

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

COMMISSION NOTICE

Commission guidelines on single-use plastic products in accordance with 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

(2021/C 216/01)

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1. INTRODUCTION

This document provides guidance on the interpretation and implementation of 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 ⁽¹⁾ (hereafter referred to as ‘the Directive’ or ‘the Single-use plastics Directive’).

The Directive applies to all single-use plastic products listed in its Annex, as well as to all products made from oxo-degradable plastics, and to fishing gear containing plastic. Its Article 12 tasks the Commission to develop guidelines, including examples of what is to be considered a single-use plastic product for the purposes of the Directive. The focus of these guidelines is on the single-use plastic products included in the Annex, listed below.

- Balloons;
- Balloon sticks;
- Beverage containers with a capacity of up to three litres, including their caps and lids;
 - Beverage containers made of expanded polystyrene, including their caps and lids;
 - Beverage bottles with a capacity of up to three litres, including their caps and lids;
- Beverage stirrers;
- Cotton bud sticks;
- Cups for beverages;
 - Cups for beverages made of expanded polystyrene, including their covers and lids;
 - Cups for beverages, including their covers and lids;
- Cutlery (forks, knives, spoons, chopsticks);
- Food containers;
 - Food containers made of expanded polystyrene;
- Lightweight plastic carrier bags;
- Packets and wrappers;
- Plates;
- Sanitary towels (pads), tampons and tampon applicators;
- Straws;
- Tobacco products with filters and filters marketed for use in combination with tobacco products;
- Wet wipes.

The Guidelines do not cover in detail fishing gear and products made from oxo-degradable plastic. As regards the latter, Article 5 of the Directive bans all oxo-degradable plastic products, single-use or not, and it makes no distinction between oxo-degradable plastic that is biodegradable and oxo-degradable plastic that is not biodegradable.

⁽¹⁾ OJ L 155, 12.6.2019, p. 1.

This document provides guidance on key definitions of the Directive and examples of products to be considered as falling within or outside its scope. These examples are non-exhaustive and serve only to provide illustration on how to interpret certain definitions and relevant requirements of the Directive in the context of the specific single-use plastic products. The content, including examples, reflects the views of the European Commission and as such is not legally binding. The binding interpretation of EU legislation is the exclusive competence of the Court of Justice of the European Union.

In particular in view of the coronavirus pandemic, it is noted that Article 11 requires that the measures transposing and implementing Articles 4 to 9 of the Directive comply with Union food law to ensure that food hygiene and food safety are not compromised. Recital 14 further requires that measures also do not compromise good hygiene practices, good manufacturing practices, and consumer information.

2. GENERAL TERMS AND DEFINITIONS ⁽²⁾

2.1. Plastic definition (point (1) of Article 3)

The definition of plastic is provided in point (1) of Article 3:

“plastic” means a material consisting of a **polymer as defined in point (5) of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾**, 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** [Emphasis added]

According to Recital 11, point (1) of Article 3 of the Directive refers to the definition laid out in Regulation (EC) No 1907/2006 (hereafter the ‘REACH Regulation’) and adds further elements to introduce an adapted and thereby separate definition.

Recital 11 explicitly points to paints, inks and adhesives as polymeric materials, which are excluded from the scope of the Directive and not considered to fall under the definition of plastic in point (1) of Article 3. Consequently, a final (otherwise) non-plastic product to which they are applied is not a single-use plastic product under this Directive. Several of the terms and concepts used in point (1) of Article 3 and Recital 11 require further clarification. The following sections provide guidance on the key terms, notably:

- polymer (section 2.1.1);
- can function as a main structural component of final products (section 2.1.2); and
- natural polymers that have not been chemically modified (section 2.1.3).

2.1.1. Polymer

Point (1) of Article 3 of the Directive refers to the definition of polymer in point (5) of Article 3 of the REACH Regulation, which reads as follows:

‘polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

- (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
- (b) less than a simple weight majority of molecules of the same molecular weight.

⁽²⁾ Guidance given in this chapter does not apply to Union legislation on food contact materials and in particular Regulation (EU) No 10/2011 on plastic food contact materials, in which in some instances similar concepts and definitions are used, but with a partially different interpretation reflecting the different contexts.

⁽³⁾ 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).

In the context of this definition a “monomer unit” means the reacted form of a monomer substance in a polymer.’

To complement the definition of polymer in the REACH Regulation, additional guidance is given in the European Chemicals Agency (ECHA) Guidance for polymers and monomers⁽⁴⁾ (hereafter referred to as ‘the ECHA Guidance’):

‘A polymer, as any other substance defined in Article 3(1) [of REACH], can also contain additives necessary to preserve the stability of the polymer and impurities deriving from the manufacturing process. These stabilisers and impurities are considered to be part of the substance.’

2.1.2. Can function as a main structural component of final products

Point (1) of Article 3 of the Directive defines plastic as ‘a material (...) which **can function as a main structural component** of final products’. The aspect of the capability to function as a main structural component of final products concerns the definition of plastic and not the definition of a single-use plastic product. Therefore, in the context of the definition of plastic this criterion is to be understood as a generic concept. As point (1) of Article 3 does not specify or restrict in any way the type of final product, nor the amount of the polymer, in principle, a wide range of polymers can function as a main structural component of final products.

2.1.3. Natural polymers that have not been chemically modified

Polymers that meet the following two conditions laid down in point (1) of Article 3 are exempt from the Directive: (i) they qualify as natural polymers and (ii) they meet the requirement of having not been chemically modified. These terms are further clarified in Recital 11:

‘**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**..., 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’ *[Emphasis added]*

‘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’ *[Emphasis added]*

(i) Natural polymers

The term natural polymer is defined in the ECHA Guidance as follows:

‘Natural polymers are understood as polymers which are the result of a polymerisation process that has **taken place in nature, independently of the extraction process** with which they have been extracted. This means that natural polymers are not necessarily “**substances which occur in nature**” when assessed according to the criteria set out in Article 3(39) of the REACH Regulation.’ *[Emphasis added]*

Point (39) of Article 3 of the REACH Regulation defines substances which occur in nature as follows:

‘**Substances which occur in nature**: means a **naturally occurring substance** as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by other means.’ *[Emphasis added]*

⁽⁴⁾ European Chemicals Agency (2012). Guidance on polymers and monomers. Section 2.2 and Section 3.2.1.3. Retrieved from: https://echa.europa.eu/documents/10162/23036412/polymers_en.pdf/9a74545f-05be-4e10-8555-4d7cf051bbed

In view of the above, the terms natural polymer and naturally occurring substance are two distinct terms and should not be confused. A key distinction relates to the extraction methods allowed. The scope of the natural polymer refers to a broader group that is independent of the method used to extract the substance from nature. Furthermore, point (39) of Article 3 of the REACH Regulation is not directly referred to in the Directive. A consequence of this distinction and applying the definition from the ECHA Guidance is, for example, that cellulose and lignin extracted from wood and corn starch obtained via wet milling meet the definition of natural polymer.

Another key distinction is whether the polymerisation process has taken place in nature or is the result of an industrial process involving living organisms. Based on the REACH Regulation and the related ECHA Guidance, polymers produced via an industrial fermentation process are not considered natural polymers since polymerisation has not taken place in nature. Therefore, polymers resulting from biosynthesis through man-made cultivation and fermentation processes in industrial settings, e.g. polyhydroxyalkanoates (PHA), are not considered natural polymers as not being the result of a polymerisation process that has taken place in nature. In general, if a polymer is obtained from an industrial process and the same type of polymer happens to exist in nature, the manufactured polymer does not qualify as a natural polymer.

(ii) Not chemically modified

Recital 11 of the Directive explains that the term not chemically modified substances should be read in accordance with point (40) of Article 3 of the REACH Regulation, which states:

'not chemically modified substance: means a substance whose **chemical structure remains unchanged**, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities.' [*Emphasis added*]

The terms have not been chemically modified in point (1) of Article 3 of the Directive, with regard to natural polymers, are to be interpreted as follows: the decision whether a polymer has been chemically modified in its production or not should take into account only the difference between the ingoing and the resulting polymer, disregarding any modifications which might have taken place during production processes, as those are not relevant for the properties and the behaviour of the polymer used and eventually potentially released into the environment.

This means that, for example, regenerated cellulose, e.g. in form of viscose, lyocell and cellulosic film, is not considered to be chemically modified, as the resulting polymers are not chemically modified compared to the ingoing polymer. Cellulose acetate is considered to be chemically modified given that, compared to the ingoing natural polymer, the chemical modifications of cellulose during the production process remain present at the end of the production process.

Where changes in the chemical structure of a polymer result from reactions that are only taking place during the extraction process of a natural polymer (e.g. wood pulping process to extract cellulose and lignin), these are not considered to result in a chemical modification of the natural polymer in the meaning of point (1) of Article 3 and Recital 11 of the Directive. Therefore, paper material resulting from the wood pulping process is not considered to be made of chemically modified natural polymers. This interpretation is also in line with the Impact Assessment accompanying the European Commission's proposal for this Directive (hereafter, 'the Impact Assessment'), in which paper-based products without plastic lining or coating have been identified as available, more sustainable, alternatives to single-use plastic products ⁽⁵⁾.

2.2. Single-Use Plastic Product (point (2) of Article 3)

Point (2) of Article 3 of the Directive provides the following definition for a single-use plastic product:

'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**' [*emphasis added*]

⁽⁵⁾ SWD(2018) 254 final, Part 3/3, pp. 29-31.

In addition, Recital 7 and Recital 12 state that the 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 plastics and products from oxo-degradable plastic – and that, for this reason, glass and metal beverage containers should not be covered by the Directive. The Directive specifically exempts glass and metal beverage containers that have caps and lids made from plastic from Parts C, E, F and G of the Annex, while including composite beverage packaging. This is in line with the objectives of the Directive to focus efforts where they are most needed.

2.2.1. *Plastic content: wholly or partly made from plastic*

Single-use plastic products listed in the Annex to the Directive are within its scope if they are wholly or only partly made from plastic as defined in points (1) and (2) of Article 3. The Directive does not envisage any *de minimis* threshold for the plastic content in a single-use product to determine whether or not that product is covered by the definition of single-use plastic product; therefore, a qualitative assessment is to be applied.

