilities for the delivery of waste from ships, amending Directive 2010/65/EU and repealing Directive 2000/59/EC (OJ L 151, 7.6.2019, p. 116).

they find appropriate. That will have a direct, positive impact on the collection rate, the quality of the collected material and the quality of the recyclates, offering opportunities for the recycling business and the market for the recyclates. It will support reaching the recycling targets for packaging waste set in Directive 94/62/EC.

- (28) In order to prevent littering and other inappropriate means of waste disposal resulting in marine litter containing plastic, it is necessary for consumers of single-use plastic products and users of fishing gear containing plastic to be properly informed about the availability of re-usable alternatives and re-use systems, the most appropriate waste management options available and/or which waste disposal options are to be avoided, about best practices with regard to sound waste management and the environmental impact of bad disposal practices, as well as about the plastic content in certain single-use plastic products and fishing gear and the impact of inappropriate waste disposal on the sewer network. Member States should therefore be required to take awareness raising measures ensuring that such information is provided to those consumers and users. The information should not contain any promotional content encouraging the use of single-use plastic products. Member States should be able to choose the measures which are the most appropriate based on the nature of the product or its use. Producers of single-use plastic products and fishing gear containing plastic should cover the costs of the awareness raising measures as part of their extended producer responsibility obligations.
- (29) The aim of this Directive is to protect the environment and human health. As the Court of Justice has held on numerous occasions, it would be incompatible with the binding effect which the third paragraph of Article 288 of the Treaty on the Functioning of the European Union ascribes to a Directive, to exclude, in principle, the possibility of an obligation imposed by a Directive from being relied on by persons concerned. That consideration applies particularly in respect of a Directive which has as its objective to prevent and reduce the impact of certain plastic products on the aquatic environment.
- (30) It is important to monitor the levels of marine litter in the Union in order to assess the implementation of this Directive. In accordance with Directive 2008/56/EC, Member States are required to regularly monitor the properties and quantities of marine litter, including plastic marine litter. That monitoring data is also to be communicated to the Commission.
- (31) Member States should lay down rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and should take all measures necessary to ensure that they are implemented. The penalties provided for should be effective, proportionate and dissuasive.
- (32) Pursuant to paragraph 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>(19)</sup>, the Commission should carry out an evaluation of this Directive. That evaluation should be based on experience gathered and data collected during the implementation of this Directive and data collected under Directives 2008/56/EC and 2008/98/EC. The evaluation should provide the basis for an assessment of possible further measures, including the setting of Union-wide reduction targets for 2030 and beyond, and an assessment whether, in view of monitoring of marine litter in the Union, the Annex listing single-use plastic products needs to be reviewed and whether the scope of this Directive can be broadened to other single-use products.
- (33) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission in respect of the methodology for the calculation and verification of the annual consumption of single-use plastic products for which consumption reduction objectives have been set, the rules for the calculation and verification of the attainment of the targets on minimum recycled content for single-use plastic beverage bottles, the specifications for the marking to be affixed on certain single-use plastic products, the methodology for the calculation and verification of the collection targets of single-use plastic products for which separate collection targets have been set and the format for the reporting of data and information on the implementation of this Directive. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>(20)</sup>.
- (34) It is appropriate to allow Member States to choose to implement certain provisions of this Directive by means of agreements between the competent authorities and the economic sectors concerned, provided that certain requirements are met.
- (35) The fight against litter is a shared effort between competent authorities, producers and consumers. Public authorities, including the Union institutions, should lead by example.

<sup>(19)</sup> OJ L 123, 12.5.2016, p. 1.

<sup>(20)</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (36) Since the objectives of this Directive, namely to prevent and to reduce the impact of certain single-use plastic products, products made from oxo-degradable plastic and fishing gear containing plastic on the environment and on human health, and to promote the transition to a circular economy, including the fostering of innovative and sustainable business models, products and materials, thus also contributing to the efficient functioning of the internal market, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

#### *Article 1*

### **Objectives**

The objectives of this Directive are to prevent and reduce the impact of certain plastic products on the environment, in particular the aquatic environment, and on human health, as well as to promote the transition to a circular economy with innovative and sustainable business models, products and materials, thus also contributing to the efficient functioning of the internal market.

#### *Article 2*

### **Scope**

1. This Directive applies to the single-use plastic products listed in the Annex, to products made from oxo-degradable plastic and to fishing gear containing plastic.
2. Where this Directive conflicts with Directive 94/62/EC or 2008/98/EC, this Directive shall prevail.

#### *Article 3*

### **Definitions**

For the purposes of this Directive, the following definitions apply:

- (1) 'plastic' means a material consisting of a polymer as defined in point 5 of Article 3 of Regulation (EC) No 1907/2006, to which additives or other substances may have been added, and which can function as a main structural component of final products, with the exception of natural polymers that have not been chemically modified;
- (2) 'single-use plastic product' means a product that is made wholly or partly from plastic and that is not conceived, designed or placed on the market to accomplish, within its life span, multiple trips or rotations by being returned to a producer for refill or re-used for the same purpose for which it was conceived;
- (3) 'oxo-degradable plastic' means plastic materials that include additives which, through oxidation, lead to the fragmentation of the plastic material into micro-fragments or to chemical decomposition;
- (4) 'fishing gear' means any item or piece of equipment that is used in fishing or aquaculture to target, capture or rear marine biological resources or that is floating on the sea surface, and is deployed with the objective of attracting and capturing or of rearing such marine biological resources;
- (5) 'waste fishing gear' means any fishing gear covered by the definition of waste in point 1 of Article 3 of Directive 2008/98/EC, including all separate components, substances or materials that were part of or attached to such fishing gear when it was discarded, including when it was abandoned or lost;
- (6) 'placing on the market' means the first making available of a product on the market of a Member State;

- (7) 'making available on the market' means any supply of a product for distribution, consumption or use on the market of a Member State in the course of a commercial activity, whether in return for payment or free of charge;
- (8) 'harmonised standard' means a harmonised standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012;
- (9) 'waste' means waste as defined in point 1 of Article 3 of Directive 2008/98/EC;
- (10) 'extended producer responsibility scheme' means extended producer responsibility scheme as defined in point 21 of Article 3 of Directive 2008/98/EC;
- (11) 'producer' means:
- (a) any natural or legal person established in a Member State that professionally manufactures, fills, sells or imports, irrespective of the selling technique used, including by means of distance contracts as defined in point (7) of Article 2 of Directive 2011/83/EU of the European Parliament and of the Council <sup>(21)</sup>, and places on the market of that Member State single-use plastic products, filled single-use plastic products or fishing gear containing plastic, other than persons carrying out fishing activities as defined in point (28) of Article 4 of Regulation (EU) No 1380/2013 of the European Parliament and of the Council <sup>(22)</sup>; or
  - (b) any natural or legal person established in one Member State or in a third country that professionally sells in another Member State directly to private households or to users other than private households, by means of distance contracts as defined in point (7) of Article 2 of Directive 2011/83/EU, single-use plastic products, filled single-use plastic products or fishing gear containing plastic, other than persons carrying out fishing activities as defined in point (28) of Article 4 of Regulation (EU) No 1380/2013;
- (12) 'collection' means collection as defined in point 10 of Article 3 of Directive 2008/98/EC;
- (13) 'separate collection' means separate collection as defined in point 11 of Article 3 of Directive 2008/98/EC;
- (14) 'treatment' means treatment as defined in point 14 of Article 3 of Directive 2008/98/EC;
- (15) 'packaging' means packaging as defined in point 1 of Article 3 of Directive 94/62/EC;
- (16) 'biodegradable plastic' means a plastic capable of undergoing physical, biological decomposition, such that it ultimately decomposes into carbon dioxide (CO<sub>2</sub>), biomass and water, and is, in accordance with European standards for packaging, recoverable through composting and anaerobic digestion;
- (17) 'port reception facilities' means port reception facilities as defined in point (e) of Article 2 of Directive 2000/59/EC;
- (18) 'tobacco products' means tobacco products as defined in point (4) of Article 2 of Directive 2014/40/EU.

#### Article 4

### Consumption reduction

1. Member States shall take the necessary measures to achieve an ambitious and sustained reduction in the consumption of the single-use plastic products listed in Part A of the Annex, in line with the overall objectives of the Union's waste policy, in particular waste prevention, leading to a substantial reversal of increasing consumption trends. Those measures shall achieve a measurable quantitative reduction in the consumption of the single-use plastic products listed in Part A of the Annex on the territory of the Member State by 2026 compared to 2022.

<sup>(21)</sup> Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (OJ L 304, 22.11.2011, p. 64).

<sup>(22)</sup> Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

By 3 July 2021, Member States shall prepare a description of the measures which they have adopted pursuant to the first subparagraph, notify the description to the Commission and make it publicly available. Member States shall integrate the measures set out in the description into the plans or programmes referred to in Article 11 upon the first subsequent update of those plans or programmes in accordance with the relevant legislative acts of the Union governing those plans or programmes, or into any other programmes drawn up specifically for that purpose.

The measures may include national consumption reduction targets, measures ensuring that re-usable alternatives to the single-use plastic products listed in Part A of the Annex are made available at the point of sale to the final consumer, economic instruments such as instruments ensuring that those single-use plastic products are not provided free of charge at the point of sale to the final consumer and agreements as referred to in Article 17(3). Member States may impose marketing restrictions in derogation from Article 18 of Directive 94/62/EC for the purposes of preventing such products from becoming litter in order to ensure that they are substituted with alternatives that are re-usable or do not contain plastic. The measures may vary depending on the environmental impact of those single-use plastic products over their life cycle, including when they become litter.

Measures adopted pursuant to this paragraph shall be proportionate and non-discriminatory. Member States shall notify the Commission of those measures in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council<sup>(23)</sup> where so required by that Directive.

In order to comply with the first subparagraph of this paragraph, each Member State shall monitor the single-use plastic products listed in Part A of the Annex placed on the market and the reduction measures taken and shall report on progress made to the Commission in accordance with paragraph 2 of this Article and Article 13(1) with a view to the establishment of binding quantitative Union targets for consumption reduction.

2. By 3 January 2021, the Commission shall adopt an implementing act laying down the methodology for the calculation and verification of the ambitious and sustained reduction in the consumption of the single-use plastic products listed in Part A of the Annex. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 16(2).

#### *Article 5*

##### **Restrictions on placing on the market**

Member States shall prohibit the placing on the market of the single-use plastic products listed in Part B of the Annex and of products made from oxo-degradable plastic.

#### *Article 6*

##### **Product requirements**

1. Member States shall ensure that single-use plastic products listed in Part C of the Annex that have caps and lids made of plastic may be placed on the market only if the caps and lids remain attached to the containers during the products' intended use stage.

2. For the purposes of this Article, metal caps or lids with plastic seals shall not be considered to be made of plastic.

3. By 3 October 2019, the Commission shall request the European standardisation organisations to develop harmonised standards relating to the requirement referred to in paragraph 1. Those standards shall in particular address the need to ensure the necessary strength, reliability and safety of beverage container closures, including those for carbonated drinks.

<sup>(23)</sup> Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

4. From the date of publication of the references to harmonised standards referred to in paragraph 3 in the *Official Journal of the European Union*, single-use plastic products referred to in paragraph 1 which are in conformity with those standards or parts thereof shall be presumed to be in conformity with the requirement laid down in paragraph 1.

5. With regard to beverage bottles listed in Part F of the Annex, each Member State shall ensure that:

(a) from 2025, beverage bottles listed in Part F of the Annex which are manufactured from polyethylene terephthalate as the major component ('PET bottles') contain at least 25 % recycled plastic, calculated as an average for all PET bottles placed on the market on the territory of that Member State; and

(b) from 2030, beverage bottles listed in Part F of the Annex contain at least 30 % recycled plastic, calculated as an average for all such beverage bottles placed on the market on the territory of that Member State.

By 1 January 2022, the Commission shall adopt implementing acts laying down the rules for the calculation and verification of the targets established in the first subparagraph of this paragraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 16(2).

