

HANDBOOK *on* *the* PREVENTION MEASURES

***Referred to in Regulation 2025/40
on Packaging and Packaging
Waste***

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Research Centre for the Circular Economy – CONAI

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Letter from the President CONAI

In a Europe that is accelerating its transition towards an increasingly circular economy, packaging design is a strategic opportunity to reduce environmental impacts from the earliest stages of a product's life cycle.

The European Regulation 2025/40 on packaging and packaging waste marks a profound and structural change. With the introduction of harmonised and binding design requirements and criteria, it aims to make all packaging on the European market more sustainable, recyclable and reusable, as well as designed to avoid material waste by complying with rules valid throughout Europe for its management and end-of-life, thus giving substance to the single European market for packaging and the recycled materials derived from it.

This is an ambitious intervention that directly affects the way packaging is designed and placed on the market.

In this scenario, companies are required to adapt within defined timeframes and with specific requirements. Many of these relate to design: from minimising weight and volume to compatibility with recycling and the use of recycled materials.

This Handbook is the result of discussions with associations of packaging manufacturers and users and the national manufacturing sector, which actively participated in the consultation phase for professionals and which has made it possible to produce a document that provides concrete support in understanding the provisions of the Regulation relating to packaging design, focusing on the preventive measures and design criteria required to ensure compliance.

The Handbook is an operational tool, which can be updated over time with FAQs and examples, capable of accompanying companies through the adaptation phase, taking into account the complexity of the framework and the numerous deadlines involved. Particular attention is paid to small and medium-sized enterprises, which constitute the productive fabric of our country and need practical guidance and applicable solutions.

After all, proper design is the main lever for preventing waste production and reducing the environmental impact of packaging: it is estimated that up to 80% of the environmental impact of packaging is determined at the design stage. Investing in this phase means acting with foresight, avoiding the risk of non-compliance and transforming regulatory obligations into opportunities for innovation. We are increasingly convinced of this.

CONAI will continue to provide technical tools, assistance and constantly updated guidelines to support companies on their path to innovation for circularity.

Ignazio Capuano
CONAI President

Foreword – Guide to reading this document

This Handbook aims to provide a **practical and easy-to-use guide** for businesses on the new **Regulation 2025/40 on packaging and packaging waste** (Packaging and Packaging Waste Regulation – PPWR), recently adopted at European level.

The document is dedicated exclusively to aspects related to the prevention of the environmental impact of packaging and packaging waste, with a specific focus on the **design criteria** introduced by the new Regulation. Businesses and trade associations will find useful information on **how to bring packaging design into line** with the new European requirements. The Handbook **does not address other areas of the regulatory text**, such as the obligations relating to Extended Producer Responsibility (EPR).

To facilitate reading of the document, it is recommended that reference be made, where necessary, to the definitions given in [Chapter 5](#).

It should also be noted that the content of the Handbook faithfully reflects the text of Regulation 2025/40, without providing any regulatory interpretation, in order to offer companies a **neutral, objective information tool that is aligned with the official text**.

Many aspects of Regulation 2025/40 are in fact delegated to secondary legislation, therefore, the Handbook may be **subject to periodic changes** and updates based on the evolution of the regulatory framework and **political decisions** at European level.

This document opens with a general introduction aimed at contextualising the new regulatory framework, clarifying the reasons that

led to the adoption of a binding legal instrument such as the Regulation, as well as the **general objectives** pursued by the European Commission in the field of sustainability, the circular economy and reducing environmental impact.

The Handbook then goes on to discuss the **main sustainability requirements** for businesses, with particular reference to **packaging design criteria**.