In the production of many materials, including non-plastic materials, polymers that meet the definition of plastic in this Directive are often used to achieve specific material properties as well as higher production process efficiencies. Those polymeric materials are often synthetic chemical additives. The use of such polymeric materials, e.g. as retention agents or binders and processing aids in the production of a material, which in itself is not plastic, does not result in the single-use product made only of that material to be considered as being made partly of plastic. In particular, paper- and board-based products have in the preparation of the legislative proposal for the Directive⁽⁶⁾ specifically been assessed for their potential to serve as a sustainable alternative to single-use plastic products. Consequently, paper- and board-based single-use products made only from paper- and board-based material and without a plastic lining or coating are not, in light of the considerations above, to be considered as single-use plastic products in the meaning of the Directive.

However, when a plastic coating or lining is applied to the surface of a paper- or board-based or other material to provide protection against water or fat, the final product is considered a composite product composed of more than one material of which one is plastic. In this case, the final product is seen as being made partly of plastic. Hence, single-use paper- or board-based products with plastic coating or lining are partly made of plastic and fall within the scope of the Directive. This is also supported by the fact that in relation to paper- and board-based cups, in contrast to other single-use paper- and board-based products without plastic lining or coating, paper- and board-based cups with a plastic layer have not been identified as an alternative option in the Impact Assessment⁽⁷⁾, being themselves not plastic-free. This interpretation is supported by the fact that the exemption for coatings originally included in the Commission proposal⁽⁸⁾ through Recital 8 no longer appears in the corresponding Recital 11 of the Directive, nor elsewhere in the Directive. The co-legislators thereby expressed the intention to not expressly exclude products made from non-plastic materials with plastic coatings and plastic linings from the scope of the Directive. In accordance with Recital 9, both large and small plastic fragments resulting from single-use plastic items cause significant terrestrial pollution, contamination of soil and can leak into the marine environment having negative impact on the marine environment. The inclusion of these items in the scope of the Directive is therefore not only in line with the objectives of the Directive but necessary to prevent and reduce the impact of certain fast-moving consumer products made wholly or partly of plastic that are prone to becoming litter that poses risks in particular to marine ecosystems, biodiversity and human health. This is also necessary to achieve the objective of promoting the transition to a circular economy with innovative and sustainable business models, products and materials that gives 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.

Another illustration is beverage cartons that generally consist of several layers of paper, plastic and in some cases aluminium necessary for providing the technical properties for the beverage container, including oxygen and water barriers. Beverage cartons are composite beverage packaging⁽⁹⁾, which is expressly included in the scope of the Directive as per Parts C, E and G of the Annex as well as Recitals 12 and 18.

⁽⁶⁾ Ibid.

⁽⁷⁾ SWD(2018) 254 final, Part 3/3, p. 30. The document states that a single-use non-plastic alternative is not included in the analysis as lined beverage cups are required for coffee to ensure the mechanical strength is maintained even when filled with very hot liquid for a certain length of time.

⁽⁸⁾ European Commission Proposal for a Directive of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment (COM(2018) 340 final, 28.5.2018).

⁽⁹⁾ See Article 3(2b) of Directive 94/62/EC on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10).

2.2.2. *Single-use*

The cumulative use of terms in point (2) of Article 3 requires that the product should be neither conceived nor designed or placed on the market to accomplish, within its life span, multiple trips or rotations. This should rule out situations where final products could potentially be placed on the market or marketed as multi-use or re-usable without having been conceived and designed as such, or without being placed on the market as part of a system or an arrangement to ensure their re-use.

Product design characteristics can help to determine whether a product should be considered as single- or multiple-use. Whether a product is conceived, designed and placed on the market for reuse, can be assessed by considering the product's expected functional life, i.e. whether it is intended and designed to be used several times before final disposal, without losing product functionality, physical capacity or quality, and whether consumers typically conceive, perceive and use it as a reusable product. Relevant product design characteristics include material composition, washability and reparability, which would allow multiple trips and rotations for the same purpose as for which the product was originally conceived. For a receptacle, which is packaging, its reusable nature can be determined in accordance with the essential requirements under the Packaging and Packaging Waste Directive⁽¹⁰⁾, including any declaration attesting to the conformity of the packaging with those essential requirements and related standards.

2.2.3. *Refillable and reusable nature of the product*

In accordance with point (2) of Article 3 of the Directive, a single-use product is a product that is not conceived, designed or placed on the market to accomplish, within its lifespan, multiple trips and rotations by:

- being returned to a producer for refill or
- reused for the same purpose for which it was conceived.

The Packaging and Packaging Waste Directive provides useful guidance to identify products that are placed on the market as packaging complying with these conditions and thus not considered single-use, in particular, through the definition of reusable packaging and the relevant part of the essential requirements on reusable packaging. Under point (2a) of Article 3 of the Packaging and Packaging Waste Directive reusable packaging means 'packaging which has been conceived, designed and placed on the market to accomplish within its lifecycle multiple trips or rotations by being refilled or reused for the same purpose for which it was conceived'. By analogy, the definition of reusable packaging provides useful guidance on reusability of non-packaging single-use plastic products because similar principles apply also to non-packaging items, e.g. regarding the intention to be reused and the possibility to recondition, clean, wash, repair the item whilst maintaining its ability to perform its intended function.

In accordance with point (2) of Annex II to the Packaging and Packaging Waste Directive, which sets out the essential requirements for packaging, reusable packaging should, among others, have physical properties and characteristics which enable a number of trips or rotations in normally predictable conditions of use. Detailed conditions for compliance with these requirements are specified in the European harmonised standard EN 13429:2004 Packaging – Reuse. The requirements listed in that standard for considering the reusable nature of packaging include:

- Intention that the package is reused (i.e. purposely designed, conceived and placed on the market);
- Design of the package enables it to accomplish a number of trips or rotations;
- The package can be emptied/unloaded without significant damage, and without risk to the integrity of the product, and health and safety;
- The package can be reconditioned, cleaned, washed, repaired, whilst maintaining its ability to perform its intended function;
- Arrangements are in place to make reuse possible, i.e. a re-use system is set up and operational.

⁽¹⁰⁾ Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10).

Where the plastic products listed in the Annex to the Directive are not placed on the market as packaging, further considerations have to be taken into account in order to determine if they are for single- or multiple-use. For example, where the same type of item that is generally placed on the market as non-reusable plastic packaging is also sold empty to final consumers (such as plastic cups or food containers), it is appropriate to consider it a single-use plastic product.

Operational reuse systems for refill or reloading are essential to make use of re-usable items and such systems could include postal or courier packaging or drop-boxes in store. In a functioning refill system, the product's functionality, physical capacity and quality are not modified by the producer and/or distributor between refills ⁽¹¹⁾. It is also noted that reuse systems for the service of food and drinks implemented and managed effectively by operators may provide a more consistent assurance in that the reusable items (e.g. cups, containers and cutlery) are properly sanitized to guarantee hygiene, protect public health and ensure customer and employee safety.

3. RELATION BETWEEN DIRECTIVE (EU) 2019/904 AND DIRECTIVE 94/62/EC

Single-use plastic products covered by the Single-use plastics Directive and that are also considered packaging as defined by point (1) of Article 3 of the Packaging and Packaging Waste Directive have to comply with the requirements of both Directives.

Recital 10 of the Single-use plastics Directive clarifies that, in the event of a conflict between the two Directives, this Directive shall prevail. This is the case regarding restrictions of placing single-use plastic products on the market. Single-use plastic food containers and cups for beverages (including their caps and lids) that are packaging may, in accordance with Article 4 of the Single-use plastics Directive, be subject to marketing restrictions in derogation from Article 18 of the Packaging and Packaging Waste Directive 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 Single-use plastics Directive supplements the Packaging and Packaging Waste Directive regarding consumption reduction measures, product design requirements, marking and extended producer responsibility rules.

Single-use plastic products that do not constitute packaging are subject to the requirements of the Single-use plastics Directive only, even if they may have functionalities or properties similar to packaging.

Table 3-1

Single-use plastic products that do and do not constitute packaging under the Packaging and Packaging Waste Directive

Single-use plastic products that constitute packaging	Single-use plastic products that do not constitute packaging
<ul style="list-style-type: none"> — Filled food containers; beverage containers, beverage bottles and cups for beverages, packets and wrappers, lightweight plastic carrier bags and plates (meet criterion (i) of Article 3(1) of the Packaging and Packaging Waste Directive) — Food containers, beverage containers, beverage bottles, cups for beverages, packets and wrappers and plates placed on the market empty but intended to be filled at the point of sale (meet criterion (ii) of Article 3(1) of the the Packaging and Packaging Waste Directive) — Caps, lids, covers, straws, stirrers and other types of packaging components and ancillary elements, when they form an integral part of the packaging (meet criterion (iii) of Article 3(1) of the the Packaging and Packaging Waste Directive) 	<ul style="list-style-type: none"> — Cutlery, straws and stirrers as they do not typically perform a packaging function (not meeting criterion (iii) of Article 3(1) of the Packaging and Packaging Waste Directive) — Receptacles, including food containers, beverage containers and beverage bottles (including their caps and lids) ⁽¹⁾, cups for beverages (and their covers and lids), that are placed on the market empty and not intended to be filled at the point of sale (not meeting criterion (ii) of Article 3(1) of the Packaging and Packaging Waste Directive) — Products that do not constitute packaging: <ul style="list-style-type: none"> — Cotton bud sticks — Balloons — Sanitary towels (pads), tampons and tampon applicators — Wet wipes — Tobacco products with filters, and filters marketed for use in combination with tobacco products

⁽¹⁾ Food containers, beverage containers and beverage bottles that are placed on the market empty and not intended to be filled at the point of sale are included in the scope of SUP Directive as according the product definitions (see part C), as the products are 'used' to contain respectively food and beverage.

⁽¹¹⁾ National Law Review (2019). The New EU Single-use Plastics Directive EU to Adopt Law on the Reduction of the Impact of Certain Plastic Products on the Environment. Retrieved from: <https://www.natlawreview.com/article/new-eu-single-use-plastics-directive-eu-to-adopt-law-reduction-impact-certain>

4. SPECIFIC PRODUCT CRITERIA

4.1. Food containers

4.1.1. Product description and criteria in the Directive

The table below gives an overview of the product descriptions for single-use plastic food containers provided in the Directive.

Table 4-1

Overview of product descriptions of food containers in the Directive

Point (2) of Part A, point (1) of Section I of Part E, and point (1) of Part G of the Annex:

'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.'

Article 12:

'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.'