#### Article 7

##### Marking requirements

1. Member States shall ensure that each single-use plastic product listed in Part D of the Annex placed on the market bears a conspicuous, clearly legible and indelible marking on its packaging or on the product itself informing consumers of the following:

(a) appropriate waste management options for the product or waste disposal means to be avoided for that product, in line with the waste hierarchy; and

(b) the presence of plastics in the product and the resulting negative impact of littering or other inappropriate means of waste disposal of the product on the environment.

The harmonised marking specifications shall be established by the Commission in accordance with paragraph 2.

2. By 3 July 2020, the Commission shall adopt an implementing act establishing harmonised specifications for the marking referred to in paragraph 1 that:

(a) provide that the marking of single-use plastic products listed in points (1), (2) and (3) of Part D of the Annex shall be placed on the sales and grouped packaging of those products. Where multiple sales units are grouped at the point of purchase, each sales unit shall bear a marking on its packaging. The marking shall not be required for packaging with a surface area of less than 10 cm<sup>2</sup>;

(b) provide that the marking of single-use plastic products listed in point (4) of Part D of the Annex shall be placed on the product itself; and

(c) consider existing sectoral voluntary approaches and pay particular attention to the need to avoid information that misleads consumers.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 16(2).

3. The provisions of this Article concerning tobacco products are in addition to those laid down in Directive 2014/40/EU.

*Article 8***Extended producer responsibility**

1. Member States shall ensure that extended producer responsibility schemes are established for all single-use plastic products listed in Part E of the Annex which are placed on the market of the Member State, in accordance with Articles 8 and 8a of Directive 2008/98/EC.

2. Member States shall ensure that the producers of the single-use plastic products listed in Section I of Part E of the Annex to this Directive cover the costs pursuant to the extended producer responsibility provisions in Directives 2008/98/EC and 94/62/EC and, insofar as not already included, cover the following costs:

- (a) the costs of the awareness raising measures referred to in Article 10 of this Directive regarding those products;
- (b) the costs of waste collection for those products that are discarded in public collection systems, including the infrastructure and its operation, and the subsequent transport and treatment of that waste; and
- (c) the costs of cleaning up litter resulting from those products and the subsequent transport and treatment of that litter.

3. Member States shall ensure that the producers of the single-use plastic products listed in Sections II and III of Part E of the Annex cover at least the following costs:

- (a) the costs of the awareness raising measures referred to in Article 10 regarding those products;
- (b) the costs of cleaning up litter resulting from those products and the subsequent transport and treatment of that litter; and
- (c) the costs of data gathering and reporting in accordance with point (c) of Article 8a(1) of Directive 2008/98/EC.

With regard to the single-use plastic products listed in Section III of Part E of the Annex to this Directive, Member States shall ensure that the producers cover, in addition, the costs of waste collection for those products that are discarded in public collection systems, including the infrastructure and its operation, and the subsequent transport and treatment of that waste. The costs may include the setting up of specific infrastructure for the waste collection for those products, such as appropriate waste receptacles in common litter hotspots.

4. The costs to be covered referred to in paragraphs 2 and 3 shall not exceed the costs that are necessary to provide the services referred to therein in a cost-efficient way and shall be established in a transparent way between the actors concerned. The costs of cleaning up litter shall be limited to activities undertaken by public authorities or on their behalf. The calculation methodology shall be developed in a way that allows for the costs of cleaning up litter to be established in a proportionate way. To minimise administrative costs, Member States may determine financial contributions towards the costs of cleaning up litter by setting appropriate multiannual fixed amounts.

The Commission shall publish guidelines for criteria, in consultation with Member States, on the costs of cleaning up litter referred to in paragraphs 2 and 3.

5. Member States shall define in a clear way the roles and responsibilities of all relevant actors involved.

With regard to packaging, those roles and responsibilities shall be defined in line with Directive 94/62/EC.

6. Each Member State shall allow the producers established in another Member State and placing products on its market to appoint a legal or natural person established on its territory as an authorised representative for the purposes of fulfilling the obligations of a producer related to extended producer responsibility schemes on its territory.

7. Each Member State shall ensure that a producer established on its territory, which sells single-use plastic products listed in Part E of the Annex and fishing gear containing plastic in another Member State in which it is not established, appoints an authorised representative in that other Member State. The authorised representative shall be the person responsible for fulfilling the obligations of that producer pursuant to this Directive on the territory of that other Member State.

8. Member States shall ensure that extended producer responsibility schemes are established for fishing gear containing plastic placed on the market of the Member State, in accordance with Articles 8 and 8a of Directive 2008/98/EC.

Member States that have marine waters as defined in point 1 of Article 3 of Directive 2008/56/EC shall set a national minimum annual collection rate of waste fishing gear containing plastic for recycling.

Member States shall monitor fishing gear containing plastic placed on the market of the Member State as well as waste fishing gear containing plastic collected and shall report to the Commission in accordance with Article 13(1) of this Directive with a view to the establishment of binding quantitative Union collection targets.

9. With regard to the extended producer responsibility schemes established pursuant to paragraph 8 of this Article, Member States shall ensure that the producers of fishing gear containing plastic cover the costs of the separate collection of waste fishing gear containing plastic that has been delivered to adequate port reception facilities in accordance with Directive (EU) 2019/883 or to other equivalent collection systems that fall outside the scope of that Directive and the costs of its subsequent transport and treatment. The producers shall also cover the costs of the awareness raising measures referred to in Article 10 regarding fishing gear containing plastic.

The requirements laid down in this paragraph supplement the requirements applicable to waste from fishing vessels in Union law on port reception facilities.

Without prejudice to technical measures laid down in Council Regulation (EC) No 850/98<sup>(24)</sup>, the Commission shall request the European standardisation organisations to develop harmonised standards relating to the circular design of fishing gear to encourage preparing for re-use and facilitate recyclability at end of life.

#### Article 9

##### Separate collection

1. Member States shall take the necessary measures to ensure the separate collection for recycling:
  - (a) by 2025, of an amount of waste single-use plastic products listed in Part F of the Annex equal to 77 % of such single-use plastic products placed on the market in a given year by weight;
  - (b) by 2029, of an amount of waste single-use plastic products listed in Part F of the Annex equal to 90 % of such single-use plastic products placed on the market in a given year by weight.

Single-use plastic products listed in Part F of the Annex placed on the market in a Member State may be deemed to be equal to the amount of waste generated from such products, including as litter, in the same year in that Member State.

In order to achieve that objective, Member States may inter alia:

- (a) establish deposit-refund schemes;
- (b) establish separate collection targets for relevant extended producer responsibility schemes.

The first subparagraph shall apply without prejudice to point (a) of Article 10(3) of Directive 2008/98/EC.

2. The Commission shall facilitate the exchange of information and sharing of best practices among Member States on the appropriate measures to meet the targets laid down in paragraph 1, inter alia, on deposit-refund schemes. The Commission shall make the results of such exchange of information and sharing of best practices publicly available.

3. By 3 July 2020, the Commission shall adopt an implementing act laying down the methodology for the calculation and verification of the separate collection targets laid down in paragraph 1 of this Article. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 16(2).

#### Article 10

##### Awareness raising measures

Member States shall take measures to inform consumers and to incentivise responsible consumer behaviour, in order to reduce litter from products covered by this Directive, and shall take measures to inform consumers of the single-use plastic products listed in Part G of the Annex and users of fishing gear containing plastic about the following:

- (a) the availability of re-usable alternatives, re-use systems and waste management options for those single-use plastic products and for fishing gear containing plastic as well as best practices in sound waste management carried out in accordance with Article 13 of Directive 2008/98/EC;
- (b) the impact of littering and other inappropriate waste disposal of those single-use plastic products and of fishing gear containing plastic on the environment, in particular on the marine environment; and

<sup>(24)</sup> Council Regulation (EC) No 850/98 of 30 March 1998 for the conservation of fishery resources through technical measures for the protection of juveniles of marine organisms (OJ L 125, 27.4.1998, p. 1).

(c) the impact of inappropriate means of waste disposal of those single-use plastic products on the sewer network.

#### Article 11

##### Coordination of measures

Without prejudice to the first subparagraph of Article 4(1) of this Directive, each Member State shall ensure that the measures taken to transpose and implement this Directive form an integral part of and are consistent with its programmes of measures established in accordance with Article 13 of Directive 2008/56/EC for those Member States that have marine waters, the programmes of measures established in accordance with Article 11 of Directive 2000/60/EC, waste management plans and waste prevention programmes established in accordance with Articles 28 and 29 of Directive 2008/98/EC and the waste reception and handling plans established under Directive (EU) 2019/883.

The measures that Member States take to transpose and implement Articles 4 to 9 of this Directive shall comply with Union food law to ensure that food hygiene and food safety are not compromised. Member States shall encourage the use of sustainable alternatives to single-use plastic where possible for materials intended to come into contact with food.

#### Article 12

##### Specifications and guidelines on single-use plastic products

In order to determine whether a food container is to be considered as a single-use plastic product for the purposes of this Directive, in addition to the criteria listed in the Annex as regards food containers, its tendency to become litter, due to its volume or size, in particular single-serve portions, shall play a decisive role.

By 3 July 2020, the Commission shall publish guidelines, in consultation with Member States, including examples of what is to be considered a single-use plastic product for the purposes of this Directive, as appropriate.

#### Article 13

##### Information systems and reporting

1. Member States shall, for each calendar year, report to the Commission the following:
  - (a) data on single-use plastic products listed in Part A of the Annex that have been placed on the market of the Member State each year, to demonstrate the consumption reduction in accordance with Article 4(1);
  - (b) information on the measures taken by the Member State for the purposes of Article 4(1);
  - (c) data on single-use plastic products listed in Part F of the Annex that have been separately collected in the Member State each year, to demonstrate the attainment of the separate collection targets in accordance with Article 9(1);
  - (d) data on fishing gear containing plastic placed on the market and on waste fishing gear collected in the Member State each year;
  - (e) information on recycled content in beverage bottles listed in Part F of the Annex to demonstrate the attainment of the targets laid down in Article 6(5); and
  - (f) data on the post-consumption waste of single-use plastic products listed in Section III of Part E of the Annex that has been collected in accordance with Article 8(3).

Member States shall report the data and information electronically within 18 months of the end of the reporting year for which they were collected. The data and information shall be reported in the format established by the Commission in accordance with paragraph 4 of this Article.

The first reporting period shall be the calendar year 2022, with the exception of points (e) and (f) of the first subparagraph for which the first reporting period shall be the calendar year 2023.

2. The data and information reported by Member States in accordance with this Article shall be accompanied by a quality check report. The data and information shall be reported in the format established by the Commission in accordance with paragraph 4.

3. The Commission shall review the data and information reported in accordance with this Article and publish a report on the results of its review. The report shall assess the organisation of the collection of the data and information, the sources of data and information and the methodology used in Member States as well as the completeness, reliability, timeliness and consistency of that data and information. The assessment may include specific recommendations for improvement. The report shall be drawn up after the first reporting of the data and information by the Member States and thereafter at the intervals envisaged in Article 12(3c) of Directive 94/62/EC.

4. By 3 January 2021, the Commission shall adopt implementing acts laying down the format for reporting data and information in accordance with points (a) and (b) of paragraph 1 and with paragraph 2 of this Article.

By 3 July 2020, the Commission shall adopt implementing acts laying down the format for reporting data in accordance with points (c) and (d) of paragraph 1 and with paragraph 2 of this Article.

By 1 January 2022, the Commission shall adopt implementing acts laying down the format for reporting data and information in accordance with points (e) and (f) of paragraph 1 and with paragraph 2 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 16(2). The format developed according to Article 12 of Directive 94/62/EC shall be taken into consideration.

#### Article 14

##### Penalties

Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by 3 July 2021, notify the Commission of those rules and those measures and shall notify it of any subsequent amendment affecting them.

#### Article 15

##### Evaluation and review

1. The Commission shall carry out an evaluation of this Directive by 3 July 2027. The evaluation shall be based on the information available in accordance with Article 13. Member States shall provide the Commission with any additional information necessary for the purposes of the evaluation and the preparation of the report referred to in paragraph 2 of this Article.

2. The Commission shall submit a report on the main findings of the evaluation carried out in accordance with paragraph 1 to the European Parliament, the Council and the European Economic and Social Committee. The report shall be accompanied by a legislative proposal, if appropriate. That proposal shall, if appropriate, set binding quantitative consumption reduction targets and set binding collection rates for waste fishing gear.