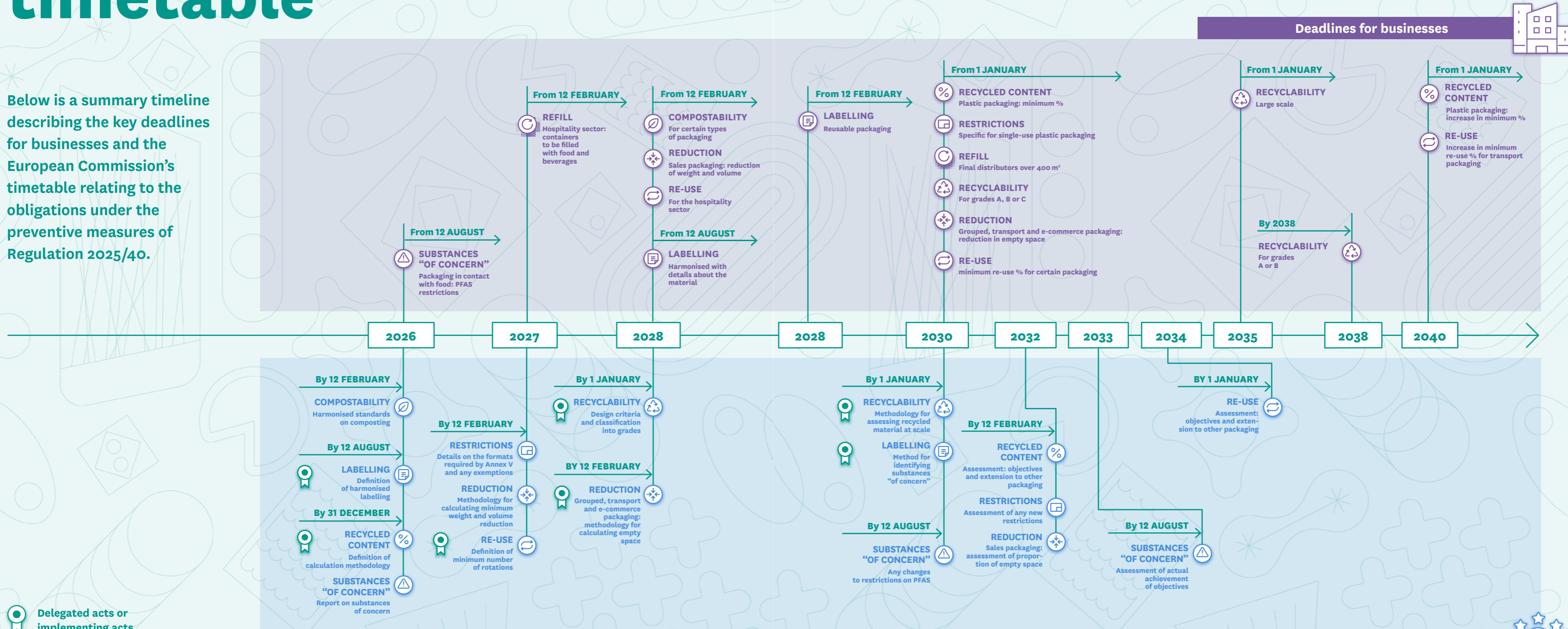
The document is structured in such a way as to facilitate consultation by businesses and provide a clear and systematic overview of the new packaging design requirements set out in the Regulation, through:

- › an orderly reconstruction of the main **deadlines** for economic operators;
- › a summary of the **timetable** for the adoption of delegated and implementing acts by the **European Commission**;
- › **boxes with further reading** on specific issues of interest to businesses;
- › a final **FAQ** section, with answers based on the most frequently asked questions received. All answers are **updated as of 30 September 2025**; any subsequent additions and/or changes will be made available with an indication of the new publication date.

As already mentioned, CONAI intends to use this tool to offer concrete support to companies in the process of adapting to the new regulatory framework, so that they can be better prepared to face the challenges associated with packaging design and make choices that are consistent with the objectives set at European level and in line with the **priorities outlined in European legislation**.

Key deadlines for businesses and European Commission timetable

Below is a summary timeline describing the key deadlines for businesses and the European Commission's timetable relating to the obligations under the preventive measures of Regulation 2025/40.



Delegated acts or implementing acts



1 Regulatory framework

1.1 From Directive to Regulation

Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904 and repealing Directive 94/62/EC (hereafter **Regulation 2025/40**) was adopted with the aim of replacing the current fragmented regulatory framework of individual national packaging laws with a uniform regulatory framework directly applicable to Member States without the need for transposition into national law. This explains why the European legislator opted for a Regulation rather than a Directive ¹.