The three criteria laid down in point (2) of Part A, point (1) of Section I of Part E, and point (1) of Part G of the Annex to the Directive apply cumulatively. Therefore, for a food container to be covered by the Directive it has to meet all three criteria that apply to the food contained.

The following indicators may be used to interpret and apply the three criteria:

- (1) Criterion: is intended for immediate consumption, either on-the-spot or take-away

Relevant indicators:

- Nature of foodstuff contained in the food container: Foodstuffs generally suitable for immediate consumption are e.g. nuts, sandwiches, yoghurts, salads and cooked meals, fruit and vegetables.
- The inclusion or attachment of items such as forks, knives, spoons and sticks and/or sauces to the single use plastic food container. However, the absence of such items should not in itself exclude the product from the scope of the Directive.

- (2) Criterion: is typically consumed from the receptacle

Relevant indicator:

- The shape of the food container allows for or facilitates eating the foodstuff it contains directly from the container, i.e. by simply opening it.

- (3) Criterion: is ready to be consumed without any further preparation, such as cooking, boiling or heating

Relevant indicators:

- The foodstuff contained in the food container can be consumed without any further preparation. For example, the foodstuff does not require freezing, cooking, boiling or heating, including frying, grilling, baking, microwaving and toasting. For example, the washing, peeling or cutting of fruit and vegetables, should not be considered as preparation and are therefore not an indicator for exclusion from the Directive, as they can be easily performed on-the-go.

- The foodstuff contained in the food container can be consumed without adding seasonings or sauces (unless those are provided together with the food product), cold or hot water or other liquids, including milk, before consumption of the foodstuff such as in the case of cereals (unless portion sized servings of cereals are sold together with an additional portion sized container of milk) or powder soups.

It should be pointed out that food containers used to contain food meeting the requirements set out in the Directive, which are sold empty and not intended to be filled at the point of sale, are also covered by the Directive.

In addition to these three cumulatively applicable criteria, Article 12 of the Directive adds a criterion related to the tendency of a food container to become litter, due to its volume or size, in particular single-serve portions. While the reference to the notion of single-serve portions in Article 12 is mentioned as a decisive guiding element, no definition, nor common understanding, of a single-serve portion is provided in the Directive. Recital 12 states that containers containing food in more than single-serve portions or single-serve portion-sized food containers sold in more than one unit are not to be considered single-use plastic products for the purposes of this Directive. In particular, the exemption of single-serve portion-sized food containers sold in more than one unit indicates that the concept of single-serve portion could relate to a portion that typically can be consumed by one person in one meal session. However, the relevant volume and the size can vary in function of the nutritional value of the food items contained and consumption habits across the Union. Furthermore, with regard to beverage containers, a clear volume and size threshold of three litres above which the Directive does not apply is established in Part C, point (3) of Section I of Part E and point (3) of Part G of the Annex to the Directive. This threshold suggests that it is considered relevant to prevent littering of single use plastic products which are portioned in a way to be typically consumed in a single serving by several people. By analogy, the same volume is suggested to be used as an upper threshold regarding food containers to determine if a portion typically can be consumed in one meal session.

4.1.2. *Product overview and list of illustrative examples*

Table 4-2 provides some illustrative examples of certain types of food containers that may be considered included or excluded from the scope of the Directive.

Table 4-2

Illustrative application of the criteria to interpret the definition of single use plastic food containers

Type of food container	General criteria		Product-specific criteria			Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Intended for immediate consumption	Typically consumed from the receptacle	Ready to be consumed without further preparation	
Plastic food container containing a portion hot meal	YES	YES	YES	YES	YES	Included
Plastic food container containing a cold meal	YES	YES	YES	YES	YES	Included
Cardboard food container with plastic lining or coating, intended to contain hot or cold meal	YES	YES	YES	YES	YES	Included
Plastic food container containing a dessert	YES	YES	YES	YES	YES	INCLUDED
Plastic food container containing vegetables or fruit	YES	YES	YES	YES	YES	INCLUDED
Plastic food container containing snacks such as nuts, crackers	YES	YES	YES	YES	YES	Included
Plastic food container containing sauces and bread spreads (e.g. mustard, ketchup or dips)	YES	YES	YES	YES	YES	Included
Plastic food container containing vegetables or fruit that do not require further preparation	YES	YES	YES	YES	YES	Included
Plastic food container containing a frozen meal which requires further preparation	YES	YES	NO	YES	NO	Excluded Not typically sold as a takeaway; foodstuff requires preparation

Type of food container	General criteria		Product-specific criteria			Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Intended for immediate consumption	Typically consumed from the receptacle	Ready to be consumed without further preparation	
Ice-cream container made of cardboard with plastic liner, from which the food is typically directly consumed	YES	YES	YES	YES	YES	Included
Fish boxes, meat trays, made out of plastic containing packed food that is not intended for immediate consumption, not typically consumed from the food container, and not ready to be consumed without further preparation	YES	YES	NO	NO	NO	Excluded foodstuff requires further preparation and is not typically consumed from the food container
Plastic food container containing dried food or foodstuff that require hot water to be poured in the receptacle (e.g. noodles, powder soups)	YES	YES	NO	YES	NO	Excluded foodstuff requires further preparation Not typically sold as a take- away

4.2. Packets and wrappers

4.2.1. Product description and criteria in the Directive

Point (2) of Section I of Part E and point (2) of Part G of the Annex describe packets and wrappers as follows: 'Packets and wrappers made from flexible material containing food that is intended for immediate consumption from the packet or wrapper without any further preparation'.

In contrast to food containers, where Article 12 and Recital 12 refer to size, volume, single-serve portions and single-serve portion-sized food containers sold in more than one unit, for packets and wrappers the Directive does not refer to specific criteria. While not explicitly mentioned in the Directive, it can be concluded from the context described in the Impact Assessment ⁽¹²⁾ that for packets and wrappers the main driver for items ending up as marine litter is the on-the-go consumption of food products and the demand for more convenience. In view of the objective of the Directive to prevent the littering of single-use plastic items in the environment and the fact that packets and wrappers are among the top littered items, it is appropriate to apply an approach consistent with beverage containers covered by the Directive as regards the three litre threshold.

The following indicators may be used to interpret and apply the product-specific criteria for packets and wrappers (and the food contained therein) included in the Annex:

(1) Criterion: made from flexible material

- Flexible packaging is packaging whose shape is easily changed, e.g. when foodstuff is added or removed as opposed to rigid packaging whose shape remains unchanged when foodstuff is added or removed.
- The design of packaging indicates that the foodstuff contained is intended for immediate consumption after purchasing. For example, a packet or wrapper can be easily opened e.g. by tearing, cutting, twisting or pulling it apart.

(2) Criterion: containing food intended for immediate consumption from the packet or wrapper without any further preparation

- Nature of foodstuff contained: foodstuffs suitable for immediate consumption (e.g. sweets, nuts, chocolate bars, cherry tomatoes, crisps).
- The design of the packet or wrapper allows for consumption directly from the package or wrapper.
- The inclusion or attachment of items such as forks, knives, spoons and sticks and/or sauces to the single use plastic packet or wrapper. However, the absence of such items should not in itself exclude the product from the scope of the Directive.
- The foodstuff contained in the packet or wrapper can be consumed without any preparation before consumption such as boiling, frying, grilling, baking, cooking, microwaving, toasting, heating or freezing. There is no requirement to add seasonings or sauces (unless those are provided together with the food product) cold water or hot water or other liquids, including milk before the consumption of the foodstuff such as in the case of cereals. Washing, peeling or cutting of a foodstuff are not considered a preparation and therefore fall under the scope of the Directive, as they can be easily performed on-the-go.

4.2.2. Product overview and list of illustrative examples

Table 4-3 provides some illustrative examples of certain types of packets and wrappers that are considered included or excluded from the scope of the Directive.

⁽¹²⁾ Ibid.

Table 4-3

Examples of packets and wrappers

Type of packet or wrapper	General criteria		Product-specific criteria		Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Made from flexible material	Intended for immediate consumption from the packet or wrapper without any further preparation	
Packet or wrapper containing food for immediate consumption (e.g. biscuits, nuts, crisps, popcorn, sweets, chocolate bars, bakery goods, frozen goods) sold by single unit	YES	YES	YES	YES	Included
Packet or wrapper containing food for immediate consumption from the packet or wrapper without any further preparation (e.g. crisps, sweets, chocolate bars, bakery goods, frozen goods) sold in one or more than one unit (i.e. within a multipack receptacle)	YES	YES	YES	YES	Included
Packet containing multiple-serve portions of food for immediate consumption from the packet and which are not individually wrapped (e.g. bakery goods, biscuits, sweets, chewing gum, crisps)	YES	YES	YES	YES	Included
Sandwich wrapper	YES	YES	YES	YES	Included
Packet containing condiment/sauce	YES	YES	YES	YES	Included
Packet containing dry breakfast cereals	YES	YES	YES	NO	EXCLUDED foodstuff is not intended for immediate consumption from the packet; milk is typically added before consumption and outside of the packet

Type of packet or wrapper	General criteria		Product-specific criteria		Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Made from flexible material	Intended for immediate consumption from the packet or wrapper without any further preparation	
Packet containing fresh/dried food that requires further preparation (e.g. entire head of lettuce, uncooked pasta, uncooked lentils)	YES	YES	YES	NO	EXCLUDED Foodstuff is typically not consumed directly from the packet or wrapper; Foodstuff is typically further prepared before consumption
Packet of cut salad leaves that do not require any further preparation before immediate consumption	YES	YES	YES	YES	INCLUDED

4.3. Cutlery, plates, straws and stirrers

4.3.1. Product descriptions in the Directive

Cutlery, plates, straws, and stirrers are addressed in Article 5 of the Directive but are not defined in the Directive. The Part B of Annex to the Directive provides product-specific guidance only on the definition of cutlery, namely, point (2) of Part B of the Annex provides that forks, knives, spoons, chopsticks are included in the definition of cutlery.

When placed on the market, these items are primarily included within the following CPV code ⁽¹³⁾: Disposable catering supplies (39222100-5) and Disposable cutlery and plates (39222110-8).

Cutlery, plates, straws and stirrers that are made entirely of natural polymers, which have not been chemically modified, fall outside the scope of the Directive.

According to point (4) of Part B of the Annex, straws that fall within the scope of Council Directive 90/385/EEC ⁽¹⁴⁾ or 93/42/EEC ⁽¹⁵⁾ as medical devices are excluded from the scope of the Directive ⁽¹⁶⁾.