3. The report shall include:

- (a) an assessment of the need to review the Annex listing single-use plastic products, including as regards caps and lids made of plastic which are used for glass and metal beverage containers;
- (b) a study of the feasibility of establishing binding collection rates for waste fishing gear and binding quantitative Union targets for the consumption reduction of, in particular, single-use plastic products listed in Part A of the Annex, taking into account consumption levels and already achieved reductions in Member States;
- (c) an assessment of the change in materials used in the single-use plastic products covered by this Directive as well as of new consumption patterns and business models based on re-usable alternatives; this shall, wherever possible, include an overall life cycle analysis to assess the environmental impact of such products and their alternatives; and
- (d) an assessment of the scientific and technical progress concerning criteria or a standard for biodegradability in the marine environment applicable to single-use plastic products within the scope of this Directive and their single-use substitutes which ensure full decomposition into carbon dioxide (CO<sub>2</sub>), biomass and water within a timescale short enough for the plastics not to be harmful to marine life and not to lead to an accumulation of plastics in the environment.

4. As part of the evaluation carried out pursuant to paragraph 1, the Commission shall review the measures taken under this Directive as regards single-use plastic products listed in Section III of Part E of the Annex and shall submit a report on the main findings. The report shall also consider the options for binding measures for the reduction of the post-consumption waste of single-use plastic products listed in Section III of Part E of the Annex, including the possibility of setting binding collection rates for that post-consumption waste. The report shall, if appropriate, be accompanied by a legislative proposal.

#### Article 16

##### Committee procedure

1. The Commission shall be assisted by the Committee established by Article 39 of Directive 2008/98/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

#### Article 17

##### Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 3 July 2021. They shall immediately inform the Commission thereof.

However, the Member States shall apply the measures necessary to comply with:

- Article 5 from 3 July 2021,
- Article 6(1) from 3 July 2024,
- Article 7(1) from 3 July 2021,
- Article 8 by 31 December 2024 but, in relation to extended producer responsibility schemes established before 4 July 2018 and in relation to single-use plastic products listed in Section III of Part E of the Annex, by 5 January 2023.

When Member States adopt the measures referred to in this paragraph, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

3. Provided that the waste management targets and objectives set out in Articles 4 and 8 are achieved, Member States may transpose the provisions set out in Articles 4(1) and 8(1) and (8), except as regards single-use plastic products listed in Section III of Part E of the Annex, by means of agreements between the competent authorities and the economic sectors concerned.

Such agreements shall meet the following requirements:

- (a) agreements shall be enforceable;
- (b) agreements need to specify objectives with the corresponding deadlines;
- (c) agreements shall be published in the national official journal or an official document equally accessible to the public and transmitted to the Commission;
- (d) the results achieved under an agreement shall be monitored regularly, reported to the competent authorities and to the Commission and made available to the public under the conditions set out in the agreement;
- (e) the competent authorities shall make provisions to examine the progress reached under an agreement; and
- (f) in case of non-compliance with an agreement Member States shall implement the relevant provisions of this Directive by legislative, regulatory or administrative measures.

#### Article 18

##### Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

#### Article 19

##### Addressees

This Directive is addressed to the Member States.

Done at Brussels, 5 June 2019.

*For the European Parliament*  
*The President*  
A. TAJANI

*For the Council*  
*The President*  
G. CIAMBA

## ANNEX

## PART A

**Single-use plastic products covered by Article 4 on consumption reduction**

- (1) Cups for beverages, including their covers and lids;
- (2) Food containers, i.e. receptacles such as boxes, with or without a cover, used to contain food which:
  - (a) is intended for immediate consumption, either on-the-spot or take-away,
  - (b) is typically consumed from the receptacle, and
  - (c) is ready to be consumed without any further preparation, such as cooking, boiling or heating,including food containers used for fast food or other meal ready for immediate consumption, except beverage containers, plates and packets and wrappers containing food.

## PART B

**Single-use plastic products covered by Article 5 on restrictions on placing on the market**

- (1) Cotton bud sticks, except if they fall within the scope of Council Directive 90/385/EEC <sup>(1)</sup> or Council Directive 93/42/EEC <sup>(2)</sup>;
- (2) Cutlery (forks, knives, spoons, chopsticks);
- (3) Plates;
- (4) Straws, except if they fall within the scope of Directive 90/385/EEC or Directive 93/42/EEC;
- (5) Beverage stirrers;
- (6) Sticks to be attached to and to support balloons, except balloons for industrial or other professional uses and applications that are not distributed to consumers, including the mechanisms of such sticks;
- (7) Food containers made of expanded polystyrene, i.e. receptacles such as boxes, with or without a cover, used to contain food which:
  - (a) is intended for immediate consumption, either on-the-spot or take-away,
  - (b) is typically consumed from the receptacle, and
  - (c) is ready to be consumed without any further preparation, such as cooking, boiling or heating,including food containers used for fast food or other meal ready for immediate consumption, except beverage containers, plates and packets and wrappers containing food;
- (8) Beverage containers made of expanded polystyrene, including their caps and lids;
- (9) Cups for beverages made of expanded polystyrene, including their covers and lids.

<sup>(1)</sup> Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

<sup>(2)</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

## PART C

**Single-use plastic products covered by Article 6(1) to (4) on product requirements**

Beverage containers with a capacity of up to three litres, i.e. receptacles used to contain liquid, such as beverage bottles including their caps and lids and composite beverage packaging including their caps and lids, but not:

- (a) glass or metal beverage containers that have caps and lids made from plastic,
- (b) beverage containers intended and used for food for special medical purposes as defined in point (g) of Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council <sup>(3)</sup> that is in liquid form.

## PART D

**Single-use plastic products covered by Article 7 on marking requirements**

- (1) Sanitary towels (pads), tampons and tampon applicators;
- (2) Wet wipes, i.e. pre-wetted personal care and domestic wipes;
- (3) Tobacco products with filters and filters marketed for use in combination with tobacco products;
- (4) Cups for beverages.

## PART E

**I. Single-use plastic products covered by Article 8(2) on extended producer responsibility**

- (1) Food containers, i.e. receptacles such as boxes, with or without a cover, used to contain food which:
  - (a) is intended for immediate consumption, either on-the-spot or take-away,
  - (b) is typically consumed from the receptacle, and
  - (c) is ready to be consumed without any further preparation, such as cooking, boiling or heating,including food containers used for fast food or other meal ready for immediate consumption, except beverage containers, plates and packets and wrappers containing food;
- (2) Packets and wrappers made from flexible material containing food that is intended for immediate consumption from the packet or wrapper without any further preparation;
- (3) Beverage containers with a capacity of up to three litres, i.e. receptacles used to contain liquid such as beverage bottles including their caps and lids and composite beverage packaging including their caps and lids, but not glass or metal beverage containers that have caps and lids made from plastic;
- (4) Cups for beverages, including their covers and lids;
- (5) Lightweight plastic carrier bags as defined in point 1c of Article 3 of Directive 94/62/EC.

**II. Single-use plastic products covered by Article 8(3) on extended producer responsibility**

- (1) Wet wipes, i.e. pre-wetted personal care and domestic wipes;
- (2) Balloons, except balloons for industrial or other professional uses and applications that are not distributed to consumers.

<sup>(3)</sup> 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).

### III. Other single-use plastic products covered by Article 8(3) on extended producer responsibility

Tobacco products with filters and filters marketed for use in combination with tobacco products.

#### PART F

#### Single-use plastic products covered by Article 9 on separate collection and by Article 6(5) on product requirements

Beverage bottles with a capacity of up to three litres, including their caps and lids, but not:

- (a) glass or metal beverage bottles that have caps and lids made from plastic,
- (b) beverage bottles intended and used for food for special medical purposes as defined in point (g) of Article 2 of Regulation (EU) No 609/2013 that is in liquid form.

#### PART G

#### Single-use plastic products covered by Article 10 on awareness raising

- (1) Food containers, i.e. receptacles such as boxes, with or without a cover, used to contain food which:
    - (a) is intended for immediate consumption, either on-the-spot or take-away,
    - (b) is typically consumed from the receptacle, and
    - (c) is ready to be consumed without any further preparation, such as cooking, boiling or heating,including food containers used for fast food or other meal ready for immediate consumption, except beverage containers, plates and packets and wrappers containing food;
  - (2) Packets and wrappers made from flexible material containing food that is intended for immediate consumption from the packet or wrapper without any further preparation;
  - (3) Beverage containers with a capacity of up to three litres, i.e. receptacles used to contain liquid such as beverage bottles including their caps and lids and composite beverage packaging including their caps and lids, but not glass or metal beverage containers that have caps and lids made from plastic;
  - (4) Cups for beverages, including their covers and lids;
  - (5) Tobacco products with filters and filters marketed for use in combination with tobacco products;
  - (6) Wet wipes, i.e. pre-wetted personal care and domestic wipes;
  - (7) Balloons, except balloons for industrial or other professional uses and applications that are not distributed to consumers;
  - (8) Lightweight plastic carrier bags as defined in point 1c of Article 3 of Directive 94/62/EC;
  - (9) Sanitary towels (pads), tampons and tampon applicators.
-

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/2151****of 17 December 2020****laying down rules on harmonised marking specifications on single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment <sup>(1)</sup>, and in particular Article 7(2) thereof,

Whereas:

- (1) Directive (EU) 2019/904 lays down general requirements on the marking of certain single-use plastic products that are frequently inappropriately disposed of. The marking is to inform consumers of the presence of plastic in the product; of the waste disposal means to be avoided for that product; and the resulting negative impact of littering or other inappropriate means of waste disposal of the product on the environment.
- (2) Directive (EU) 2019/904 requires the Commission to establish harmonised specifications for the marking of single-use plastic products listed in Part D of its Annex. The harmonised specifications for the position, size and design of the marking should take into account the different product groups covered. The format, colours, minimum resolution and font sizes to be used should be specified in order to ensure that each element of the marking is fully visible.
- (3) The Commission evaluated existing markings identified through a stakeholder online survey and the market overview, in order to understand the assessment mechanism and the requirements behind the markings and their impact.
- (4) The Commission has consulted representative groups of consumers and has performed a field test to ascertain that the markings are effective and easily understandable and to avoid misleading information.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 39 of Directive 2008/98/EC of the European Parliament and of the Council <sup>(2)</sup>,

HAS ADOPTED THIS REGULATION:

*Article 1***Packaging**For the purposes of this Regulation, 'packaging' means sales packaging and grouped packaging as defined in point 1 of Article 3 of Directive 94/62/EC of the European Parliament and of the Council <sup>(3)</sup>.<sup>(1)</sup> OJ L 155, 12.6.2019, p. 1.<sup>(2)</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).<sup>(3)</sup> European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10).

*Article 2***Harmonised marking specifications**

1. The harmonised marking specifications for sanitary towels (pads), and for tampons and tampon applicators are laid down in Annex I.
2. The harmonised marking specifications for wet wipes, i.e. pre-wetted personal care and domestic wipes are laid down in Annex II.
3. The harmonised marking specifications for tobacco products with filters and filters marketed for use in combination with tobacco products are laid down in Annex III.
4. The harmonised marking specifications for beverage cups are laid down in Annex IV.

*Article 3***Languages**

The information text of the marking shall be written in the official language or languages of the Member State(s) where the single-use plastic product is placed on the market.

*Article 4***Entry into force and application**

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

It shall apply from 3 July 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 December 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX I

**Harmonised marking specifications for sanitary towels (pads), and for tampons and tampon applicators**

1. Packaging of sanitary towels (pads), with the surface area of 10 cm<sup>2</sup> or more, shall bear the following printed marking:



*Note:* the black line bordering the marking is not part thereof. Its only purpose is to show the thin white line bordering the marking against the white page.

By way of derogation from the first sentence of this point, the marking of packaging of sanitary towels (pads) placed on the market before 4 July 2022 may be affixed by means of stickers.

2. Packaging of tampons and tampon applicators, with the surface area of 10 cm<sup>2</sup> or more, shall bear the following printed marking:



*Note:* the black line bordering the marking is not part thereof. Its only purpose is to show the thin white line bordering the marking against the white page.