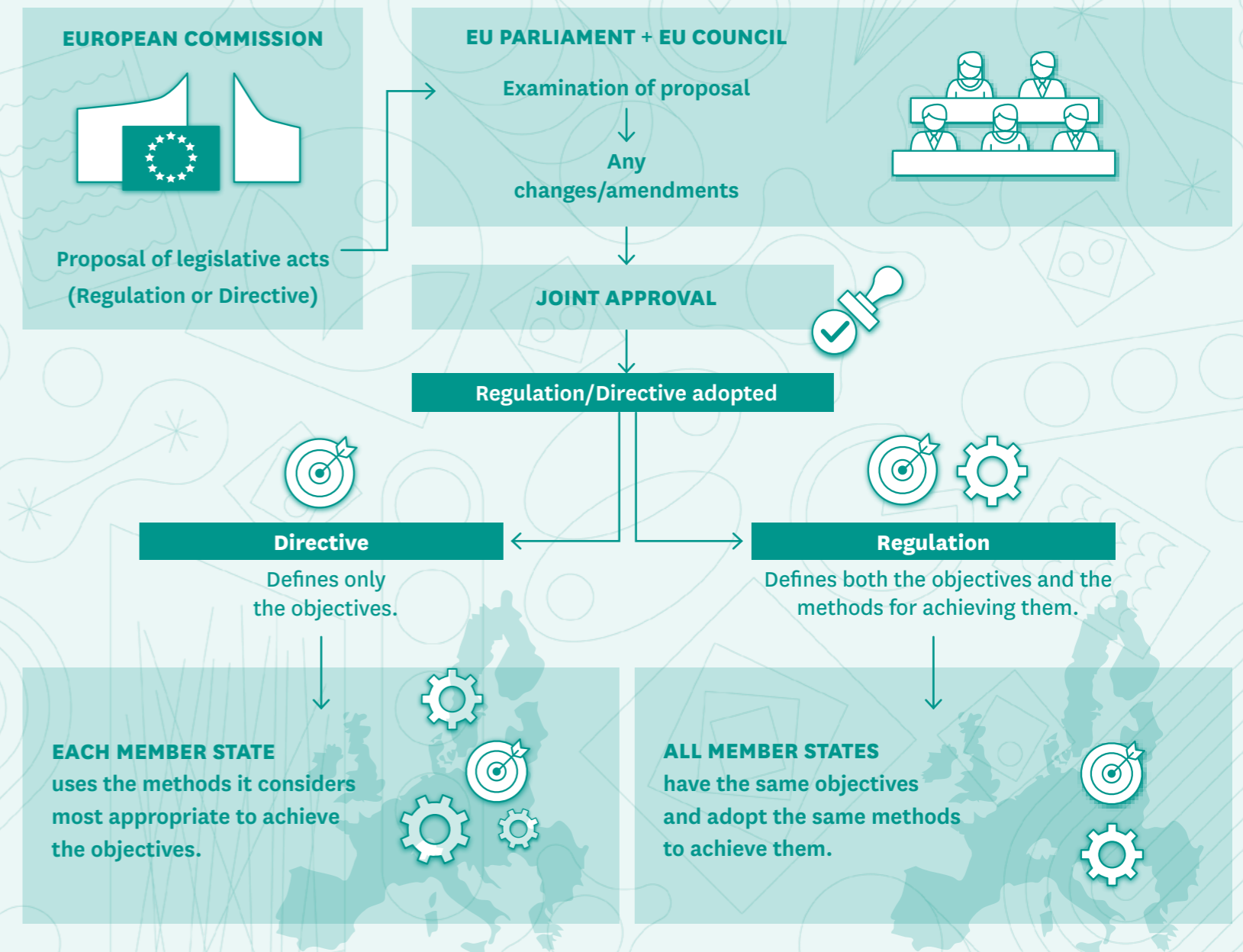
Regulation 2025/40:

- › provides for measures concerning the entire life cycle of packaging that contribute to the efficient functioning of the internal market;
- › harmonises national regulations, considering the reduction of the environmental impact of packaging and packaging waste on the environment and human health.

Regulation 2025/40 therefore repeals Directive 94/62/EC which set, for example, prescriptions on the essential requirements relating to the composition of packaging, its reusability and recyclability, establishing recovery and recycling targets. Furthermore, following the adoption of the new Regulation 2025/40, amendments have been made to Regulation (EU) 2019/1020 of 20 June 2019 on market surveillance and product compliance and Directive (EU) 2019/904 of 5 June 2019 on the reduction of the impact of certain plastic products on the environment (SUP).

¹

Regulations are directly applicable in the legal system of the individual Member States, whereas Directives set objectives that individual Member States must achieve using the means they deem most appropriate.



The primary objective of Regulation 2025/40 is to ensure a high level of environmental protection through:

- › reducing the release of certain packaging onto the market;
- › reducing the production of packaging waste.

The regulatory provisions introduced in Regulation 2025/40 contribute to the transition to a circular economy in line with the objectives of the European Green Deal and the Circular Economy Action Plan (CEAP).

In particular, the European Parliament resolution of February 10, 2021, on the new Circular Economy Action Plan, called on the EU Commission to adopt a legislative proposal establishing appropriate instruments to:

- › make all packaging reusable or recyclable in an economically sustainable manner by 2030;
- › reduce excessive packaging, including in e-commerce;
- › increase the recycled content of packaging;
- › phase out hazardous and harmful substances in packaging;
- › promote the re-use of packaging.

To achieve these objectives, Regulation 2025/40 establishes a series of measures for prevention at source, reduction of primary resource use and recycling, which will be analysed in this document.