EU Guidance for the application of Directive 93/42/EEC ⁽¹⁷⁾ provides guidelines on the classification of medical devices ⁽¹⁸⁾ for the purposes of risk assessment. No specific examples of straws used as medical devices are given in these guidelines. However, the specific definition of medical device from Directive 90/385/EEC and Directive 93/42/EEC includes articles used specifically for alleviation of or compensation for an injury or handicap. Plastic straws, if considered as medical devices, must be intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, or diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, and must be CE marked under Directive 93/42/EC the same way as under Regulation (EU) 2017/745 of the European Parliament and of the Council ⁽¹⁹⁾.

4.3.2. Product overview and list of illustrative examples

Table 4-4 provides some examples of single use plastic cutlery, plates, straws, stirrers that are considered included in or excluded from the scope of the Directive.

⁽¹³⁾ The Common Procurement Vocabulary establishes a single classification system for public procurement aimed at standardising the references used by contracting authorities and entities to describe procurement contracts available at: https://ec.europa.eu/growth/single-market/public-procurement/digital/common-vocabulary_en

⁽¹⁴⁾ 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).

⁽¹⁵⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

⁽¹⁶⁾ By 3 July 2021, which is the transposition deadline for the majority of the requirements of Directive (EU) 2019/904, Directives 90/385/EEC and 93/42/EEC will no longer apply. As of 26 May 2021, the placing on the market of medical devices will be governed by Regulation (EU) 2017/745 on medical devices.

⁽¹⁷⁾ DG Health and Consumer, 2010. Medical Devices: Guidance document – Classification of medical devices – MEDDEV 2.4/1 rev.9 available at: <http://ec.europa.eu/DocsRoom/documents/10337/attachments/1/translations>

⁽¹⁸⁾ Council Directive 90/385/EEC and Council Directive 93/42/EEC both define medical devices as follows: “medical device” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;.

⁽¹⁹⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

Table 4-4

Illustrative application of the criteria to interpret the definition of single use plastic cutlery, plates, straws, stirrers

Types of cutlery; plates; straws; stirrers	General criteria		Product-specific criteria		Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Non-durable material	Not a medical device	
Single-use cutlery, plates, straws, stirrers made wholly of plastic	YES	YES	YES	YES	INCLUDED
Single-use cutlery, plates, straws, stirrers made partly of plastic, e.g. made predominantly of non-plastic material but with a plastic lining/coating	YES	YES	YES	YES	INCLUDED
Single-use plastic straws attached to/integrated into a beverage container	YES	YES	YES	YES	INCLUDED (under Art 5)
Single-use plastic cutlery attached to/integrated into food packaging	YES	YES	YES	YES	INCLUDED (under Art 5)
Single-use cutlery, plates, straws, stirrers not made of plastic, e.g. paper- or wood-based without a plastic lining/coating	NO	YES	YES	YES	EXCLUDED: Product does not contain plastic
Multiple-use cutlery, plates, straws, stirrers not made of plastic but of durable material, e.g. ceramics or metal	NO	NO	NO	YES	EXCLUDED: Product not intended for single-use
Multiple-use durable plastic cutlery, plates, straws, stirrers purposely designed and placed on the market with the objective to be used more than once and typically conceived and used by consumer as such	YES	NO	NO	YES	EXCLUDED: Product not intended for single-use
Plastic straws intended for use as medical device and carrying respective CE marking	YES	YES	YES	NO	EXCLUDED: Product intended for use as medical device

4.4. Beverage containers, beverage bottles and cups for beverages (including their caps, covers and lids)

4.4.1. Product descriptions and criteria in the Directive

Table 4-5 provides an overview of the product criteria relating to beverage containers, beverage bottles, and cups for beverages, provided in the Directive.

Table 4-5

Relevant descriptions of beverage containers; beverage bottles; and cups for beverages, including their caps and lids in the Directive

Beverage containers:

Parts C and F of the Annex describe beverage containers as follows:

'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[(2)] of Regulation (EU) No 609/2013 of the European Parliament and of the Council that is in liquid form.'

Point (3) of Section I of Part E and point (3) of Part G of the Annex describe beverage containers as follows:

'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'.

Beverage bottles are referred to in Part F of the Annex, as follows:

'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[(2)] of Regulation (EU) No 609/2013 that is in liquid form.'

Cups for beverages are defined in point (1) of Part A, point (4) of Section I of Part E and point (4) of Part G of the Annex to the Directive as cups for beverages, including their covers and lids. In addition Part D(4) of the Annex refers to cups for beverages, but without referring to covers and lids.

The following two main descriptors are used to define both single-use plastic beverage containers and beverage bottles:

(1) capacity of up to three litres, and

(2) receptacles used to contain liquid.

A beverage container is, in principle, sold and consumed for a product that is in liquid form, and consumed by drinking. In addition, Part C, point (3) of Section I of Part E, point (3) of Part G, and Part F (beverage bottles only) of the Annex specify that caps and lids are included in the definition of beverage containers and beverage bottles. Furthermore, composite beverage packaging is also included in the scope of the Directive.

With regard to cups for beverages, the Directive does not provide for a specific description, criteria or examples. Point (1) of Part A, point (4) of Section I of Part E and point (4) of Part G of the Annex merely specify that covers and lids are also to be included in this product category. Examples of beverages as per Recital 12 of the Directive include beer, wine, water, liquid refreshments, juices and nectars, instant beverages or milk ⁽²⁰⁾. Further clarifications in relation to the definition of beverage are provided in section 4.5.1. of this document (i.e. liquid that is ingested/consumed through drinking). It should be pointed out that cups for beverages used to contain a liquid meeting the requirements set out above, which are sold empty, are also covered by the Directive.

4.4.2. Caps, lids and covers

The Directive refers to caps and lids as closures for beverage containers and beverage bottles, whereas for cups for beverages the Directive refers to lids and covers.


Caps, lids and covers close beverage containers with the objective to retain its contents. They are used in combination with beverage containers, beverage bottles, and cups for beverages to ensure that the liquid product contained does not overflow and can be transported. The Directive does not provide a clear definition, nor does any existing EU legislation or technical standards. Nevertheless, the following guidance can be used to define them:

- Caps: closures that are fitted onto beverage containers or beverage bottles, for example, in order to prevent the contained liquid from leaking (also after for example a lid has been removed) and to allow for safe transportation. Caps are currently typically of screw or hinged snap types. Screw caps can be flat top, which is the most common form, or be the base support for e.g. a drinking spout generally termed a sports cap. Sports caps can in turn be either of the push-pull shutter or flip-top types which by nature are designed to remain attached to the beverage container. This type of cap will often include a tamper-evident feature.
- Lids: plastic or composite material that include plastic films sealed onto beverage containers, beverage bottles and cups for beverages. They can be peeled or torn-off. Once such a lid is removed on first opening by a consumer it cannot be placed back on the product. Lids can also refer to certain larger diameter or non-round caps.
- Covers: Closure used on cups for beverages which protect the liquid contained but generally do not provide a complete seal. They can be re-placed on the product after having been removed without losing their closure function. Some covers may have a tamper-evident feature, which is considered part of the closure assembly.



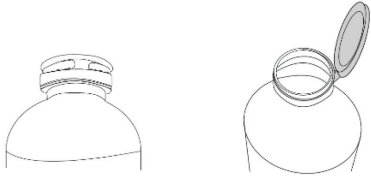
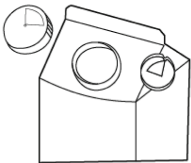
Illustrative examples of caps and lids for single-use plastic beverage containers and beverage bottles, and covers and lids for single-use plastic cups for beverages and whether they are considered included in or excluded from the scope of the Directive are provided in **Table 4-6**.





Table 4-6

Illustrative examples of different types of caps, lids and covers

Type of caps, lids and covers	Included in or excluded from the scope of the directive
<p>Caps made of plastic, used in combination with single-use plastic beverage bottles (illustration) and beverage cartons (no illustration)</p> 	<p>INCLUDED</p>

⁽²⁰⁾ Whereas Recital 12 provides examples of beverages only for beverage containers and beverage bottles, the same examples are also relevant for the definition of 'beverage' in the context of cups for beverages.

Type of caps, lids and covers	Included in or excluded from the scope of the directive
<p data-bbox="178 342 951 400">Sports caps made of plastic, used in combination with single-use plastic beverage bottles</p> 	INCLUDED
<p data-bbox="178 792 951 851">Caps made of plastic, used in combination with single-use plastic beverage pouches</p> 	INCLUDED
<p data-bbox="178 1256 746 1285">Flip-top caps for single-use plastic beverage containers</p> 	INCLUDED
<p data-bbox="178 1695 951 1753">Plastic cap with separate sealing membrane (two-step closure) used in combination with a single-use plastic beverage container</p> 	INCLUDED

Type of caps, lids and covers	Included in or excluded from the scope of the directive
<p>Covers made of plastic, used with single-use plastic cups for beverages</p> 	<p>INCLUDED</p>
<p>Roll on pilfer proof aluminium cap with plastic seal and plastic tamper evident band used in combination with single-use plastic beverage containers and beverage bottles</p> 	<p>PARTIALLY INCLUDED</p> <p>Metal caps or lids with plastic seals are subject to the requirements of the Directive, except the product requirements in Article 6.</p>
<p>Pull ring caps with plastic seal and plastic pull tab used in combination with single-use plastic beverage containers and beverage bottles</p> 	<p>PARTIALLY INCLUDED</p> <p>Metal caps or lids with plastic seals are subject to the requirements of the Directive, except the product requirements in Article 6.</p>
<p>Foil lid seal on a single-use plastic beverage container</p> 	<p>INCLUDED</p> <p>The sealing membrane does not enter into the definition of 'cap' or 'lid' and is not in the scope of Article 6.</p>

4.4.3. Product-specific exemptions

Point (a) of Part C, point (3) of Section I of Part E, point (a) of Part F and point (3) of Part G of the Annex to the Directive explicitly exclude glass or metal beverage containers that have caps and lids made from plastic, from the requirements of the Directive applicable to single-use plastic beverage containers.

Beverage containers and beverage bottles used for food for special medical purposes as defined in point (g) of Article 2(2) of Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽²¹⁾ that is in liquid form are exempted from Article 6 pursuant to point (b) of Part C and point (b) of Part F of the Annex.

⁽²¹⁾ 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).

The product's volume and size are also relevant. Beverage containers and beverage bottles with the capacity above 3 litres will fall outside the scope of the Directive.