By way of derogation from the first sentence of this point, the marking of packaging of tampons and tampons applicators placed on the market before 4 July 2022 may be affixed by means of stickers.

3. The marking set out in points 1 and 2 shall comply with the requirements laid down in this point.

(a) Position of the marking

The marking shall be placed horizontally on the external front or top surface, whichever is more clearly visible, of the packaging.

Where the marking of the minimum size cannot fit in its entirety on the external front or top surface of the packaging, it may be placed partly on two sides of the packaging, i.e. top and front, or front and side, whichever is more clearly visible.

Where it is not possible to place the marking horizontally due to the shape or size of the packaging, it may be rotated 90° and placed vertically.

The boxes of the marking shall not be separated.

When opening the packaging in accordance with any instructions, the marking should not be torn or made illegible.

(b) Size of the marking

The marking shall be composed of two equal-sized red and blue boxes, which are placed next to each other, and a rectangular black box containing the information text 'PLASTIC IN PRODUCT', placed below the two equal-sized boxes. The ratio between the height and length of the marking shall be 1:2.

Where the area of the external front or top surface of the packaging on which the marking is placed is less than 65 cm<sup>2</sup>, the minimum size of the marking shall be 1,4 cm by 2,8 cm (3,92 cm<sup>2</sup>). In all other cases, the marking shall cover at least 6 % of the surface area on which it is placed. The maximum required size of the marking shall be 3 cm by 6 cm (18 cm<sup>2</sup>).

(c) Design of the marking

The design of the marking shall be reproduced without adding any effects, adjusting the colours, retouching or extending the background. The marking shall be reproduced at a minimum resolution of 300 dots per inch when printed in actual size. The marking shall be bordered by a thin white line.

The information text 'PLASTIC IN PRODUCT' shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt and a maximum of 14 pt.

Where the information text is translated into another or several official languages of the Member States, the translated information text shall be placed either close below the marking, or inside the rectangular black box below the first language, and shall be in both cases clearly visible. In exceptional cases due to spatial constraints on the external front or top surface of the packaging, the information text translated into another or several official languages of the Member States may be placed elsewhere on the packaging as close as possible to the marking and where it is clearly visible. The translated information text shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt and a maximum of 14 pt. Where the information text in additional languages is placed in the rectangular black box, derogations from the maximum required size of the marking are possible.

The colours having the following colour codes shall be used:

- White: C = 0 / M = 0 / Y = 0 / K = 0
  - Black: C = 0 / M = 0 / Y = 0 / K = 100
  - Red: C = 0 / M = 90 / Y = 60 / K = 0
  - Blue: C = 60 / M = 0 / Y = 0 / K = 0.
-

## ANNEX II

**Harmonised marking specifications for wet wipes**

1. Packaging of wet wipes (i.e. pre-wetted personal care and domestic wipes), with the surface area of 10 cm<sup>2</sup> or more, shall bear the following printed marking:



Note: the black line bordering the marking is not part thereof. Its only purpose is to show the thin white line bordering the marking against the white page.

By way of derogation from the first sentence of this point, the marking of packaging of wet wipes placed on the market before 4 July 2022 may be affixed by means of stickers.

2. The marking shall comply with the requirements laid down in this point.

- (a) Position of the marking

The marking shall be placed horizontally on the external front or top surface, whichever is more clearly visible, of the packaging.

Where the marking of the minimum size cannot fit in its entirety on the external front or top surface of the packaging, it may be placed partly on two sides of the packaging, i.e. top and front, or front and side, whichever is more clearly visible.

Where it is not possible to place the marking horizontally due to the shape or size of the packaging, it may be rotated 90° and placed vertically.

The boxes of the marking shall not be separated.

When opening the packaging in accordance with any instructions, the marking should not be torn or made illegible.

- (b) Size of the marking

The marking shall be composed of two equal-sized red and blue boxes, which are placed next to each other, and a rectangular black box containing the information text 'PLASTIC IN PRODUCT' placed below the two equal-sized boxes. The ratio between the height and length of the marking shall be 1:2.

Where the area of the external front or top surface of the packaging on which the marking is placed is less than 65 cm<sup>2</sup>, the minimum size of the marking shall be 1,4 cm by 2,8 cm (3,92 cm<sup>2</sup>). In all other cases, the marking shall cover at least 6 % of the surface area on which it is placed. The maximum required size of the marking shall be 3 cm by 6 cm (18 cm<sup>2</sup>).

- (c) Design of the marking

The design of the marking shall be reproduced without adding any effects, adjusting the colours, retouching or extending the background. The marking shall be reproduced at a minimum resolution of 300 dots per inch when printed in actual size. The marking shall be bordered by a thin white line.

The information text 'PLASTIC IN PRODUCT' shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt and a maximum of 14 pt.

Where the information text is translated into another or several official languages of the Member States, the translated information text shall be placed either close below the marking, or inside the rectangular black box below the first language, and shall be in both cases clearly visible. In exceptional cases due to spatial constraints on the external front or top surface of the packaging, the information text translated into another or several official languages of the Member States may be placed elsewhere on the packaging as close as possible to the marking and

where it is clearly visible. The translated information text shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt and a maximum of 14 pt. Where the information text in additional languages is placed in the rectangular black box, derogations from the maximum required size of the marking are possible.

The colours having the following colour codes shall be used:

- White: C = 0 / M = 0 / Y = 0 / K = 0
  - Black: C = 0 / M = 0 / Y = 0 / K = 100
  - Red: C = 0 / M = 90 / Y = 60 / K = 0
  - Blue: C = 60 / M = 0 / Y = 0 / K = 0.
-

## ANNEX III

**Harmonised marking specifications for tobacco products with filters and filters marketed for use in combination with tobacco products**

1. Unit packet as defined in point 30 of Article 2 of Directive 2014/40/EU ('unit packet') and outside packaging as defined in point 29 of Article 2 of Directive 2014/40/EU ('outside packaging') for tobacco products with filters with the surface area of 10 cm<sup>2</sup> or more; and packaging for filters marketed for use in combination with tobacco products with the surface area of 10 cm<sup>2</sup> or more shall bear the following printed marking:



*Note:* the black line bordering the marking is not part thereof. Its only purpose is to show the thin white line bordering the marking against the white page.

By way of derogation from the first sentence of this point, the marking of unit packet and outside packaging for tobacco products with filters and packaging for filters marketed for use in combination with tobacco products placed on the market before 4 July 2022 may be affixed by means of stickers.

2. The marking shall comply with the requirements laid down in this point.

- (a) Position of the marking

- (i) Tobacco products with filters

The marking shall be placed horizontally on the external back surface of the unit packet and on the outside packaging.

Where the marking of the minimum size cannot fit horizontally on the external back surface of the unit packet, it may be rotated 90° and placed vertically on the back surface or on any of the external lateral surfaces of the unit packet. In all cases, it shall be clearly visible.

The boxes of the marking shall not be separated.

The marking shall not obstruct in any way the visibility of the health warnings required by Directive 2014/40/EU.

The marking shall not be totally or partially covered by other labels or stamps.

When opening the unit packet and of the outside packaging in accordance with any instructions, the marking should not be torn or made illegible.

- (ii) Filters marketed for use in combination with tobacco products

The marking shall be placed horizontally on the external front or top surface, whichever is more clearly visible, of the packaging.

Where the marking of the minimum size cannot fit in its entirety on the external front or top surface of the packaging, it may be placed horizontally partly on two sides of the packaging, i.e. top and front or front and side, whichever is more clearly visible.

Where it is not possible to place the marking horizontally due to the shape or size of the packaging, it may be rotated 90° and placed vertically.

The boxes of the marking shall not be separated.

When opening of the packaging in accordance with any instructions, the marking should not be torn or made illegible.

(b) Size of the marking

The marking shall be composed of two equal-sized red and blue boxes, which are placed next to each other, and a rectangular black box containing the information text 'PLASTIC IN FILTER' placed below the two equal-sized boxes. The ratio between the height and length of the marking shall be 1:2.

(i) Tobacco products with filters

Where the area of the external back surface of the unit packet is less than 65 cm<sup>2</sup>, the minimum size of the marking shall be 1,4 cm by 2,8 cm (3,92 cm<sup>2</sup>). In all other cases, the marking shall cover at least 6 % of the surface area on which it is placed. The maximum required size of the marking shall be 3 cm by 6 cm (18 cm<sup>2</sup>).

(ii) For filters marketed for use in combination with tobacco products

Where the area of the external front or top surface of the packaging on which the marking is placed is less than 65 cm<sup>2</sup>, the minimum size of the marking shall be 1,4 cm by 2,8 cm (3,92 cm<sup>2</sup>). In all other cases, the marking shall cover at least 6 % of the surface area on which it is placed. The maximum required size of the marking shall be 3 cm by 6 cm (18 cm<sup>2</sup>).

(c) Design of the marking

The design of the marking shall be reproduced without adding any effects, adjusting the colours, retouching or extending the background. The marking shall be reproduced at a minimum resolution of 300 dots per inch when printed in actual size. The marking shall be bordered by a thin white line.

The information text 'PLASTIC IN FILTER' shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt and a maximum of 14 pt.

Where the information text is translated into another or several official languages of the Member States, the translated information text shall be placed either close below the marking, or inside the rectangular black box below the first language, and shall be in both cases clearly visible. In exceptional cases due to spatial constraints on the external front or top surface of the packaging, the information text translated into another or several official languages of the Member States may be placed elsewhere on the packaging as close as possible to the marking and where it is clearly visible. The translated information text shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt and a maximum of 14 pt. Where the information text in additional languages is placed in the rectangular black box, derogations from the maximum required size of the marking are possible.

The colours having the following colour codes shall be used:

— White: C = 0 / M = 0 / Y = 0 / K = 0

— Black: C = 0 / M = 0 / Y = 0 / K = 100

— Red: C = 0 / M = 90 / Y = 60 / K = 0

— Blue: C = 60 / M = 0 / Y = 0 / K = 0.

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## ANNEX IV

**Harmonised marking specifications for beverage cups**

1. Beverage cups made partly from plastic shall bear the following printed marking:



*Note:* the black line bordering the marking is not part thereof. Its only purpose is to show the thin white line bordering the marking against the white page.

By way of derogation from the first sentence of this point, the marking of beverage cups made partly from plastic placed on the market before 4 July 2022 may be affixed by means of stickers.

2. Beverage cups made wholly from plastic shall bear either the following printed marking or the following engraved/embossed marking:

*Printed*



*Note:* the black line bordering the marking is not part thereof. Its only purpose is to provide contrast against the white page.

By way of derogation from the first sentence of this point, the marking of beverage cups made wholly from plastic placed on the market before 4 July 2022 may be affixed by means of stickers.

*Engraved/embossed*



*Note:* the black line bordering the marking and grey background are not part thereof. Its only purpose is to provide contrast against the white page.

3. The marking for beverage cups made partly from plastic shall comply with the requirements laid down in this point.

(a) Position of the marking

(i) Traditional cups:

The marking shall be placed horizontally on the external surface of the cup away from the rim to avoid contact with the consumer's mouth when drinking. The marking shall not be placed under the base of the cup.

(ii) Champagne-type cups:

The marking shall be placed horizontally on the external surface of the cup, including the upper side of the base that holds the stem. The marking shall be placed away from the rim to avoid contact with the consumer's mouth when drinking. The marking shall not be placed under the base of the cup.

Where it is not possible to place the marking horizontally due to the shape or size of the cup, it may be rotated 90° and placed vertically.

The boxes of the marking shall not be separated.

(b) Size of the marking

The marking shall be composed of two equal-sized red and blue boxes, which are placed next to each other, and a rectangular black box containing the information text 'PLASTIC IN PRODUCT' placed below the two equal-sized boxes. The ratio between the height and length of the marking shall be 1:2.

For cups with a volume of less than 500 ml, the minimum size of the marking shall be 1,4 cm by 2,8 cm (3,92 cm<sup>2</sup>).

For cups with a volume of 500 ml or more, the minimum size of the marking shall be 1,6 cm by 3,2 cm (5,12 cm<sup>2</sup>).