MAIN OBJECTIVES OF THE NEW REGULATION 2025/40

Prevention	Reduction	Recycling								
<ul style="list-style-type: none"> › Prevent the generation of packaging waste and reduce its quantity <table border="1"> <thead> <tr> <th>Year</th> <th>% Reduction in packaging waste per capita vs 2018</th> </tr> </thead> <tbody> <tr> <td>2030</td> <td>5%</td> </tr> <tr> <td>2035</td> <td>10%</td> </tr> <tr> <td>2040</td> <td>15%</td> </tr> </tbody> </table> <ul style="list-style-type: none"> › Apply restrictions to particular types/formats of packaging › Promote reusable and refillable packaging solutions 	Year	% Reduction in packaging waste per capita vs 2018	2030	5%	2035	10%	2040	15%	<ul style="list-style-type: none"> › Minimisation of packaging › Minimum targets for recycled material in plastic packaging › Recycled materials market 	<ul style="list-style-type: none"> › Promote high-quality recycling, making all packaging on the EU market recyclable in an economically sustainable manner by 2030.
Year	% Reduction in packaging waste per capita vs 2018									
2030	5%									
2035	10%									
2040	15%									



1.2 Scope of application of the Regulation

Regulation 2025/40 applies:

- › to all packaging ², regardless of the material used and the context in which it is used.
- › to all packaging waste, regardless of the context from which it originates: industry, other manufacturing activities, retail or distribution, offices, services or households.
- › all Member States of the European Union.



Regulation 2025/40 is without prejudice to the provisions, for example, of [Directive 2008/98/EC](#) on the management of hazardous waste, as well as Union regulatory requirements relating to the safety, quality, health protection and hygiene of packaged products and transport requirements. However, if Regulation 2025/40 conflicts with [Directive 2008/68/EC](#) on the inland transport of dangerous goods, [Directive 2008/68/EC](#) shall prevail.

[Directive \(EU\) 2019/904](#) requires Member States to take measures to reduce the consumption of certain single-use plastic products, including market restrictions; such market restrictions should apply and prevail over any conflicting provisions of Regulation 2025/40.

Therefore, in the event of a conflict between [Directive \(EU\) 2019/904](#) and Regulation 2025/40, [Directive \(EU\) 2019/904](#) should prevail as far as its scope is concerned. It should be noted that Regulation 2025/40 provides for a restriction on the placing on the market of plastic products listed in [Annex V, point \(3\)](#), while [Directive \(EU\) 2019/904](#) allows Member States to take the necessary measures to

² Some provisions of Regulation 2025/40 provide for exemptions for packaging of specific products.

achieve a reduction in the consumption of these single-use plastic products. Since national implementing measures under [Directive \(EU\) 2019/904](#) can be less restrictive than a ban on placing on the market, [Regulation 2025/40](#) should take precedence over [Directive \(EU\) 2019/904](#) with regard to products falling under the definition of packaging, in order to reduce the placing on the market of single-use plastic packaging and its dispersion in the environment. As a consequence, it should not be possible for Member States to adopt an exemption from the ban in [Directive \(EU\) 2019/904](#) on placing packaging made of expanded polystyrene on the market. To this end, [Directive \(EU\) 2019/904](#) has been amended accordingly.³



Click here to consult the Implementation Guidelines for the SUP Directive.

RELATIONSHIP BETWEEN REGULATION 2025/40 AND THE SUP DIRECTIVE (SINGLE USE PLASTIC DIRECTIVE)

As the SUP Directive is special legislation, it should take precedence over [Regulation 2025/40](#) with regard to its scope of application.

However, it should be noted that the marketing ban established by Article 25 of [Regulation 2025/40](#) for the specific types of goods listed in [Annex V](#) prevails over any national derogations provided for in relation to the ban referred to in Article 5 of the SUP Directive (transposed in Italy by Article 5 of [Legislative Decree 196 of 8 November 2021](#)).

An example of a measure in the SUP Directive that prevails over [Regulation 2025/40](#) is the provision in Article 5 on restrictions on placement on the market, transposed in Italy by Article 5 of [Legislative Decree 196 of 8 November 2021](#)).

Specifically, the measure provides for a general ban on placing on the market (without prejudice to the derogation referred to in Article 5, paragraph 3, of [Legislative Decree 196 of 8 November 2021](#)) for a list of single-use plastic goods, including certain packaging such as, for example, food containers made of expanded polystyrene, i.e. receptacles such as boxes, with or without a cover, used to contain food which:

- a. is intended for immediate consumption, either on-the-spot or take-away;
- b. is typically consumed from the receptacle; and
- c. is ready to be consumed without any further preparation, such as cooking, boiling or heating, including food containers used for fast food or other meal ready for immediate consumption, except beverage containers, plates and packets, and wrappers containing food.