The Directive does not set a specific threshold on the volume or size of cups for beverages. While not explicitly mentioned in the Directive, it can be concluded from the context described in the Impact Assessment ⁽²²⁾ that for cups for beverages the main driver for these items ending up as marine litter is the on-the-go consumption of food and beverage products and the demand for more convenience. In view of the objective of the Directive to prevent the littering of single-use plastic items in the environment and the fact that cups for beverages are among the top littered items, it is appropriate to apply an approach consistent with other beverage containers covered by the Directive as regards the three litre threshold.

4.4.4. *Product overview and list of illustrative examples*

The tables below provide a non-exhaustive list of examples to illustrate how the different beverage containers, beverage bottles, and cups for beverages can be assessed based on the criteria and indicators provided above and whether they are considered included in or excluded from the scope of the Directive.

⁽²²⁾ SWD(2018) 254 final, Part 1/3, p. 25.

Table 4-7

Illustrative examples of beverage containers and beverage bottles

Types of beverage containers and beverage bottles	General criteria		Product-specific criteria		Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Capacity	Liquid container	
Pouches (fully plastic or with plastic layer, up to three litres)	YES	YES	YES	YES	INCLUDED (Beverage Container)
Plastic bottles (up to three litres)	YES	YES	YES	YES	INCLUDED (Beverage Bottle)
Plastic container with single-serve portion of milk or cream (e.g. for coffee or tea)	YES	YES	YES	YES	INCLUDED (Beverage Container)
Composite beverage carton (up to three litres)	YES	YES	YES	YES	INCLUDED (Beverage Container)
Flexible plastic beverage container (up to three litres) in a carton box separable by hand	YES	YES	YES	YES	INCLUDED (Beverage Container)
Plastic water bottle above 3 litres	YES	NO	NO	YES	EXCLUDED The capacity is over 3 litres
Reusable and refillable plastic beverage bottles in case designed and placed on the market for such purpose and typically conceived and used by consumer as such	YES	NO	YES	YES	EXCLUDED Reusable bottle
One piece plastic beverage container with a moulded break-off closure	YES	YES	YES	YES	INCLUDED (Beverage Container)

Table 4-8

Illustrative examples of cups for beverages

Type of cups for beverages	General criteria		Product-specific criteria	Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Filled or intended to be filled with a beverage	
Cups for cold beverages made of 100 % plastic (with or without cover or lid)	YES	YES	YES	INCLUDED (CUP for BEVERAGE)
Pre-filled paper-based cups with plastic lining or coating for (usually cold) beverages (with or without cover or lid)	YES	YES	YES	INCLUDED (CUP for BEVERAGE)
Cups sold in retail and wholesale stores made of 100 % plastic for juices or alcohol containing drinks	YES	YES	YES	INCLUDED (CUP for BEVERAGE)
Empty cups made of 100 % plastic and empty paper-based cups with plastic lining or coating for hot or cold beverages (with or without cover or lid)	YES	YES	YES	INCLUDED (CUP for BEVERAGE)
Paper-based cups with plastic lining or coating sold in retail and wholesale stores	YES	YES	YES	INCLUDED (CUP for BEVERAGE)
Paper-based cups with bio-based or biodegradable plastic lining or coating sold in retail and wholesale stores	YES	YES	YES	INCLUDED (CUP for BEVERAGE)
Re-usable plastic cups sold as part of refill schemes	YES	NO	YES	EXCLUDED The cup is reusable (part of a refill system)
Plastic cup with instant beverage powders to which the addition of e.g. milk or water is necessary before the product can be consumed	YES	YES	YES	INCLUDED (CUP for BEVERAGE)

Type of cups for beverages	General criteria		Product-specific criteria	Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Filled or intended to be filled with a beverage	
Plastic cup with instant soup powder to which the addition of e.g. water is necessary before the product can be consumed	YES	YES	NO	EXCLUDED The cup is intended to be used for preparing a soup, which is not a beverage under the Directive
Reusable beverage cups sold in retail shops for multiple uses in case designed and placed on the market for such purpose and typically conceived and used by consumer as such	YES	NO	YES	EXCLUDED The cup is reusable
Refillable cups sold in retail shops for multiple uses	YES	NO	YES	EXCLUDED The cup is reusable

4.5. Differentiation between certain (related) product categories

Point (2) of Part A, point (1) of Section I of Part E, and point (1) of Part G of the Annex to the Directive exclude beverage containers, plates and packets and wrappers containing food from products that shall be considered as single-use plastic food containers for the purpose of the Directive. In some cases, the packaging shape may raise doubts as to whether the product is a food container, or a beverage container, or even other type of packaging covered by the Directive, such as packets, wrappers, beverage cups or plates.

The sections below provide further guidance for the differentiation between different but related product categories.

4.5.1. Key elements to distinguish food containers from beverage containers

The key step in distinguishing food containers from beverage containers, beverage bottles, and cups for beverages, is to establish whether the receptacle contains a food or a beverage product. The following criteria for distinguishing between a food (also referred to as foodstuff) and a beverage are to be used:

- The consumption mode of the product contained and the consistency of the product contained in a receptacle plays a decisive role in the distinction between food containers and beverage containers, beverage bottles and cups for beverages. With regard to food, Recital 12 of the Directive provides non-exhaustive examples of foodstuff, namely wrap, salads, fruits, vegetables and desserts. A beverage product is sold and consumed in liquid form, and can be consumed through drinking. Examples of beverage containers provided in Recital 12 include packaging of beer, wine, water, liquid refreshments, juices and nectars, instant beverages and milk.
- The unit in which the quantity of the food or beverage product is expressed. In general, beverages are expressed in volume (e.g. millilitres) and food generally in weight (e.g. grams). In some cases, however, the quantity of the foodstuff or beverage is not always indicated on the receptacle, particularly for those that are filled at the point of sale.

- The design characteristics of the container may be specific to the content. For example, the shape of the container and whether the foodstuff contained requires cutlery or not to be consumed indicate if the product is intended to be consumed through drinking or eating.

As Recital 12 specifically refers to milk bottles as a beverage container, milk should also be considered a beverage for the purposes of the Directive. This is in line with general criteria on consumption through drinking, its density and viscosity (liquid) and the type of receptacle, which for milk is similar to that for other beverages.






Certain foods, such as soups, yoghurts (unless they are drinkable) and fruit purees should not be classified as beverages for the purposes of the Directive, as they are typically not consumed through drinking and cutlery is typically used for their consumption, which distinguishes them from beverage products.

Certain products in liquid form, even where they are drinkable (e.g. vinegar, liquid toppings, soya sauce, lemon juices, edible oils, products requiring dilution before consumption such as cordials, squashes, syrups or concentrates) are not consumed directly from the container or need further dilution before being drinkable. For that reason, they do not qualify as beverages under the Directive, as they are not consumed and ingested through drinking.

The table below provides an overview of the guidance indicators, such as intended usage and shape and form of the receptacle, including illustrative examples to help distinguish food containers from beverage containers.

Table 4-9

Illustrative examples to differentiate between food containers and beverage containers

Single-use plastic food container		Single-use plastic beverage container	
Plastic multilayer pouch containing fruit puree (150 ml)		Plastic multilayer pouch containing fruit juice (150 ml)	
Plastic container containing yogurt (100g)		Plastic container containing drinkable yogurt (150 ml)	
		Milk carton (500 ml)	

4.5.2. Key elements to distinguish food containers from cups for beverages

With regard to cups for beverages, in addition to determining whether the product contained is a food or a beverage, guidance is to be given on how to consider cups that are placed on the market empty by manufacturers but which can be filled by retailers both with food and beverage products. An example of this type of cup is provided in the figure below.

The intended use of single-use plastic cups for beverages and whether they are intended for food or beverages is typically known by the initial distributor or the filler of the cups. If at the time of placing on the market it is unclear whether a product is a beverage cup or a food container, as it can be the case for certain containers sold in retail and wholesale stores, the manufacturer must comply with the requirements of the Directive for both types of products. For example, the product must be labelled in accordance with Article 7, to ensure compliance with the Directive.

Figure 4-1

Containers sold in retail and wholesale stores



4.5.3. Key elements to distinguish between beverage containers, beverage bottles and cups for beverages

The Directive does not draw a clear distinction between beverage containers, beverage bottles (a subcategory of beverage containers) and cups for beverages (which do not constitute beverage containers). However, the following generic characteristics relevant to this Directive can be made:

- In accordance with Part C, point (3) of Section I of Part E and point (3) of Part G of the Annex, beverage containers are ‘receptacles with a capacity of up to 3 litres, including their caps and lids, used to contain beverages’. Recital 12 also indicates that composite beverage packaging is to be seen as beverage container, not as beverage bottle.
- Beverage bottles are beverage containers with a narrow neck or mouth and with a capacity of up to 3 litres, including their caps and lids, used to contain beverages, excluding composite beverage packaging, as per differentiation made in the Directive with beverage containers.
- Cups for beverages are typically round, usually bowl-shaped drinking vessels with or without a cover or a lid, sold empty or containing beverages⁽²³⁾. As also explained in Recital 12, cups for beverages are a separate category of single-use plastic products for the purposes of the Directive.




The key element for distinguishing between the three product categories is their shape. The table below provides illustrative examples of beverage containers, beverage bottles, and cups for beverages that indicate the shape-related elements to be considered for the classification of these product categories.

Table 4-10

Illustrative examples of beverage containers, beverage bottles, and cups for beverages

Beverage containers	Beverage bottles (part of beverage containers)	Cups for beverages (not part of beverage containers)
Receptacles with a capacity of up to 3 litres, used to contain beverages (includes also beverage bottles)	Rigid beverage containers with a narrow neck or mouth and a capacity of up to 3 litres, including their caps and lids, used to contain beverages	Typically round, usually bowl-shaped drinking vessels with or without a cover or a lid, sold empty or containing beverages

⁽²³⁾ According to Macmillan dictionary.

Beverage containers	Beverage bottles (part of beverage containers)	Cups for beverages (not part of beverage containers)
		


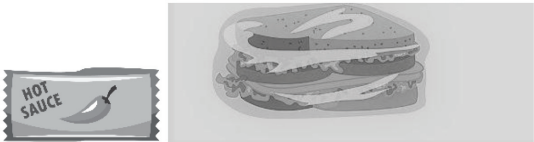
4.5.4. Key elements to distinguish food containers from packets and wrappers

The differentiation between food containers and packets and wrappers should be based on the rigidity of the container. For the purposes of the Directive, foodstuff products with rigid and partly rigid packaging should be considered to be food containers, whereas products with flexible packaging materials should be considered to be packets and wrappers.