(c) Design of the marking

The design of the marking shall be reproduced without adding any effects, adjusting the colours, retouching or extending the background. The marking shall be reproduced at a minimum resolution of 300 dots per inch when printed in actual size. The marking shall be bordered by a thin white line.

The information text 'PLASTIC IN PRODUCT' shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt for the cups of less than 500 ml and of 6 pt for the cups of 500 ml or more.

Where the information text is translated into another or several official languages of the Member States, the translated information text shall be placed either close below the marking, or inside the rectangular black box below the first language, and shall be in both cases clearly visible. In exceptional cases due to spatial constraints on the external surface of the cup, the information text translated into another or several official languages of the Member States may be placed elsewhere on the cup as close as possible to the marking and where it is clearly visible. The translated information text shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt for the cups of less than 500 ml and 6 pt for the cups of 500 ml and more. Where the information text in additional languages is placed in the rectangular black box, derogations from the maximum required size of the marking are possible.

The colours having the following colour codes shall be used:

— White: C = 0 / M = 0 / Y = 0 / K = 0

— Black: C = 0 / M = 0 / Y = 0 / K = 100

— Red: C = 0 / M = 90 / Y = 60 / K = 0

— Blue: C = 60 / M = 0 / Y = 0 / K = 0.

4. The marking for beverage cups made wholly from plastic shall comply with the requirements laid down in this point

(a) Position of the marking

(i) Traditional cups

The marking shall be placed horizontally on the external surface of the cup, wherever is more clearly visible. The marking shall not be placed under the base of the cup. When printed, the marking shall be placed away from the rim to avoid contact with the consumer's mouth when drinking. In the case of ridged cups, the marking shall not be embossed/engraved on the ridges.

## (ii) Champagne-type cups

The marking shall be placed horizontally on the external surface of the cup, including the upper side of the base that holds the stem, wherever is more clearly visible. The marking shall not be placed under the base of the cup. When printed, the marking shall be placed away from the rim to avoid contact with the consumer's mouth when drinking. In the case of ridged cups, the marking shall not be embossed/engraved on the ridges.

Where it is not possible to place the marking horizontally due to the shape or size of the cup, it may be rotated 90° and placed vertically.

## (b) Size of the marking

The marking shall be rectangular-shaped and ratio between the height and length is 1:2.

For cups with a volume of less than 500 ml, the minimum size of the marking shall be 1,4 cm by 2,8 cm (3,92 cm<sup>2</sup>).

For cups with a volume of 500 ml or more, the minimum size of the marking shall be 1,6 cm by 3,2 cm (5,12 cm<sup>2</sup>).

## (c) Design of the marking

## (i) Printed:

The design of the marking shall be reproduced in black ink without adding any effects, retouching or extending the background. The marking shall be reproduced at a minimum resolution of 300 dots per inch when printed in actual size. The marking should have sufficiently high contrast to the background to be highly readable. To this end, the outline of the marking should be printed in one of the following colours.

— White: C = 0 / M = 0 / Y = 0 / K = 0

— Black: C = 0 / M = 0 / Y = 0 / K = 100

— Red: C = 0 / M = 90 / Y = 60 / K = 0

— Blue: C = 60 / M = 0 / Y = 0 / K = 0.

## (ii) Engraved/embossed:

The design of the marking shall be reproduced without adding effects, retouching or extending the background. The white outline as shown in the marking under point 1.2 of this Annex represents the lines to be engraved or embossed on the cup.

The information text 'MADE OF PLASTIC' shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt for the cups of less than 500 ml and of 6 pt for the cups of 500 ml or more.

Where the information text is translated into another or several official languages of the Member States, the translated information text shall be placed either close below the marking, or inside the rectangular black box below the first language, and shall be in both cases clearly visible. In exceptional cases due to spatial constraints on the external surface of the cup, the information text translated into another or several official languages of the Member States may be placed elsewhere on the cup as close as possible to the marking and where it is clearly visible. The translated information text shall be in upper case and in Helvetica Bold font. The font size shall be a minimum of 5 pt for the cups of less than 500 ml and 6 pt for the cups of 500 ml and more.

When printed, the colours having the following colour codes shall be used:

— White: C = 0 / M = 0 / Y = 0 / K = 0

— Black: C = 0 / M = 0 / Y = 0 / K = 100.

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TÜVRheinland®

DIN CERTCO

Precisely Right.



## Certification Scheme

**flustix PLASTIC-FREE**

(Edition: November 2020)

## Foreword

DIN CERTCO was founded in 1972 by DIN Deutsches Institut für Normung e. V. (German Institute for Standardization) for the awarding of DIN marks and provides certification for products, persons, services and companies on the basis of DIN standards and similar specifications.

In order to prove our impartiality, independency and competence, we are voluntary accredited according to DIN EN ISO/IEC 17065. For the satisfaction and trust of our clients and their data, we maintain furthermore a certified

- Quality Management System according to DIN EN ISO 9001
- Environmental Management System according to DIN ISO 14001
- Occupational Health and Safety Management System according to OHSAS 18001

This certification scheme offers the possibility to mark plastic-free consumer goods, products, packaging and semi-finished products or materials intended for further processing with the independent certification mark "flustix - NO PLASTICS" if they qualify for one of the flustix PLASTIC-FREE certifications. Product components such as packaging or its contents can be tested and marked separately. In order to clearly communicate the plastic savings to the end consumer, the marking is done according to four specific categories:

- total product
- content free from microplastics
- product
- packaging

We offer the consumer a reliable guidance for plastic-reduced shopping, protect the environment and help innovative economic players to communicate their sustainability with regard to plastics through independent certification and regular monitoring by DIN CERTCO in cooperation with FLUSTIX GmbH.

Towards consumers the confidence is created that an independent, neutral and competent institution examined and evaluated the test criteria carefully by the certification mark "flustix - NO PLASTICS".

The certification mark "flustix - NO PLASTICS" is the first Europe-wide certification mark for plastic-free products registered as a EU certification mark, which represents a test seal and a word as well as a picture mark protected by trademark law.

In addition to the general terms and conditions of DIN CERTCO and the testing, registration and certification regulations of DIN CERTCO, this certification scheme forms the basis for suppliers to mark their plastic-free products with the certification mark "flustix - NO PLASTICS". They thus document that their products meet all requirements of this certification scheme.

Plastic-free products receive the certification mark "flustix - NO PLASTICS" if they meet the requirements listed in section 4 according to the procedure described in this certification scheme.

All certificate holders can be viewed on the daily up-dated homepage of DIN CERTCO ([www.dincertco.tuv.com](http://www.dincertco.tuv.com)).

## Start of validity

This certification scheme applies from 2020-11-01.

**Modification**

Compared to the Certification Scheme “flustix PLASTIC-FREE” (2020-06) the following changes were made:

- a) Editorial alterations
- a) Clarification of the scope of the examination
- b) Exclusion of polymers that occur in nature or are biodegradable

**Earlier versions**

Certification Scheme “flustix PLASTIC-FREE” (2020-06)

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## 1 Scope

This certification scheme applies to plastic-free consumer goods, products, packaging and semi-finished products and contains, in conjunction with the test specifications listed below, all requirements for awarding the certification marks "flustix NO PLASTICS - plastic-free total product", "flustix NO PLASTICS - content free from microplastics", "flustix NO PLASTICS - plastic-free product" and "flustix NO PLASTICS - plastic-free packaging".

This certification scheme establishes requirements depending on the certification mark that need to be met by the consumer good, product, packaging or semi-finished product itself, as well as requirements relating to the associated testing, monitoring and certification.

## 2 Test and certification specifications

The basis for testing and certification are the documents listed below. For dated references, only the referenced version shall apply. For undated references the latest edition of the referenced document including any amendment applies.

DIN EN ISO 472	Plastics – Vocabulary (ISO/TC 61/SC1)
DIN EN 643	Paper and board – European list of standard grades of paper and board for recycling
ISO/TR 21960:2020	Plastics – Environmental aspects – State of knowledge and methodologies
Regulation (EU) No 10/2011	Commission regulation on plastic materials and articles intended to come into contact with food
ECHA	ANNEX XV RESTRICTION REPORT, PROPOSAL FOR A RESTRICTION, VERSION NUMBER: 1, DATE: 11 January 2019, European Chemicals Agency (ECHA), Annankatu 18, PO BOX

- this certification scheme
- Form "Positive analysis result" from DIN CERTCO
- [the general terms and conditions of TÜV Rheinland DIN CERTCO](#)
- [the testing, registration and certification regulations of DIN CERTCO](#)
- the schedule of fees in its most current version

The obligation to comply with laws and regulations governing the respective products is in no way affected by this certification scheme.

## 3 Definitions

The definitions apply to plastic-free consumer goods, products and packaging of all kinds, in particular goods from the food and non-food (such as cosmetics), fashion, home and garden (including compost and fertilizers or soil additives) or leisure sectors. In addition, the definitions of plastic-free semi-finished products or materials intended for further processing apply.

Where a consumer product is offered and placed on the market without packaging, these definitions apply only to the product itself. The term plastic-free in the sense of the definition does not intend to make a statement about how a consumer good is to be classified in terms of quality.

### 3.1 Consumer goods

Consumer goods are goods that are produced and traded for the private use or consumption of consumers. A consumer good consists of the respective product and its packaging ("total product"). If a consumer good is offered and/or placed on the market at the final stage of trade without packaging, this definition refers only to the product itself.

#### 3.1.1 Products

Products are defined in this certification scheme as the goods or contents of a consumer good, such as a piece of clothing or tableware.

#### 3.1.2 Packaging

Packaging refers to containers, wrappings and outer packaging of a product or a semi-finished product for example sales packaging or cardboard packaging, such as those used for shipping or transporting consumer goods.

#### 3.1.3 Consumer

A consumer is the end user who no longer resells the consumer goods in the form delivered to him/her on a commercial basis.

### 3.2 Semi-finished products

Semi-finished products are intermediate products or materials intended for further processing.

### 3.3 Polymer

The term polymer is used to describe chemical compounds consisting of chain or branched molecules (macromolecules), which in turn consist of a large number of identical or similar units known as monomers.<sup>1</sup>

Polymers that occur naturally and have not been chemically modified (other than by hydrolysis) are excluded from this certification scheme as well as polymers that are (bio) degradable.<sup>2</sup>

### 3.4 Plastics

Plastics are organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or a similar process of molecules with a lower molecular weight or by chemical modification of natural molecules. Other substances or materials may also be added to these compounds. The starting materials for plastics have a natural basis (fossil raw materials), which are specifically produced by chemical reactions to form polymeric materials. A distinction is made between elastomers, thermoplastics and duroplastics.<sup>3</sup>

The term synthetic material means plastic.

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<sup>1</sup> vgl. IUPAC Compendium of Chemical Terminology (the "Gold Book")

<sup>2</sup> vgl. ECHA: ANNEX XV RESTRICTION REPORT, PROPOSAL FOR A RESTRICTION, VERSION NUMBER: 1, DATE: 11 January 2019, European Chemicals Agency (ECHA), Annankatu 18, PO BOX 400, FI-00121, Helsinki, Finland.

<sup>3</sup> Regulation (EU) No 10/2011; DIN EN 13130-1; DIN EN ISO 472

### 3.5 Fresh fiber paper

Fresh fibre paper characterizes industrially produced paper that does not consist of waste paper, but is produced directly from raw materials such as wood.

### 3.6 Microplastic

The term microplastics refers to a material consisting of solid polymer particles to which additives or other substances may have been added.

According to ISO/TR 21960:2020, a distinction is made between microplastics and large microplastics:

1. Microplastics: all solid plastic particles insoluble in water with dimensions between 1 µm and 1000 µm (= 1 mm)
2. Large microplastics: all solid plastic particles insoluble in water with dimensions between 1 mm and 5 mm

### 3.7 Primary microplastic

Primary microplastics in this certification scheme describes industrially produced plastic particles in the order of magnitude according to section 3.6, which are used, for example, as additives in cosmetics and/or detergents, cleaning agents and cleaning products. In this certification scheme microplastics from a size of 6 µm are examined.

### 3.8 Unavoidable residues

Unavoidable residues describe plastics which can arise, for example, due to contamination through environmental influences, residues in materials used, contamination in the manufacturing process, as a result of the use of recycled materials or during packaging, transport, storage, rearrangement and packing.