Such packaging, while meeting all the sustainability requirements of [Regulation 2025/40](#), cannot be marketed in any case, as it is subject to a specific ban under the SUP Directive.

The Directive also sets out certain specific requirements in addition to those laid down in [Regulation 2025/40](#) for certain categories of packaging, the main ones being the marking requirements laid down in Article 7, which also apply to beverage cups, and the requirement that caps remain attached to containers, which applies to bottles and composite beverage packaging.

It should also be noted that some details relating to specific objectives and measures provided for in [Regulation 2025/40](#) are referred to the definition of implementing decrees and acts to be adopted by the European Commission by certain dates indicated in the text of the individual criteria (see the [timeline “Key deadlines for businesses and European Commission timetable”](#) on pages 10 and 11).

1.3 Placement on the market

Within Member States, packaging shall only be placed on the market if it complies with [Regulation 2025/40](#), after it can be considered applicable, i.e. from 12 August 2026. Placement on the market is considered to have taken place when the packaging, whether empty or containing a product, has been made available on the Union market for the first time, being supplied by the manufacturer or importer for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge. Thus, packaging already placed on the Union market before the date of application of relevant requirements and in the

³

Article 67 of [Regulation 2025/40](#).

stocks of distributors, including retailers and wholesalers, should not need to comply with the requirements laid down in Regulation 2025/40⁴.



“Placing on the market” means the first making available of packaging, whether empty or with a product, on the Union market. In this regard, Recital 14 of Regulation 2025/40 specifies that: *“Packaging should be considered to have been placed on the market when the packaging is made available for the first time on the Union market, which means supplied by the manufacturer or importer for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge”*.



“Making available on the market” means any supply of packaging, whether empty or with a product, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.



“Making available on the territory of the Member State” means any supply of packaging, whether empty or with a product, for distribution, consumption or use on the territory of the Member State in the course of a commercial activity, whether in return for payment or free of charge.

⁴

Please refer to Recital 14 of Regulation 2025/40, which states that “Packaging should be placed on the market only if it complies with the sustainability requirements and labelling requirements laid down in or pursuant to this Regulation. Packaging should be considered to have been placed on the market when the packaging is made available for the first time on the Union market, which means supplied by the manufacturer or importer for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge. Thus, packaging already placed on the Union market before the date of application of relevant requirements and in the stocks of distributors, including retailers and wholesalers, should not need to meet the sustainability and labelling requirements laid down in or pursuant to this Regulation”.

2 Sustainability measures: prevention measures and criteria for packaging design

Below are the sustainability criteria set out in Articles 5 to 11 of Regulation 2025/40, which refer to packaging design⁵, and the obligations regarding packaging refilling incumbent on specific economic operators.

As mentioned in the foreword, it should be noted that these criteria refer to the adoption of delegated and implementing acts to be adopted by the European Commission within the deadlines set by each criterion, which will detail the individual requirements.

⁵

Other requirements concerning the labelling of packaging and restrictions on the use of certain packaging formats are addressed in Chapter 3, “Other obligations”.

2.1 Requirements for substances in packaging

The text of this section refers to the content of Article 5 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulatory reference

Article 5.

Deadlines for businesses



From 12 August

- ⚠ Packaging in contact with food may not be placed on the market if it contains PFAS above the following limits:
 - > 25 ppb for each individual PFAS (targeted analysis, polymeric PFAS are excluded);
 - > 250 ppb for the sum of all PFAS (targeted analysis, other methodologies possible; polymeric PFAS are excluded);
 - > 50 ppm for PFAS (including polymeric PFAS); if the total fluorine content exceeds 50 mg/kg, additional evidence must be provided upon request.

2026

2030

2033

By 31 December

⚠ The European Commission, assisted by the European Chemicals Agency (ECHA), will submit a report to the European Parliament and the Council on the presence of substances of concern in packaging and on possible further measures.

By 12 August

⚠ The European Commission will assess the need to amend or repeal existing restrictions on PFAS to avoid overlap with further regulations.

By 12 August

⚠ The European Commission will assess whether the objective has been effectively achieved.

Timetable for the European Commission



Design requirement



SUBSTANCES "OF CONCERN"
Requirements for substances in packaging

2.1.1 Objective

To minimise substances of concern throughout the entire life cycle of packaging, from manufacture to use and end of life, including waste management.

2.1.2 Scope

All packaging placed on the EU market.

2.1.3 Deadlines and timeframes

From 12 August 2026.