Flexible packaging implies that it bends easily without breaking. The same considerations apply to non-packaging items that fall within the scope of the Directive. Some foodstuffs are packaged in a combination of rigid and more flexible material (see left column in Table 4-11), e.g. a sandwich in a rigid container with a film on one side or certain fruits or prepared foods sold in paper trays and covered by plastic wrappers. In those cases, the presence of rigid materials in the packaging should classify the product as a food container.

Table 4-11

Illustrative examples to differentiate between single-use plastic food containers and packets and wrappers

Single-use plastic food container	Single-use plastic packet and wrapper
<p>The container is made fully or partly from rigid material containing plastic</p>	<p>The container is made from flexible material containing plastic</p>
	

4.5.5. Key elements to distinguish plates from food containers



Point (2) of Part A, point (1) of Section I of Part E and point (1) of Part G of the Annex to the Directive exclude beverage containers, plates and packets and wrappers containing food from the product category of food containers for the purpose of the Directive.

Plates refer to dishes from which food is eaten or served, whereas food containers are receptacles such as boxes, with or without a cover, used to contain food.

Table below provides some illustrative examples of how to distinguish between a single-use plastic food container and plate.

Table 4-12

Illustrative example to differentiate between food containers from plastic plates

Single-use plastic food container	Single-use plastic plate
<p>Indicators indicating that the receptacle is a food container:</p> <ul style="list-style-type: none"> — Receptacles such as boxes sold with or without a lid — Able to contain food — May facilitate transport of food — Receptacle usually sold with printed information regarding contents, ingredients and often product weight 	<p>Indicators indicating that the receptacle is a plate:</p> <ul style="list-style-type: none"> — Dish sold without a lid, regardless of whether it is covered e.g. by foil or film, at the point of sale — Used to serve or eat food from, but presence of food is not required at the moment of purchase — While being predominantly flat, typically it has a slightly bevelled or raised perimeter to stop food rolling or spilling off it — Printed information including contents, ingredients or weight are usually not present. 

4.6. Lightweight plastic carrier bags4.6.1. *Product description and criteria in the Directive*

The table below provides an overview of the relevant descriptions in the Directive for lightweight plastic carrier bags.

Table 4-13

Descriptions of lightweight plastic carrier bags in the Directive

Point (5) of Section I of Part E and point (8) of Part G of the Annex: 'Lightweight plastic carrier bags as defined in point 1c of Article 3 of Directive 94/62/EC'.

Point (1c) of Article 3 of the Packaging and Packaging Waste Directive defines lightweight plastic carrier bags: 'lightweight plastic carrier bags' shall mean plastic carrier bags with a wall thickness below 50 microns.'

In addition, point (1d) of Article 3 of the Packaging and Packaging Waste Directive defines very lightweight plastic carrier bags as follows: 'very lightweight plastic carrier bags' shall mean plastic carrier bags with a wall thickness below 15 microns which are required for hygiene purposes or provided as primary packaging for loose food when this helps to prevent food wastage'.

The general term 'plastic carrier bags' is defined in point (1b) of Article 3 of the Packaging and Packaging Waste Directive: 'plastic carrier bags' shall mean carrier bags, with or without handle, made of plastic, which are supplied to consumers at the point of sale of goods or products'.

The product-specific criteria for single-use light-weight carrier bags provided in the Annex to the Directive can be clarified on the basis of the following indicators:

- Product design characteristic: in accordance with point (1c) of Article 3 of Directive 94/62/EC, wall thickness below 50 microns indicates that these bags are not purposely designed, conceived and placed on the market to be re-used. This criterion duly reflects the Directive's objective to reduce (marine) litter. As stated in Recital 4 of Directive (EU) 2015/720 ⁽²⁴⁾ such bags are less frequently reused than thicker plastic carrier bags, become waste more quickly, and are more prone to littering due to their light weight.
- Point of sale or distribution: refers to the point of sale where the product is supplied or distributed to the consumer (as described in point (1b) of Article 3 of the Packaging and Packaging Waste Directive).

The Directive covers all lightweight plastic carrier bags. This includes very lightweight plastic carrier bags (those with a wall thickness below 15 microns), which may be excluded from certain Packaging and Packaging Waste Directive requirements.

4.6.2. Product overview and list of illustrative examples

Table 4-14 provides illustrative examples on whether certain types of plastic carrier bags are included in or excluded from the scope of the Directive.

Table 4-14

Illustrative examples of different types of plastic carrier bags

Type of plastic carrier bag	General criteria		Product-specific criteria	Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Lightweight plastic carrier bag	
Lightweight plastic carrier bag supplied to consumer at point of sale (wall thickness below 50 microns)	YES	YES	YES	Included
Very lightweight plastic carrier bag supplied to consumer at point of sale (wall thickness below 15 microns)	YES	YES	YES	Included
Thicker plastic carrier bag (wall thickness above 50 microns)	YES	NO	NO	EXCLUDED Not lightweight carrier bag, and therefore out of the scope of the Directive
Waste collection bags made of plastic	YES	YES	NO	EXCLUDED Not 'carrier bag' and, therefore, out of the scope of the Directive

⁽²⁴⁾ Directive (EU) 2015/720 of the European Parliament and of the Council of 29 April 2015 amending Directive 94/62/EC as regards reducing the consumption of lightweight plastic carrier bags (OJ L 115, 6.5.2015, p. 11).

4.7. Cotton bud sticks

4.7.1. Product description and criteria in the Directive

Single-use plastic cotton bud sticks are referred to in point (1) of Part B of the Annex as 'Cotton bud sticks, except if they fall within the scope of Council Directive 90/385/EEC or Council Directive 93/42/EEC'. The Directive does not provide for a product definition for cotton bud sticks.

A cotton bud stick typically refers to a short stick with a small amount (or wad) of cotton at one or both of its ends, often used for personal hygiene, especially for the cleaning of ears or the application of make-up⁽²⁵⁾. When placed on the EU market, these items are included within a single Common Procurement Vocabulary (CPV) code: Cotton buds 33711410-4.

The following product design characteristics help define single-use cotton bud sticks for the purposes of the Directive:

- Thickness of the stick: Cotton bud sticks intended for non-medical purposes or for use by individuals at home are typically characterised by a short, thin, non-durable stem.
- Non-cleanable buds: Glue used to permanently affix single-use cotton buds to the end(s) of the stick preventing them from being dislodged from the stick during use. Ear cleaning sticks which are able to be washed or cleaned therefore ensuring their re-usability fall outside the scope of the Directive.

4.7.2. Product-specific exemptions

According to point (1) of Part B of the Annex to the Single-use plastics Directive, cotton bud sticks that fall within the scope of Directive 90/385/EEC or Directive 93/42/EEC as medical devices are excluded from the scope of the Directive⁽²⁶⁾. The definition of medical device from Directive 90/385/EEC and Directive 93/42/EEC includes articles used specifically for alleviation of or compensation for an injury or handicap. Cotton bud sticks, if considered as medical devices, must be intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, or diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, and must be CE marked under Directive 93/42/EC the same way as under Regulation (EU) 2017/745.

EU Guidance for the application of Directive 93/42/EEC on Medical Devices provides guidelines on the classification of medical devices for the purposes of risk assessment. The example of '(s)wabs to sample exudates' included⁽²⁷⁾ within these guidelines is considered to relate for example to 'medical swabs'⁽²⁸⁾.

Cotton bud sticks intended for medical use are also designed to be single-use. However, they are usually designed to specifically facilitate the use of sterile techniques, and are generally:

- Clearly labelled for medical use (e.g. 'medical swab');
- Often sold as sterile;
- Characterised by a longer, sturdier stem;
- Single tipped;
- Sold or distributed direct to healthcare professionals via professional circuits (e.g. business-to-business) e.g. swabs provided or used for forensic, medical or scientific purposes including: for collection of samples or specimens from humans or surfaces, for clinical microbiology, cytology, and DNA testing purposes.

⁽²⁵⁾ Cambridge Dictionary. Retrieved from: <https://dictionary.cambridge.org/dictionary/english/cotton-bud?q=cotton+buds>

⁽²⁶⁾ By 3 July 2021, which is the transposition deadline for the majority of the requirements of Directive (EU) 2019/904, Directives 90/385/EEC and 93/42/EEC will no longer apply. As of 26 May 2021, the placing on the market of medical devices will be governed by Regulation (EU) 2017/745 on medical devices.

⁽²⁷⁾ MEDDEV 2.4/1 rev.9 page 31: Examples provided for 'Rule 6 – Surgically invasive devices intended for transient use (< 60 minutes)'.

⁽²⁸⁾ Pirro V, Jarmusch AK, Vincenti M, Cooks RG. Direct drug analysis from oral fluid using medical swab touch spray mass spectrometry. *Analytica Chimica Acta*. 2015 Feb;861:47-54. DOI: 10.1016/j.aca.2015.01.008. <http://europepmc.org/article/PMC/4513665> According to Pirro et al (2015), 'Medical swabs are widely used in clinical microbiology, cytology, and DNA testing to sample body orifices and surfaces. Their design is specific to each application, with appropriate shape and materials being chosen for each type of application. Commonly, the swab tip is made of cotton, rayon, or polyester in brush, rounded, squared or fused shapes. The shaft can be made of plastic, wood, rolled paper or metallic wire.'

4.7.3. Product overview and list of illustrative examples

The table below provides illustrative examples on whether certain types of cotton bud sticks are included in or excluded from the scope of the Directive.

Table 4-15

Illustrative examples of different types of cotton bud sticks

Type of cotton bud stick	General criteria		Product-specific criteria			Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Non-durable stem	Non-cleanable buds	Not a medical device	
Plastic stemmed, double-tipped cotton bud stick	YES	YES	YES	YES	YES	INCLUDED
Non-plastic stemmed cotton bud stick	NO	YES	YES	YES	YES	EXCLUDED: Product does not contain plastic
Plastic stemmed, single-tipped specimen collection swab	YES	YES	YES	YES	NO	EXCLUDED: Product intended for medical use
Plastic, reusable ear cleaning stick	YES	NO	NO	NO	YES	EXCLUDED: Product intended for multiple use

4.8. Balloons and balloon sticks

4.8.1. Product description and criteria in the Directive

Balloons are addressed in Articles 8 and 10, whereas balloon sticks are subject to Article 5 of the Directive, but are not defined as such in the Directive.