Unavoidable residues must not exceed 0.2% of the total weight of the relevant consumer good, product, packaging or semi-finished product marked as plastic-free.

### 3.9 Technical unavailability

A consumer good, product, packaging or semi-finished product is considered to be free of plastic if it contains a plastic that is not avoidable according to the current state of the art, such as plastics used in the production of recycled paper. The tolerance limits for unwanted materials for recycled paper in this certification scheme refers to DIN EN 643.

#### 3.9.1 Special case fresh fiber paper

A consumer good, product, packaging or semi-finished product consisting of virgin fibre paper is considered to be free of plastic if it contains a plastic material up to 0.75% by weight, which is technically necessary to ensure the functioning of the consumer good, product, packaging or semi-finished product or to contribute to its durability. Adhesive on the binding of a book or a paper cup is considered to be a technically necessary plastic when used with fresh fibre paper.

## **4 Product requirements**

### **4.1 Plastic-free total product, plastic-free packaging**

A consumer good or packaging according to section 3 shall be deemed to be free of plastics if, taking into account sections 3.8 and 3.9, it consists of components, materials, ingredients and/or materials that do not contain plastics within the meaning of section 3.4.

### **4.2 Plastic-free product**

A product as defined in section 3.1.1 is considered to be free of plastics if, taking into account sections 3.8 and 3.9, it consists of components, materials, ingredients and/or materials that do not contain plastics as defined in section 3.4.

### **4.3 Content free from microplastics**

A technically manufactured product content does not contain microplastic if, taking into account Section 3.8, it consists of components, materials, contents and/or materials that do not contain primary microplastic according to section 3.7 in the range from 6 µm upwards.

The method of production, the auxiliary materials used, the transport before and after purchase by the consumer or processor and their presentation by the point of sale have no influence on the classification as plastic-free.

When using the definition, care must be taken to ensure that the informed consumer is not misled in the sense of fair trading law.

## **5 Testing**

### **5.1 General information**

DIN CERTCO uses its recognized testing laboratories to carry out the necessary tests as a basis for the evaluation and certification of consumer goods, products, packaging and semi-finished products.

### **5.2 Types of tests**

#### **5.2.1 Initial test (Type testing)**

The initial test is a type test (type examination) which serves to determine whether the consumer good, product, packaging or semi-finished product meets the requirements of section 4 of this certification scheme.

#### **5.2.2 Verification test (Control test)**

Verification testing is carried out every two years and serves to determine whether the certified consumer good, product, packaging or semi-finished product corresponds to the type-tested consumer good, product, type-tested packaging or type-tested semi-finished product in the production phase. It is commissioned by DIN CERTCO and must be verified by a positive test report in due time.

The scope of the verification test corresponds to the initial test in section 5.2.1

### 5.2.3 Supplementary testing

Supplement testing is performed when supplements, expansions or additions (see section 6.9) are intended for a certified consumer good, product, certified packaging or certified semi-finished product which have an influence on conformity with the underlying requirements.

The type and scope of supplementary testing will be determined by DIN CERTCO in individual cases in coordination with the laboratory.

### 5.2.4 Special test

A special test is conducted when

- defects are detected
- the production has been suspended for a period of more than 6 months
- required by DIN CERTCO - reasons to be specified
- requested in writing by a third party if a particular interest in the maintenance of proper conduct of market procedures in relation to competition or quality is involved.

The type and scope of special test will be determined by DIN CERTCO in each individual case, where applicable in coordination with the laboratory.

If defects are detected in a special test, or if a special test is performed due to a stop in production, then the certificate holder shall bear the costs of the examination procedure.

Should the special test at the request of a third party reveal no defects, the costs shall be borne by said third party.

## 5.3 Sampling

For initial and verification testing, the manufacturer usually delivers two test samples per consumer good, product, packaging or semi-finished product to the testing laboratory and to FLUSTIX. The manufacturer bears the associated costs.

At the same time, all documents such as information on the composition and ingredients of the respective test sample are sent by the applicant to the assigned testing laboratory.

## 5.4 Test procedure

### 5.4.1 General information

Upon receipt of the test samples together with the submitted documents, the testing laboratory checks whether the test is feasible and whether the test sample can pass the test. If this is the case, at least one test sample per type (see section 6.2) will be tested by the testing laboratory after submission of the application with document template according to section 6.1. In addition, the testing laboratory determines the scope of testing.

### 5.4.2 Testing of plastic-free semi-finished products, complete products, products and packaging

Depending on the test sample, a qualitative analysis is carried out either by FTIR, Raman or scanning electron microscopy and by pyrolysis GC/MS. If necessary, a sample preparation is necessary, which depends on the certification object.

If plastics are detected during the test, it shall be basically clarified whether the detected plastics originate from unavoidable residues according to section 3.8 or are technically unavoidable according to section 3.9. This is done by the manufacturer's declaration of intent using the form "Positive analysis result" and, if necessary, by checking the documents.

#### **5.4.3 Testing of content free from microplastics for products and semi-finished products**

In sample preparation, specialized preparation procedures separate and clean the microplastic from various matrices (water, cosmetic products, etc.). The detection of microplastics is done spectroscopically and/or thermos-analytically by means of:

- FT-IR microscopy: Examination of single particles by combining light microscopy and IR spectroscopy; detection of particles > 20 µm
- RAMAN-microscopy: Examination of single particles by combining light microscopy and Raman spectroscopy; detection of particles > 6 µm
- Pyrolysis gas chromatography/mass spectrometry (Pyrolysis-GC/MS): Analysis of macromolecules (e.g. polymers) by determination of the resulting thermal degradation products or pyrolysis fragments; allocation via database or reference material

#### **5.5 Test report**

The testing laboratory informs the client of the test results by means of a test report. An original copy of it shall be submitted to DIN CERTCO.

As a rule, the test report may not be older than 6 months at the time of application. In individual cases, older test reports can be recognised if the testing laboratory confirms the validity of the results by means of a test report.

The test report must correspond to DIN EN ISO/IEC17025 and must at least contain the following information:

- Name and address of the manufacturer
- Name and address of the applicant (if different than manufacturer)
- Test basis (certification scheme) with date of issue
- Type of test (e.g. type test, additional test, etc.)
- Test date
- Results and evaluation of test
- Name and signature of the individual responsible for the test
- Product description including picture, dimensions to clearly identify the test sample

### **6 Certification**

Certification in the sense of this certification scheme relates to the assessment of conformity of a consumer good, product, packaging or semi-finished product by DIN CERTCO on the basis of test reports submitted by testing laboratories recognized by DIN CERTCO.

In doing so, the certified consumer goods, products, packaging or semi-finished products being registered for conformity with the requirements specified in section 4 are examined and subsequently monitored.

The right to use the certification mark “flustix - NO PLASTICS” will be granted by the issuing of the respective certificate.

## 6.1 Application for certification

Applicants can be both manufacturers according to Article 4 of the Produkthaftungsgesetz (ProdHaftG) [German Product Liability Act] or retailers who market the consumer goods, products, packaging or semi-finished products independently within the meaning of the Produkthaftungsgesetz with the written consent of the certificate holder.

The following documents must be submitted by the applicant to DIN CERTCO:

- The original application for certification, with a legally binding signature and company stamp
- Current test report in accordance with section 5.5 on an initial test (see section 5.2.1), unless the test was commissioned by DIN CERTCO
- Description of the consumer good, product, packaging or semi-finished product and its use
- All information about the composition/ingredients
- Listing of all raw materials and additives used with indication of the respective mass fractions in %.
- Information as precise as possible about auxiliary materials used in production and possible contamination entry paths
- Short process description of all production steps of the manufacturer

After receipt of the application, the applicant will receive a confirmation of order from DIN CERTCO with a procedure number and information on further processing.

## 6.2 Classification of types and subtypes

Plastic-free consumer goods, products, packaging or semi-finished products, which differ in essential certification-relevant characteristics, are defined as type or model. Certification-relevant characteristics are e.g. the use of different materials or properties that significantly influence safety, function or handling and are therefore sold under a separate trade name. A separate certificate is issued for each type.

Sub-types are generally defined as those consumer goods, products, packaging or semi-finished products of a model/type that differ only in size/performance, formal or non-certification relevant characteristics. They can be combined on one certificate (e.g. similar tea bags of different flavors).

The classification of types and subtypes is carried out by DIN CERTCO, if necessary in consultation with the testing laboratory.

## 6.3 Conformity assessment

On the basis of the documents submitted, DIN CERTCO conducts the conformity examination. The assessment is made with the aid of the test report as to whether the consumer good, product, packaging or semi-finished product meets the requirements of the certification scheme.

The applicant will receive written notification from DIN CERTCO in the event of any possible deviations.

## 6.4 Certificate and the right to use the mark

After successful testing and conformity assessment of the application documents submitted, DIN CERTCO issues a certificate to the applicant and issues the right to use the respective

certification mark "flustix - NO PLASTICS" in conjunction with the respective registration number.

Certification object	Structure of the register number	Certification marks
Plastic-free total product	FPG000	
Content free from microplastics	FPM000	
Plastic-free product	FPP000	
Plastic-free packaging	FPV000	

Plastic-free consumer goods, products, packaging or semi-finished products, for which the right to use the certification mark "flustix PLASTIC-FREE" has been granted, must be marked with the respective certification mark "flustix PLASTIC-FREE" and the corresponding register number.

The mark and register number may only be used for the type for which the certification has been issued and which corresponds to the type-tested consumer goods, product, packaging or semi-finished product.

For each respective type, a registration number shall be issued. For design types (sub-types) of a type, the same registration number shall be issued (for information, see section 6.2).

In addition to this, the [General Terms and Conditions of DIN CERTCO](#) as well as the [Testing, Registration and Certification Regulations of DIN CERTCO](#) shall apply.

## 6.5 Publications

All certificate holders can be viewed on the daily up-dated homepage of DIN CERTCO [www.dincertco.tuv.com](http://www.dincertco.tuv.com) and via the homepage of FLUSTIX [www.flustix.com](http://www.flustix.com). Manufacturers, users and consumers use this research possibility for obtaining information on certified products.

## 6.6 Validity of the certificate

The certificate is valid for 5 years. The period of validity is shown on the certificate. On expiry of the certificate, the right to use the mark also expires.

## 6.7 Renewal of the certificate

If the certification shall continue to apply beyond the date shown on the certificate, DIN CERTCO must receive a current positive test report in good time before the validity expires. DIN CERTCO carries out the conformity assessment on the basis of the test report.

Proof of conformity with the requirements of the testing and certification principles according to section 2 is provided in the scope of an initial test according to section 5.2.1, which is assessed by DIN CERTCO.

## 6.8 Expiry of the certificate

In the event that the new standard conformity examination according to section 5 has not been completed before expiration of the validity period, the right to use the certification mark "flustix PLASTIC-FREE" and the registration number expires without the necessity for explicit notification from DIN CERTCO.

Furthermore, certificates can expire if, for example:

- the surveillance according to section 8 is not performed punctually or completely,
- the certification mark "flustix PLASTIC-FREE" is misused by the certificate holder.
- the requirements laid down in the certification scheme or its accompanying documents are not fulfilled.
- the certification fees are not paid on the due date.
- the prerequisites for the issuing of the certificate or confirmation of acceptability are no longer fulfilled.

## **6.9 Alterations/Amendments**

### **6.9.1 Alteration/Amendment to a consumer good, product, on the packaging or semi-finished product**

The certificate holder is obliged to notify DIN CERTCO of all alterations to that are subject to certification. DIN CERTCO will decide in coordination with the laboratory the extent to which testing according to Section 5.2.3 must be performed and whether the change is significant. The respective test report shall be forwarded to DIN CERTCO by the laboratory.

Should DIN CERTCO determine a substantial alteration, the certificate with the corresponding registration number shall expire. For the modified manufactured item, a new application for initial certification authorising the use of the “flustix PLASTIC-FREE” mark may be submitted.

The certificate holder remains obliged to notify of any changes in the formal details (e.g. name of certificate holder or his address).