2.1.4 Content of the measure

Packaging placed on the market shall be manufactured in such a way as to minimise the presence and concentration of substances of concern in the constituents of the packaging material or any of the packaging components, including their presence in emissions and any result of waste management, such as secondary raw materials, ash or other materials destined for final disposal, and the negative impact on the environment due to microplastics.

Regulation 2025/40 sets specific limits for the sum of the concentrations of lead, cadmium, mercury and hexavalent chromium in packaging or packaging components and for PFAS (per- and polyfluoroalkyl substances) contained in packaging in contact with food products. More specifically, paragraph 4 of Article 5 of Regulation 2025/40 provides that, without prejudice to the restrictions on chemicals set out in Annex XVII to Regulation (EC) 1907/2006 or, where applicable, the restrictions and specific measures on food-contact materials and articles in Regulation (EC) 1935/2004, the sum of the concentrations of lead, cadmium, mercury and hexavalent chromium resulting from substances present in packaging or packaging components shall not exceed 100 mg/kg. ⁶

Furthermore, pursuant to the provisions of paragraph 5 of Regulation 2025/40, as of 12 August 2026, packaging in contact with food products may not be placed on the market if it contains PFAS in a concentration equal to or greater than the limit values set out below (all three conditions a, b and c must be met):

- a. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFAS excluded from quantification);
- b. 250 ppb for the sum of PFAS measured as the sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFAS excluded from quantification); and
- c. 50 ppm for PFAS (including polymeric PFAS); if total fluorine exceeds 50 mg/kg the manufacturer, importer or downstream user as defined respectively in Article 3, points (9), (11) and (13) of Regulation (EC) 1907/2006 shall, upon request, provide to the manufacturer or the importer as defined respectively in Article 3, paragraph 1, points (1), (13) and (17) of Regulation 2025/40, proof of the quantity of fluorine measured as content of either PFAS or non-PFAS in order for them to draw up the technical documentation as referred to in Annex VII to Regulation 2025/40.

That said, further limits may be introduced following the publication of the report issued by the EU Commission on the presence of substances of concern in packaging and packaging components. This is without prejudice to the restrictions on chemicals set out in Annex XVII to Regulation (EC) 1907/2006 or, where applicable, to the restrictions and specific measures on food-contact materials and articles in Regulation (EC) 1935/2004.

2.1.5 Exemptions from the measure

No exemptions are provided for. ⁷

⁶

Article 226 of Legislative Decree 152/2006 paragraph 4 states that: “it is prohibited to place on the market packaging or packaging components, with the exception of packaging made entirely of crystal, with total concentrations of lead, mercury, cadmium and hexavalent chromium exceeding 100 parts per million (ppm) by weight. Decision 2001/171/EC applies to glass packaging and Decision 1999/177/EC applies to plastic packaging.”

⁷

For glass packaging, the derogation set out in Decision 2001/171/EC remains in force; for plastic crates and pallets, those set out in Decision 2009/292/EC remain in force until and unless they are repealed by specific delegated acts of the Commission as per Article 70 paragraph 3 of Regulation 2025/40.

2.1.6 Means of verification – EU declaration of conformity



Compliance with the requirements relating to substances contained in packaging (Article 5 paragraphs 4 and 5 of Regulation 2025/40) shall be demonstrated in the documentation drawn up in accordance with Annex VII of Regulation 2025/40 (see Chapter 4.1 on the conformity assessment procedure).



NOTE

- › By 31 December 2026, the Commission, assisted by the European Chemicals Agency (ECHA), shall prepare a report on the presence of substances of concern in packaging and packaging components, to determine the extent to which they negatively affect the re-use and recycling of materials or impact chemical safety. That report may list the substances of concern present in packaging and packaging components and indicate the extent to which they could present an unacceptable risk to human health and the environment.
- › From 12 August 2026, food-contact packaging may not be placed on the market if it contains per- and polyfluoroalkyl substances (PFAS) in a concentration equal to or above the following limit values (provided that such a concentration is not prohibited pursuant to another EU legal act) set out in Regulation 2025/40. For the purposes of Regulation 2025/40, “PFAS” means any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it), except substances that only contain the following structural elements: CF₃-X or X-CF₂-X', where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R''' ; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-).
- › By 12 August 2030, the Commission shall carry out an evaluation to assess the need to amend or repeal the indicated limit values in order to avoid overlaps with restrictions or

prohibitions on the use of PFAS laid down in accordance with Regulation (EC) 1907/2006 ⁸, Regulation (EU) 2019/1021 ⁹ or Regulation (EC) 1935/2004 ¹⁰.

2.1.7 Summary table



Requirements for substances in packaging

Regulatory reference

Article 5.

Obligated party

Manufacturers or importers.

Deadline (by when)

From 12 August 2026.