Table below provides an overview of the relevant descriptions of balloons and balloon sticks in the Directive.

Table 4-16

Descriptions of balloons and balloon sticks in the Directive

Balloons:

- Point (2) of Section II of Part E and point (7) of Part G of the Annex: 'Balloons, except balloons for industrial or other professional uses and applications that are not distributed to consumers.'

Balloon sticks:

- Point (6) of Part B of the Annex: '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'.

The following general characteristics can be identified to determine the balloons in the scope of this Directive:

- Balloon typically refers to a non-porous bag of light material that is intended to be inflated with air or gas. When placed on the market, these items are primarily included within the following CPV code: Toy balloons and balls (37525000-4).
- Balloon stick: In accordance with point (6) of Part B of the Annex to the Directive sticks that are attached to and support balloons.

As indicated in Recital 11, latex does not qualify as a natural non-chemically modified polymer, and latex balloons are thus covered by the Directive, because the definition of plastics 'should (...) cover polymer-based rubber items'.

The following product design characteristics help define single-use balloons and balloon sticks for the purposes of the Directive:

- Seals, valves and closure mechanisms: The absence of a valve or a seal to enable multiple inflations and deflations. Balloons, which require the application of a knot, string or ribbon to the neck in order to prevent air from escaping, lose quality through unknotting and reknitting. They are therefore considered to be single-use. Balloons designed to be inflated and deflated via a (re)closable valve, with no loss of quality or functionality between uses, are considered to be multiple use.
- Refillable: Balloons purchased ready-filled with air or helium are considered to be single-use due to the inability of the customer to refill them. Self-filling balloons (with integral filling mechanism) are also considered to be single-use.

4.8.2. *Product-specific exemptions*

According to point (2) of Section II of Part E and point (7) of Part G of the Annex balloons for industrial or other professional uses and applications that are not distributed to consumers should be excluded from the relevant provisions of the Directive.

Similarly, point (6) of Part B of the Annex excludes from the scope of the Directive sticks to be attached to and to support balloons for industrial or other professional uses and applications that are not distributed to consumers, including the mechanisms of such sticks.

The point of purchase, distribution channel and type of end user are important elements to determine whether balloons are intended for domestic or professional use.

The following balloons should be considered to be for industrial or professional use:

- balloons and the sticks to be attached to support those balloons, which are sold through industrial or professional channels, e.g. business to business;
- balloons and the sticks to be attached to support those balloons for industrial or professional use or applications, e.g. research, weather balloons, industrial, professional decoration, and that are not distributed to consumers.

However, balloons and balloon sticks which are sold through business to consumers channels or distributed to private consumers, e.g. balloons and balloon sticks which can be purchased by individual consumers at a shop or are distributed to consumers at a private event, are not considered to be for professional or industrial use or application, but instead for domestic use. These products should therefore be included in the scope of the Directive. Also balloons and balloon sticks for which, at the time they are placed on the market, it is unclear if the intended use is industrial or domestic should be included in the scope of the Directive to avoid circumvention of the Directive.

4.8.3. Product overview and list of illustrative examples

The table below provides illustrative examples on whether certain types of balloons and balloon sticks are included in or excluded from the scope of the Directive.

Table 4-17

Illustrative examples of different balloons and balloon sticks

Types of balloons; balloon sticks	General criteria		Product-specific criteria	Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Intended for domestic use	
Single-use latex balloons for domestic use or application	YES	YES	YES	INCLUDED
Single-use mylar or foil balloons for domestic use or application	YES	YES	YES	INCLUDED
Single-use plastic balloon sticks for domestic use	YES	YES	YES	INCLUDED
Reusable, plastic inflatable toys and 'selfie-frames' including resealable valve	YES	NO	YES	EXCLUDED: Product intended multiple use
Reusable plastic balloon stands	YES	NO	NO	EXCLUDED: Product intended multiple use
Balloons for industrial uses and applications e.g. hot-air balloon, weather balloon.	YES	NO	NO	EXCLUDED: Product intended for professional or industrial use

4.9. Sanitary towels (pads), tampons, and tampon applicators

4.9.1. Product description and criteria in the Directive

The Directive does not provide for definitions for sanitary towels (pads), tampons and tampon applicators in the scope of the Directive. The following generic characteristics can be identified to determine sanitary towels (pads), tampons and tampon applicators in the scope of this Directive:

- Single-use sanitary towels are hygiene products used to absorb and retain fluid, generally intended to be disposed of after single use.
- Single-use sanitary towels are often composed of multiple material layers including an absorbent core, which is mainly made of cellulosic and synthetic fibres and absorb fluids. For the purposes of the Directive, sanitary towels refer not only to pads or napkins, but also panty liners as these products are a sub-category of sanitary towels (pads) ⁽²⁹⁾ and as such fulfil the criteria of a single-use plastic product. Both products are composed of similar materials and have the same tendency to become marine litter with regard to inappropriate disposal i.e. if flushed down toilets after use, and may enter the marine environment through the waste water treatment system.

⁽²⁹⁾ See EDANA at <https://www.edana.org/nw-related-industry/nonwovens-in-daily-life/absorbent-hygiene-products/feminine-care>, retrieved on 9 March 2021.

Single-use plastic tampons are generally composed of three layers including an absorbent core, which is made of either viscose, cotton, polyester, or a mixture of these fibres⁽³⁰⁾. They can be contained in a tampon applicator, usually composed of coated paper (containing a thin plastic sheet) or hard plastic. While some categories of tampons are made of cotton, many come with a plastic netting. The latter refers to a thin layer of non-woven or perforated plastic film used to help reduce fibre loss and facilitate the insertion and removal of tampons. Section 2.1 provides guidance to determine whether the fibre in question fulfils the criterion for the exception for natural polymers that have not been chemically modified.

Product design characteristics of sanitary towels, tampons and tampon applicators intended for single-use include those that are not washable or reusable multiple times because washing processes degrade the structure and function of those products.

4.9.2. Product overview and list of illustrative examples

The table below provides examples on whether certain types of sanitary towels, tampons and tampon applicators are included in or excluded from the scope of the Directive.

Table 4-18

Illustrative examples of different sanitary towels, tampons and tampon applicators

Type of sanitary towels, tampons and tampon applicators	General criteria		Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	
Sanitary towel, tampon and tampon applicator which contains plastic includes all categories of sanitary towels regardless of the shape, size, thicknesses and absorbency level containing plastics and intended to be disposed of after use	YES	YES	INCLUDED
Sanitary towels (including panty liners), or tampons which do not contain plastic	NO	YES	EXCLUDED: No plastic contained in the product
Reusable (washable) menstrual products such as washable cloth pads, reusable menstrual cup (alternative to tampon), period underwear (washable panty with integrated absorption pad)	NO/Washable pads that do not contain plastic YES/Reusable tampons, tampon applicators, and pads may contain plastic (e.g. clip for washable cloth pads)	NO	EXCLUDED: Products are not single-use

4.10. Wet wipes

4.10.1. Product description, criteria and exemptions in the Directive

Table 4-19 provides an overview of the relevant descriptions of single-use plastic wet wipes in the Directive.

⁽³⁰⁾ EDANA. (2019, December). Absorbent Hygiene Products components Pad/Liners. Retrieved from: <https://www.edana.org/nw-related-industry/nonwovens-in-daily-life/absorbent-hygiene-products/feminine-care>

Table 4-19

Descriptions of wet wipes in the Directive

Point (2) of Part D, point (1) of Section II of Part E and point (6) of Part G of the Annex: 'Wet wipes, i.e. pre-wetted personal care and domestic wipes'.

Recital 12: 'Wet wipes for personal care and domestic use should also be within the scope of this Directive, whereas industrial wet wipes should be excluded.'

Wet wipes, which are made using non-natural polymers or natural polymers that have been chemically modified, like polyester and polyhydroxyalkanoates (PHA), fall within the scope of the Directive. Wet wipes, which are entirely made of natural polymers that have not been chemically modified, like viscose and lyocell, fall outside the scope of the Directive.

The following main product specific criteria are provided by the Directive to determine whether a single-use wet wipe is included in its scope: pre-wetted and personal and domestic wipes.

In light of the above, a wet wipe in the context of the Directive can be understood as a small piece of pre-moistened or pre-wetted material containing plastic and which is conceived, designed and placed on the market for single-use (disposable) and intended for personal care e.g. personal hygiene or domestic use e.g. household cleaning purposes. Pre-wetted wipes typically contain an impregnation liquid which has been added to the wipe before it is placed on the market.

A personal care wet wipe is intended to be used for hygiene purposes. These include cleansing and caring of skin of both human adults and babies e.g. baby wipes, cosmetic/make-up removal wipes, intimate care wipes, etc.

A domestic use wet wipe is intended to be used in domestic premises. These include wet wipes used for household cleaning purposes e.g. wipes used to clean kitchen and bathroom surfaces, wet wipes used to clean personal vehicles, spectacle cleaning wipes, etc.

Furthermore, these products are typically sold on the market in packs containing several single-use wet wipes.

While not explicitly mentioned in the Directive, wet wipes, which are conceived, designed and placed on the market for professional use, such as medical or healthcare wipes would not meet the criterion for personal care or domestic use. These products are therefore not considered to fall within the scope of the Directive.

The point of purchase, distribution channel and type of end user are important elements that should be considered in order to determine whether certain wet wipes are intended for domestic or professional use. For instance, wet wipes sold through professional distribution channels e.g. business-to-business channels, and which are used by healthcare professionals are considered to be intended for professional use and would not be included in the scope of the Directive. However, wet wipes which are sold in business-to-consumer channels and distributed to non-professional consumers, e.g. wet wipes, which can be purchased by individual consumers at a pharmacy and used at home, are not considered as professional use. These products are therefore included in the scope of the Directive.