The certificate holder may apply to DIN CERTCO for an extension of the existing certificate for further design-types (sub-types) of the same type. It is for DIN CERTCO to decide whether these amendments require a complementary examination. The design-types shall be entered in the certificate for the already certified product and, provided that the conditions are fulfilled, shall be regarded as an integral part of same.

### **6.9.2 Alterations to the basic test specifications**

If the basic test specifications for the certification are modified, an application for the alteration of the certification shall be generally submitted within 6 months of receiving notification from DIN CERTCO, and, as a rule, after 12 months, proof of conformity with the modified examination specifications shall be submitted in the form of a positive test report, if applicable (see Section 5.2.3).

## **6.10 Defects in the consumer goods, products, packaging or semi-finished products**

In the event that a certified consumer good, product, packaging or semi-finished product on the market is found to be defective, the certificate holder shall be summoned in writing by DIN CERTCO to rectify the defects.

The manufacturer must ensure that, until the defects have been rectified, the consumer goods, products, packaging or semi-finished products are no longer marked with the mark of conformity.

The defects must also be rectified without delay in installed products or consumer goods, products, packaging or semi-finished products in storage. The manufacturer must submit proof to DIN CERTCO within 3 months, in the form of a test report on a special test in accordance with section 5.2.4, that the defects have been rectified and that the consumer good, product, packaging or semi-finished product in question again fulfils the stipulated requirements.

Should the manufacturer fail to observe these deadlines, he and the distributor of product will no longer be permitted to use the certification mark “flustix PLASTIC-FREE”.

Should grounds for complaint continue to exist, DIN CERTCO shall initially suspend the certificate and at the same time issue a final deadline for the rectification of the defects. Should the certificate holder fail to meet this demand, or fail to meet it within the grace period, or if it is again not possible to prove that the defects have been rectified, the certificate shall be annulled.

## **7 Surveillance by the manufacturer**

The manufacturer must ensure, by suitable quality management measures, that the consumer good, product, packaging or semi-finished product characteristics confirmed by the certification are maintained.

This can be accomplished by means of an in-house factory production control (FPC) focused on the consumer good, product, packaging or semi-finished product itself or on the production and, in addition, can be guaranteed within the framework of a quality management system (QM-System) in accordance with the standard series DIN EN ISO 9000 ff.

DIN CERTCO recommends the installation and certification of the quality management system in conformity with the standard series DIN EN ISO 9000 ff.

## **8 Surveillance by DIN CERTCO**

An essential part of the certification is the constant surveillance of the certified consumer good, product, packaging or semi-finished product during the entire term of the certificate. The surveillance takes place in regular intervals of 2 years.

DIN CERTCO checks and assesses the conformity of the product with the requirements specified in the certification scheme by means of surveillance tests in accordance with the initial test according to clause 5.2.1.



Brussels, 21.02.2014

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

### **Version History**

<b>Version</b>	<b>Date</b>	<b>Change</b>
1.0	28.11.2013	original version
1.1*	12.01.2016	information update on this title page

\* Translated versions have not been updated

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

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

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

This document is made available on the DG Sanco website on food contact materials:

[http://ec.europa.eu/food/safety/chemical\\_safety/food\\_contact\\_materials/legislation/index\\_en.htm](http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation/index_en.htm)

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# 1 Introduction

## 1.1 Purpose of the Guidance document

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

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

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

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

## 2 Chapter I – General provisions

### 2.1 Subject matter and scope

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

Plastic materials and articles include the following types of products:

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

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

<sup>2</sup> "Applicability of generally recognised diffusion models for the estimation of specific migration in support of Directive 2002/72/EC" [http://ihcp.jrc.ec.europa.eu/our\\_labs/eurl\\_food\\_c\\_m/guidance-documents](http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m/guidance-documents).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Plastics Regulation sets out rules concerning the following aspects:

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

The Plastics Regulation does not apply to:

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

#### NOTE:

Waxes are a complex group of materials of natural, mineral, petroleum derived or synthetic origin with many different uses. Depending on their use, they may be covered by the Plastics Regulation.

Waxes are covered by the Plastics Regulation when they are used as an additive or a polymer production aid and are listed as individual substances in the Union list in Table 1 of Annex I of the Plastics Regulation.

Waxes are not covered by the Plastics Regulation when they are the sole or a major component of surface coatings. This is the case, for instance, for paraffin waxes, including

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

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

**NOTE:**

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

**NOTE:**

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

## **2.2 Definitions**

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

- "Adhesives" means non-metallic substance capable of joining materials by surface bonding (adhesion<sup>9</sup>), and the bond possessing adequate internal strength (cohesion<sup>10</sup>)<sup>11</sup>.
- "Blend" is any mixture of plastics in the same physical state, each of which is capable of functioning as a main structural component of finished materials and articles.
- "Coating" means a non-self-supporting layer composed of substances applied on an already existing substrate in order to impart special properties or improve technical performances of the finished article.

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<sup>9</sup> Adhesion is the force of attraction between molecules in different layers.

<sup>10</sup> Cohesion is the force of attraction between molecules within the same layer.

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

- "Inorganic surface coating" means a non-self-supporting layer composed of inorganic substances applied on an already existing substrate, e.g. a silicon dioxide coating.
- "Organic surface coating" means any resinous or polymerised preparation which is converted to a thin, solid polymer layer used to provide a functional effect on a surface and which is not capable of acting by itself as a main structural component of a final material and article.
- "Dual use additives" means additives which are covered by a listing<sup>12</sup> in the Union list and which are also listed as food additives or flavourings in Regulations (EC) No 1333/2008<sup>13</sup> and (EC) No 1334/2008<sup>14</sup> and their implementing measures.
- "Fat consumption Reduction Factor" (FRF) is a factor between 1 and 5 by which measured migration of lipophilic substances, as indicated in Annex I of the Plastics Regulation, into a fatty food or simulant D1 or D2 and its substitutes shall be divided before comparison with the SMLs.
- "Ion exchange resin" covers ion exchange and adsorbent resins, made of synthetic organic macromolecular components, which can be used in the processing of foodstuffs to bring about exchange of ions or adsorption of foodstuffs constituents. They do not include, however, cellulosic ion exchangers.
- "Layer" means a homogenous continuous or semi-continuous<sup>15</sup> material of defined composition that is extended in two dimensions separated by an interface from another homogenous continuous or semi-continuous material of a defined but different composition<sup>16</sup>.
- "Masterbatch" means a preparation of one or more polymers which encapsulate a high concentration of ingredients like colorants, fillers, fibres or stabilizers that influence the physical properties of the final preparation. A masterbatch is intended to be blended with a polymer and not used to make an article as such.
- "Migration modelling" means a calculation of the specific migration level of a substance based on the residual content of the substance in the material or article applying generally recognised diffusion models. These are based on scientific

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

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

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

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

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

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

- "Migration test" means the determination of the release of substances from the material or article either into food or into a food simulant.
- "Oligomer" means a substance consisting of a finite number of repeating units which has a molecular weight of less than 1000 Da.
- "Product from intermediate stages of manufacture" also referred to as "Plastic intermediate materials" means a plastic powder, granules or flakes (including "masterbatch"), pre-polymer (excluding Article 6(3)(d) of the Plastics Regulation), any semi-finished material and article such as a film, sheet or laminate requiring further processing/re-formulation steps to become a "finished" material or article. In short, this is any product which is not a basic chemical and not yet a finished plastic material or article.
- "Polymeric additive" means any polymer which is used as an additive having a physical or chemical effect in the plastic and which cannot be used in the absence of other polymers as a main structural component of finished materials and articles.
- "Pre-polymer" is a polymer of relatively low molecular weight, usually an intermediate between the monomer and the final polymer or resin.
- "Printing inks" are mixtures of colorants with other substances which are applied on materials to form a print design on this material<sup>17</sup>.
- "QM" means maximum permitted residual content of a substance in the final material or article expressed as weight per weight concentration in the final article.
- "QMA" means maximum permitted residual quantity of a substance in the final material or article expressed as weight per surface area of the article in contact with food.
- "Repeated use article" means an article intended to be used several times that comes into contact with different portions of foods during its lifetime. For example, kitchenware, reusable containers or components of packaging machinery.
- "Rubber" means low shear modulus materials, either natural<sup>18</sup> or synthetic, made up of carbonaceous macromolecules, and characterised by long polymer chains arranged in a three-dimensional flexible network held by chemical covalent cross-links. They present, at service temperature and until their decomposition, elastic physical properties which allow the material to be substantially deformed under stress and recover almost its original shape when the stress is removed. The definition does not cover thermoplastic elastomers.
- "Set-off" is the phenomenon of the transfer of substances from outer layer of materials and articles to the inner food contact layer through direct contact and not via diffusion through the material. Set-off may occur, where there is a contact between the outside

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

<sup>18</sup> For example, caoutchoucs which are naturally derived rubber from latex originating from the sap of trees.

and inside of the material or article during, for example, storage or transport. Such direct contact may occur when materials are wound in reels or stacked in sheets or when articles such as trays and pots are nested inside each other. Unlike migration under these conditions, set-off may occur in both materials and articles with or without a functional barrier.

- "Single use article" means an article intended to be used once and coming into contact with not more than a single portion of foodstuffs during its lifetime. (Food packaging should be regarded as single use article, even if the consumer may re-use it. This includes, for example, lids for jars. Disposable gloves should be regarded as single use articles, even if the user may be in contact with several portions of food with them).
- "Silicones" means macromolecular substances or materials based on organopolysiloxanes and which are crosslinked forming a three-dimensional network having elastomeric or rubber-like properties.
- "Substances in nanoform" refers to nanomaterials as defined in Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial<sup>19</sup>. This Recommendation defines a nanomaterial as a natural, incidental or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and, where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.
  - 'particle' is defined as a minute piece of matter with defined physical boundaries;
  - 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
  - 'aggregate' means a particle comprising of strongly bound or fused particles.

Remark: Once discussions are concluded on how to implement in the food area the definition of nanomaterials included in the Recommendation, an amendment to the Plastics Regulation will be proposed, taking into account the definition in the food area and the specific requirements of the food contact materials sector.

- "Supply chain" means all business operators, including food business operators who directly or indirectly participate in the production, converting, distribution and use of materials and articles intended to come into contact with foods, such as ingredient suppliers, raw materials manufacturers, converters, food packers and retailers.
- "Surface biocide" means a substance intended to keep the surface of a material or article free from microbial contamination, but which is not intended to have a preservative effect on the food itself.
- "Thermoplastic elastomer" means polymer or blend of polymers that does not require vulcanisation or cross-linking during processing, yet has properties, at its service temperature, similar to those of vulcanised rubber. These properties disappear at processing temperature, so that further processing is possible, but return when the

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<sup>19</sup> OJ L 275, 20.10.2011, p. 38.

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

### **2.3 Placing on the market of plastic materials and articles**

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

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

## **3 Chapter II - Compositional requirements**

### **3.1 Union list of authorised substances**

#### **3.1.1 Union list**

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

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

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

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

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<sup>20</sup> Indicative list of functions covered.

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

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

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

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

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<sup>21</sup> Indicative list of functions covered.

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

### **3.1.2 Addition of new substances to the Union list**

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

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/nat\\_contact\\_points\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/nat_contact_points_en.pdf)

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

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

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

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

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

## **3.2 *Derogations for substances not included in the Union list***

This section on derogations deals with substances:

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

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

### **3.2.1 Polymer production aids (PPA)**

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

### **3.2.2 Salts of authorised acids, alcohols and phenols**

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

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

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

### **3.2.3 Mixtures**

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

### **3.2.4 Polymeric additives**

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

### **3.2.5 Polymeric starting substances**

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

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

## ***3.3 Substances not included in the Union list***

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

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

This covers the following groups of substances:

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

### **3.3.1 Aids to polymerisation**

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

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

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

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

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<sup>23</sup> Incorporated in this context means reacted onto or becoming a part of the chemical structure of the polymer.