Obligation

The sum of the concentration levels of lead, cadmium, mercury and hexavalent chromium in substances present in packaging or packaging components may not exceed 100 mg/kg.

Packaging in contact with food may not be placed on the market if it contains PFAS above the following limits:

- › 25 ppb for each individual PFAS (targeted analysis, polymeric PFAS are excluded);
- › 250 ppb for the sum of all PFAS (targeted analysis, other methodologies possible; polymeric PFAS are excluded);
- › 50 ppm for PFAS (including polymeric PFAS); if the total fluorine content exceeds 50 mg/kg, additional evidence must be provided upon request.

This is without prejudice to the restrictions on chemicals set out in Annex XVII to Regulation (EC) 1907/2006 or, where applicable, to the restrictions and specific measures on food-contact materials and articles in Regulation (EC) 1935/2004.

8

Regulation (EC) 1907/2006 of the European Parliament and of the Council 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) 793/93 and Commission Regulation (EC) 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.

9

Regulation (EU) 2019/1021 of the European Parliament and of the Council on persistent organic pollutants.

10

Regulation (EC) 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.



Criterion

By 31 December 2026, the Commission, assisted by the ECHA, shall prepare a report on the presence of substances of concern in packaging and packaging components, to determine the extent to which they negatively affect the re-use and recycling of materials or impact chemical safety.

Means of verification

The manufacturer or importer shall demonstrate compliance with the requirements relating to substances of concern (or “hazardous”) in the technical information and declaration of conformity referred to in [Annexes VII and VIII](#) to Regulation 2025/40.

Exemptions

No exemptions are provided for.

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

2.1.8**FAQ** Requirements for substances in packaging

Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 – FAQ](#)):

2.1|F1

Should analyses of chemical content (PFAS) be repeated for each production batch? Even if the same types of raw materials or components are used, but from different suppliers?

2.1|F2

Will there be a definitive list of PFAS substances subject to restrictions under the PPWR or will reference be made to existing regulatory frameworks (e.g. REACH/POP)?

2.1|F3

Is it correct to say that there are no transitional measures for PFAS? There is mention of the placing on the market of packaging containing PFAS, but no mention of the placing on the market of finished products containing them. What should companies do?

2.2 Recyclable packaging

The text of this section refers to the content of Article 6 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