The following table provides a non-exhaustive list of the wet wipe categories included in or excluded from the scope of the Directive ⁽³¹⁾:

Table 4-20

Examples of wet wipe categories

Product category: wet wipes	
Covered by the Directive	Personal care
	<ul style="list-style-type: none"> — Baby wipes — Cleansing wipes for skin (including hands and body) — Disinfection wipes for hands, including if provided to consumers in aircrafts, airports, trains or other venues — Facial/cosmetic wipes (e.g. facial masks or 'sheet masks', face cleaning/make-up removal wipes) — Intimate care wipes — Toilet tissue wipe
Covered by the Directive	Domestic use wet wipes
	<ul style="list-style-type: none"> — Household cleaning wipes used to remove stains and clean surfaces such as floors, bathrooms, kitchens, furniture, windows, TV and computer screens, etc. — Disinfection wipes intended for domestic use, including if provided to consumers in aircrafts, airports, trains or other venues — Spectacle (eye glasses) cleaning wipes — Car wipes intended for domestic use — Pet wipes intended for domestic use
Excluded from the Directive	Industrial wet wipes
	<ul style="list-style-type: none"> — Automotive wipes (surface preparation, polishing, oil and chemical absorbents) intended for industrial or professional use — Electronic and computer industry wipes (dust removal, delicate and intricate cleaning wipes) intended for industrial or professional use — Food industry wipes (machine cleaning, maintenance, fluid absorbent, hand cleaning wipes) intended for industrial or professional use — Janitorial wipes (polishing, equipment cleaning and maintenance, wet floor cleaning, dust removal) intended for industrial or professional use — Manufacturing, engineering and maintenance wipes (machine cleaning, maintenance, fluid absorbent, hand cleaning wipes) intended for industrial or other professional use — Optical industry wipes (polishing, dust removal wipes) intended for industrial or professional use — Printing industry wipes (machine cleaning, maintenance, fluid absorbent, hand cleaning wipes) intended for industrial or professional use — Transportation industry wipes (vehicle cleaning and maintenance, window cleaning wipes) intended for industrial or professional use

⁽³¹⁾ EDANA, (n.d). Industrial wipes. Retrieved from: www.edana.org/nw-related-industry/nonwovens-in-daily-life/wipes/industrial-wipes

 Product category: wet wipes

	Professional use
	<ul style="list-style-type: none"> — Medical/healthcare wipes such as hospital grade disinfectant wipes to clean and disinfect surfaces and intended for industrial or professional use — Medical/healthcare wipes such as patient care wipes for human hygiene purposes and intended for industrial or professional use

Wet wipes for which it is unclear if the intended use is industrial or professional or domestic are included in the scope of the Directive to avoid circumvention of the Directive.

4.10.2. *Product overview and list of illustrative examples*

Table 4-21 provides guidance on how to interpret the general and product-specific criteria for wet wipes, along with examples on whether certain types of wet wipes are included in or excluded from the scope of the Directive.

Table 4-21

Examples of different types of wet wipes

Type of wet wipes	General criteria		Product-specific criteria		Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Pre-wetted	Personal care or domestic use	
Wet wipe which contains plastic	YES	YES	YES	YES	INCLUDED
Wet wipe which is made of viscose or lyocell (regenerated cellulose) and does not contain polyester or other plastics	NO	YES	YES	YES	EXCLUDED: Product is not wholly or partly made of plastic
Pre-wetted wipe (e.g. which can be indicated on product packaging as follows: 'pre-moistened towelettes' or 'pre-wetted')	YES	YES	YES	YES	INCLUDED
Dry wipe (e.g. not pre-wetted before placed on the market; can also be indicated on product packaging as follows: 'skin cleansing dry wipes')	YES	YES	NO	YES	EXCLUDED: Product is not 'pre-wetted'
Personal care wet wipe (e.g. which can be indicated on product packaging as follows: 'makeup-removal wet wipes' or 'Baby wipes')	YES	YES	YES	YES	INCLUDED
Domestic use wet wipe (e.g. which can be indicated on product packaging as follows: 'Multipurpose household cleaning wipe')	YES	YES	YES	YES	INCLUDED
Industrial wet wipe (e.g. wet wipes used in industry for cleaning machines)	YES	YES	YES	NO	EXCLUDED: Product is considered to be an industrial wet wipe
Professional use wet wipe (e.g. medical/healthcare wipes sold through professional business-to-business distribution channels and intended for use by healthcare professionals)	YES	YES	YES	NO	EXCLUDED: Product is not intended for domestic use

4.11. Tobacco products with filters, filters marketed for use in combination with tobacco products

4.11.1. Product description and criteria in the Directive

The table below provides an overview of the relevant descriptions that relate to tobacco products with filters, and filters for use in combination with tobacco products, according to the Directive.

Table 4-22

Descriptions of tobacco products with filters, and filters, in the Directive

Point (18) of Article 3 refers to tobacco products as defined in point (4) of Article 2 of Directive 2014/40/EU of the European Parliament and of the Council ⁽¹⁾.

Point (3) of Part D, Section III of Part E and point (5) of Part G of the Annex describe tobacco products as ‘Tobacco products with filters and filters marketed for use in combination with tobacco products’.

Point (4) of Article 2 of Directive 2014/40/EU, defines ‘tobacco products’ as follows:

‘ “tobacco products” means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not’.

⁽¹⁾ 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).

Tobacco products with filters or filters marketed for use in combination with tobacco products containing cellulose acetate are deemed to constitute a chemically modified natural polymer and, provided they fulfil the other relevant conditions for those products, they therefore fall within the scope of the Directive.

The main product specific criteria to determine whether a tobacco product with filter, or a filter marketed for use in combination with a tobacco product falls within the product scope of the Directive, are:

- Product is a tobacco product (as defined in point (4) of Article 2 of Directive 2014/40/EU) and product contains a filter: e.g. a cigarette or cigar;
- Product is a separate filter for use with tobacco products: e.g. a filter tip or mini filter.

4.11.2. Product overview and list of illustrative examples

Illustrative examples on whether certain types of tobacco products with a filter, or filters marketed for use with tobacco products, are included in or excluded from the scope of the Directive are provided in **Table 4-23**.

Table 4-23

Examples of different types of tobacco products with filters and filters marketed for use in combination with tobacco products

Type of tobacco product or filter	General criteria		Product-specific criteria	Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Tobacco product with filter or filter marketed for use in combination with tobacco products	
Cigarette or cigar with filter containing plastic	YES	YES	YES	Included

Type of tobacco product or filter	General criteria		Product-specific criteria	Included in or excluded from the scope of the directive (fulfilment of all general and product-specific criteria?)
	Plastic	Single-use	Tobacco product with filter or filter marketed for use in combination with tobacco products	
Separate single-use filters containing plastic	YES	YES	YES	Included
Electronic cigarette or vape products, including plastic or non-plastic filters	YES	NO	NO	EXCLUDED: Product is intended for multiple use; product does not contain tobacco
Electronic device to be used with heated tobacco product including single-use filter containing plastic	YES	YES (the filter)	YES	Included: While the electronic device is intended for multiple use, the tobacco and the filters are single-use
Loose tobacco e.g. for use in a pipe or hand-rolled cigarette without filter containing plastic	NO	YES	NO	EXCLUDED: Product is not made wholly or partly of plastic; product does not contain a filter

ANNEX

OVERVIEW OF THE SINGLE-USE PLASTIC PRODUCTS, THEIR DESCRIPTIONS AND RELEVANT REQUIREMENTS LAID OUT IN THE DIRECTIVE

Single-use plastic products	Relevant Part of the Annex and the applicable substantive requirements, except reporting obligations		Most relevant Part of the Annex to the Directive containing product descriptions
Balloons	Part E	Extended producer responsibility (Article 8(3))	Part E Section II point (2)
	Part G	Awareness raising (Article 10)	
Balloon sticks	Part B	Restrictions on placing on the market (Article 5)	Part B point (6)
Beverage bottles ≤ 3L, including their caps and lids	Part C	Product requirements (Article 6(5))	Parts C and F
	Part F	Separate collection (Article 9)	
Beverage containers ≤ 3L, incl. their caps and lids	Part C	Product requirements (Article 6(1) to (4))	Part C
	Part E	Extended producer responsibility (Article 8(2))	Part E Section I point (3)
	Part G	Awareness raising (Article 10)	Part G point (3)
Beverage containers made of expanded polystyrene, including their caps and lids	Part B	Restrictions on placing on the market (Article 5)	No product-specific descriptions provided
Beverage stirrers	Part B	Restrictions on placing on the market (Article 5)	No product-specific descriptions provided
Cups for beverages	Part D	Marking requirements (Article 7)	No product-specific descriptions provided
Cups for beverages, including their covers and lids	Part A	Consumption reduction (Article 4)	
	Part G	Awareness raising (Article 10)	
Cups for beverages made of expanded polystyrene, incl. their covers and lids	Part E	Extended producer responsibility (Article 8(2))	No product-specific descriptions provided
	Part B	Restrictions on placing on the market (Article 5)	
Cotton bud sticks	Part B	Restrictions on placing on the market (Article 5)	No product-specific descriptions provided

Single-use plastic products	Relevant Part of the Annex and the applicable substantive requirements, except reporting obligations		Most relevant Part of the Annex to the Directive containing product descriptions
Cutlery (forks, knives, spoons, chopsticks)	Part B	Restrictions on placing on the market (Article 5)	No product-specific descriptions provided
Food containers	Part A	Consumption reduction (Article 4)	Part A point (2)
	Part E	Extended producer responsibility (Article 8(2))	Part E Section I point (1)
	Part G	Awareness raising (Article 10)	Part G point (1)
Food containers made of expanded polystyrene	Part B	Restrictions on placing on the market (Article 5)	Part B point (7)
Lightweight plastic carrier bags	Part E	Extended producer responsibility (Article 8(2))	Article 3(1c) of Directive 94/62/EC
	Part G	Awareness raising (Article 10)	
Packets and wrappers	Part E	Extended producer responsibility (Article 8(2))	Part E Section I point (2)
	Part G	Awareness raising (Article 10)	Part G point (2)
Plates	Part B	Restrictions on placing on the market (Article 5)	No product-specific descriptions provided
Sanitary towels (pads), tampons and tampon applicators	Part D	Marking requirements (Article 7)	No product-specific descriptions provided
	Part G	Awareness raising (Article 10)	
Straws	Part B	Restrictions on placing on the market (Article 5)	No product-specific descriptions provided
Tobacco products with filters and filters marketed for use in combination with tobacco products	Part D	Marking requirements (Article 7)	Article 2(4) of Directive 2014/40/EU
	Part E	Extended producer responsibility (Article 8(3))	
	Part G	Awareness raising (Article 10)	
Wet wipes	Part D	Marking requirements (Article 7)	Part D point (2)
	Part E	Extended producer responsibility (Article 8(3))	Part E Section II point (1)
	Part G	Awareness raising (Article 10)	Part G point (6)

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