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

- **Catalyst modifiers**  
A catalyst modifier is a substance that is modifying the catalytic activity of a catalyst. They are often referred to as co-catalyst or promoters in cooperative catalysis.
- **Chain scission reagents**  
A chain scission reagent is used to generate radicals in an existing polymer chain by thermal treatment. This radical on the chain induces a scission of the polymer chains in two shorter macromolecules. A chain scission reagent induces a decrease of the molecular weight and an improvement of the melt flow properties, e.g.: organic peroxides used for visbreaking of polypropylene.
- **Chain transfer or extending agents or molecular weight regulators**  
Chain transfer is a polymerization mechanism by which the activity of a growing polymer chain is transferred to another molecule. Chain transfer agents are often used to control and reduce the average molecular weight of the final polymer. The chain transfer reactions can be either controlled deliberately during the polymerization by using a chain transfer agent or it may be an unavoidable side-reaction with various components of the polymerization. Chain transfer agents are sometimes called “chain modifiers” or “chain regulators”, e.g. thiols, especially n-dodecylmercaptane, and halocarbons, such as carbon tetrachloride.
- **Chain stop reagents**  
A chain stop reagent is a substance used for ending polymer chain propagation at a specific point in time, so as to obtain desirable molecular weight distribution and the linked polymer properties.
- **Cross-linking agents (that are not incorporated in the polymer)**  
A cross linking agent is a substance linking with a chemical bond one polymer chain to another. The chemical bonds can be covalent bonds or ionic bonds. Cross linking agents are used to modify the mechanical properties of a polymer and the resulting modifications of mechanical properties are strongly depending of the cross-link density. Cross-linking agents (e.g. organic peroxides) used here does not include polyfunctional monomers or starting substances that are incorporated in the polymer and covered by the Union list.
- **Cross-linking catalysts or Cross-linking accelerators**  
They are substances that improve the efficiency of a cross linking agent.
- **Desensitizing agent**  
Desensitizing agents are added to initiators to improve their thermal, chemical and mechanical stability during transport<sup>24</sup> and storage to prevent auto-decomposition, e.g. organic/inorganic solids, organic liquids with high boiling point, or under certain circumstances water.
- **Initiators and promoters**

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

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

- **Polymerisation inhibitors**

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

- **Redox agents**

A redox agent is a chemical that has the ability to generate an oxydo-reduction reaction. Redox agents are substances that have the ability to oxidize or reduce other substances. Substances able to oxidize other substances are also called “oxidizing agents”, “oxidants”, or “oxidizers”. Substances that have the ability to reduce other substances are known as “reducing agents”, “reductants” or “reducers”. If the redox-reaction is used to initiate radical polymerization, this type of initiation is referred to as “redox initiation”, “redox catalyst”, or “redox activation”. For example, iron salts or Cr<sup>2+</sup>, V<sup>2+</sup>, Ti<sup>3+</sup>, Co<sup>2+</sup>, and Cu<sup>+</sup> salts can be used for the reduction of hydrogen peroxide or organic peroxide.

### **3.3.2 Non-intentionally added substances (NIAS)**

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

### **3.3.3 Stabilisers in monomers, starting substances and additives**

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

### **3.3.4 Coatings, printing inks and adhesives**

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

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

Example:

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

### **3.3.5 Colorants**

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

### **3.3.6 Solvents**

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

## **3.4 *The status of antimicrobial substances***

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

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

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

- (1) Process biocides, that keep the material or preparations which are to be processed into final food contact materials (e.g. pre-polymer solutions) free from microbial contamination during the production, storage or handling process;
- they are used as components in the manufacture of food contact materials, but not intended to be present in the food contact material itself;
  - as no antimicrobial function is exerted on the final food contact material, the substance would be regarded as polymer production aid;
  - their incorporation into the food contact material could be regarded as an unintentional but unavoidable carry-over.

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

- (2) Surface biocides, that keep the surface of the food contact material free from microbial contamination (e.g. used on inner surface of fridges, cutting boards, gaskets, conveyer belts, storage containers);
- they are used in the manufacture of food contact materials and are intended to be present in the food contact material itself;
  - as an antimicrobial function is exerted on the final food contact material, the substance would be regarded as an additive;
  - currently, no surface biocides are included in the Union list of the Plastics Regulation. The provisional list of additives covered by Article 7 of the Plastics Regulation contains 10 surface biocides which can be used in accordance with national law. (For the status of the provisional list see also point 3.5. of this Guidance document)

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

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

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

### ***3.5 Establishment and management of the provisional list of additives***

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

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

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

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/080410\\_provisional\\_list\\_7\\_21\\_1009.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/080410_provisional_list_7_21_1009.pdf)

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

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

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

### **3.6 General requirements on substances**

#### **3.6.1 Specifications and restrictions for substances, materials and articles**

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

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

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

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

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

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

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

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

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

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

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

[http://www.efsa.europa.eu/cs/BlobServer/Scientific\\_Opinion/sc\\_op\\_ej958\\_nano\\_en.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en.pdf?ssbinary=true)

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

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

A database characterising commercially available authorised substances including specifications has been established at the website of the EU Reference Laboratory for food contact materials (EURL FCM):

[http://ihcp.jrc.ec.europa.eu/our\\_labs/eurl\\_food\\_cm/resource-centre-legislative-docs/reference\\_substances](http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_cm/resource-centre-legislative-docs/reference_substances)

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

### **3.6.2 Specific migration limits (SMLs)**

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

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

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

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

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

### **3.6.3 Dual-use additives**

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

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

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

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

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

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

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

**Table 1: Food Additives**

FCM number	PM REF	CAS	FCM name	E-number	Food additive name
9	30610		acids, C <sub>2</sub> -C <sub>24</sub> , aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	E471 E 470a E 470b	Mono- and diglycerides of fatty acids  Magnesium salts of fatty acids  Potassium salts of fatty acids
10	30612		acids, C <sub>2</sub> -C <sub>24</sub> , aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	E471 E 470a E 470b	Mono- and diglycerides of fatty acids

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

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

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

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

**Table 2: Food Flavourings**

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

### 3.6.4 Overall migration limit (OML)

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

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

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

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

## **4 Chapter III - Specific provisions for certain materials and articles**

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

### **4.1 Plastic multi-layer materials or articles**

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

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

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

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

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

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

## **4.2 Multi-material multi-layer materials or articles**

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

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

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

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

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

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

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

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

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

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

## **5 Chapter IV - Declaration of compliance and Documentation**

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

### **5.1 Declaration of compliance (DoC)**

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

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

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

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

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

## **5.2 Supporting documentation**

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

### **NOTE**

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

## **6 Chapter V - Compliance**

### **6.1 Expression of migration test results**

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

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

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

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

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

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

## **6.2 Testing of migration**

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

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

## **6.3 Assessment of substances not included in the Union list**

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

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

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

## 7 Chapter VI - Final provisions

### 7.1 Amendments of EU acts

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

**Table 3: Food Simulants used until 31.12. 2012**

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

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

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

**Table 4: Food Simulants used as from 31.12.2012**

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

### 7.2 Repeal of EU acts

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

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

<sup>32</sup> Also known as MPPPO or TENAX®.

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

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

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

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

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

### **7.3 Application and transitional provisions**

The Plastics Regulation is applicable as from 1 May 2011.

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

#### **Applicable as from 1 May 2011 (Article 23 2<sup>nd</sup> subparagraph)**

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<sup>33</sup> OJ L 213, 16.8.1980, p. 42.

<sup>34</sup> OJ L 167, 24.6.1981, p. 6.

<sup>35</sup> OJ L 220, 15.8.2002, p. 18.

<sup>36</sup> OJ L 165, 30.4.2004, p. 1.

<sup>37</sup> OJ L 44, 15.2.1978, p. 15.

<sup>38</sup> OJ L 297, 23.10.1982, p. 26.

<sup>39</sup> OJ L 372, 31.12.1985, p. 14.

- Union list of authorised substances: all substances on the list or covered by the Union list (combinations of metals and acids, salts, alcohols) may be used in accordance with the specifications and restrictions. For substances for which the restrictions and specifications have been changed a transitional period until 31. December 2012 has been introduced (Article 22(5)). For articles for which the rules have been changed, a transitional period until 31. December 2012 has been introduced (Article 22(5)).
- The overall migration limit of 10 mg/dm<sup>2</sup>: with the exemption of those intended for infant food, for which 60 mg/kg food applies. For those materials with a volume between 500 ml and 10 l for which the overall migration limit was expressed before in 60 mg/kg a transitional period until 31. December 2012 has been introduced (Article 22(5)).
- The general restriction for certain metal ions in Annex II to the Plastics Regulation.
- Substances in nanoform can only be used if explicitly authorised and mentioned in the specifications in the Union list.
- Plastic layers in multi-material multilayers, which are not separated from the food by a functional barrier, have to be manufactured with monomers, starting substances and additives listed in the Union list.
- The rules for expressing the results of migration testing. For articles for which the rules have been changed, a transitional period until 31. December 2012 has been introduced (Article 22(5)).
- The screening methods for assessing compliance with migration limits.
- Obligation for risk assessment of substances not subject to inclusion in the Union list. For materials containing these substances which comply with Article 3 of the Framework Regulation for which, however, no formal risk assessment is available, a transitional period until 31. December 2012 has been introduced (Article 22(5)).
- The DoC and the supporting documentation.
- Repeal of vinyl chloride testing methods.
- The application of the migration testing regime set out in Directives 82/711/EEC and 85/572/EEC is obligatory for enforcement authorities to come to a decision whether a material is not compliant with the Plastics Regulation.
- A DoC can be issued if the supporting documentation is based on testing in accordance with the screening methods of the Plastics Regulation or with methods in accordance with Council Directive 82/711/EEC (including simulants referred to in the directive). (Article 22(1) of the Plastics Regulation)
- A **transitional period** has been introduced **until 31. December 2012** meaning that materials and **articles which have been lawfully placed on the market** complying with the requirements set out in former Directive 2002/72/EC<sup>40</sup> as regards
  - the compositional requirements
  - the OMLs,
  - the SMLs,
  - the restrictions and specifications, and
 which are accompanied by a DoC referring to Directive 2002/72/EC and for which supporting documentation in line with Directive 2002/72/EC is available, can

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

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

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

In these applications other additives than those listed in the Union list may be used. (Article 23 3<sup>rd</sup> and 4<sup>th</sup> subparagraph)

- Ban on use of Bisphenol A for the manufacture of polycarbonate infant feeding bottles (no transitional period applicable) (Regulation (EU) No 321/2011<sup>41</sup> Article 2 2<sup>nd</sup> subparagraph)

#### **Applicable as from 1 June 2011 (1<sup>st</sup> amendment Regulation (EU) No 321/2011)**

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

#### **Applicable as from 31 December 2012 (Art. 23 5<sup>th</sup> subparagraph)**

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

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

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

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

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

## Overview transitional provisions

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

## Examples

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

### CASE A

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

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

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

### CASE B

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

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

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

### CASE C

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

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

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

#### CASE D

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

## 8 Annex I - Substances

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

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

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

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

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

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

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

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

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

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

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

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

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<sup>42</sup> [http://ec.europa.eu/food/fs/sc/scf/out149\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out149_en.pdf).

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

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

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

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

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

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

## **8.2 Group restriction of substances (Table 2)**

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

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

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

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

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

## **8.3 Notes on verification of compliance (Table 3)**

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

#### **8.4 Detailed specification on a substance (Table 4)**

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

### **9 Annex II - Restrictions on materials and articles**

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

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

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

### **10 Annex III - Food simulants**

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

Modified polyphenylene oxide (MPPO) is assigned as the simulant for dry foods. It is a porous polymer with a high molecular weight (500000 to 1000000 Da) a very high temperature stability ( $T_{max} = 350\text{ }^{\circ}\text{C}$ ), a high surface area and a low specific mass (0,23

g/cm<sup>3</sup>). The substance is commercially known as Tenax ®. The pore size range is important and the reference used is 60 mesh to 80 mesh. Caution should be used, as gas chromatograms obtained from extracts of new commercial MPPO have shown that unacceptably high levels of impurities may be present. Therefore, prior to its first use in this test procedure, the MPPO shall be purified by soxhlet extraction, using diethylether or acetone. MPPO cleaned in this way can be used repeatedly.

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

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

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

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

## **11 Annex IV - Declaration of compliance**

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

## **12 Annex V - Compliance testing**

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

## **13 Abbreviations**

The following abbreviations are used in this Guidance document

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

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