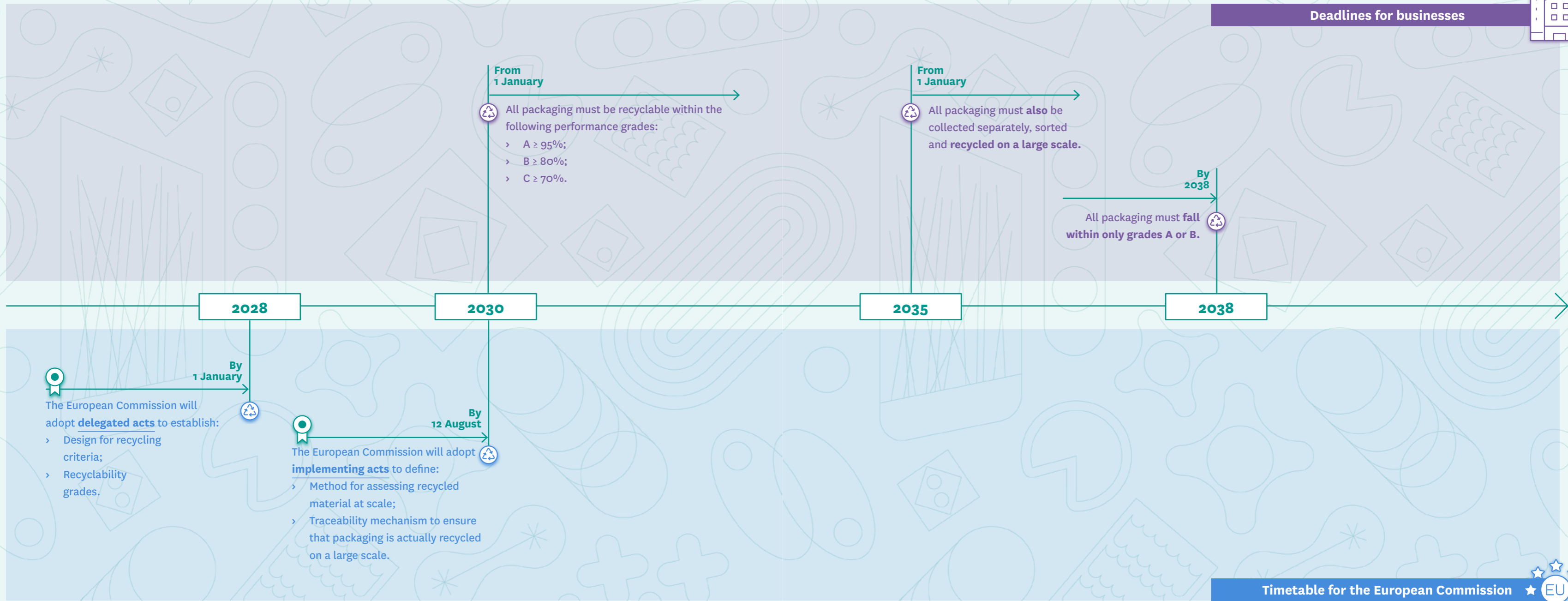
Regulatory reference

Article 6.



Delegated acts or implementing acts

Deadlines for businesses



Design requirement



RECYCLABILITY
Recyclability of the packaging

Timetable for the European Commission



Pending the publication of the delegated acts, companies are encouraged to refer to the design for recycling guidelines developed by trade associations, in particular European ones and those proposed by Member States, such as:

- > for flexible packaging, the [CEFLEX Design for Recycling Guidelines](#);
- > for plastic packaging, the [Recyclclass Guidelines](#);
- > for plastic bottles, the [EPBP Guidelines](#).

For paper packaging, on the other hand, the existing references are the Aticelca Assessment System, the CEPI or 4evergreen method.¹¹

2.2.1 Objective



To establish measures that encourage manufacturers to place more recyclable packaging on the market, thereby helping Member States to achieve their recycling targets.

2.2.2 Scope



All packaging placed on the EU market.

¹¹

This is a list by way of example and not exhaustive. CONAI does not promote these guidelines, but provides the “Progettare Riciclo” (Design for Recycling) platform, a tool that offers design guidelines aimed at improving the recyclability of packaging, based on an in-depth analysis of the entire collection, sorting and recycling chain.

2.2.3 Deadlines and timeframes



**ANNEX II – TABLE 3
CATEGORIES AND PARAMETERS FOR ASSESSMENT
OF RECYCLABILITY OF PACKAGING**

2030		2035			2038		
Recyclability performance grade	Design for recycling (DfR) Assessment of recyclability per unit, in terms of weighting	Recyclability performance grade (for DfR)	Design for recycling (DfR) Assessment of recyclability per unit, in terms of weighting	Recyclability performance grade (for recycled-at-scale assessment)	Recyclability performance grade	Design for recycling (DfR) Assessment of recyclability per unit, in terms of weighting	Recyclability performance grade (for recycled-at-scale assessment)
Grade A	higher or equal to 95 %	Grade A	higher or equal to 95 %	Grade A RaS	Grade A	higher or equal to 95 %	Grade A RaS
Grade B	higher or equal to 80 %	Grade B	higher or equal to 80 %	Grade B RaS	Grade B	higher or equal to 80 %	Grade B RaS
Grade C	higher or equal to 70 %	Grade C	higher or equal to 70 %	Grade C RaS	Grade C CANNOT BE PLACED ON THE MARKET	higher or equal to 70 %	Grade C RaS
TECHNICALLY NON-RECYCLABLE	lower than 70 %	TECHNICALLY NON-RECYCLABLE	lower than 70 %	NOT RECYCLED AT SCALE (below thresholds of Article 3(1), point (39).	TECHNICALLY NON-RECYCLABLE	lower than 70 %	NOT RECYCLED AT SCALE (below thresholds of Article 3(1), point (39).

From 1 January 2030 (or, if later, 24 months after the date of entry into force of future delegated acts establishing performance criteria for recycling and recyclability performance grades) all packaging placed on the market shall be designed for material recycling in accordance with the criteria defined by the European Commission through secondary legislation (expected by 1 January 2028) so as to enable the use of resulting secondary raw materials that are of sufficient quality when compared to the original material that they can be used to substitute primary raw materials.¹²

From 1 January 2035 (or, as regards the recycled-at-scale requirement, from 1 January 2035 or five years from the date of entry into force of the implementing acts by which the Commission shall establish the methodology for assessing recycled material at scale by packaging category), all packaging placed on the market shall be recyclable in the sense that when it becomes waste, it can be separately collected and can be sorted into specific waste streams without compromising the recyclability of other waste streams and recycled at scale.¹³

As of 1 January 2030 (or 24 months after the entry into force of the delegated acts referred to in Article 6, paragraph 4 if that date is later¹⁴), packaging that is not recyclable according to grades A, B or C referred to in Table 3 of Annex II to Regulation 2025/40 may not be placed on the market. By 1 January 2038, on the other hand, packaging may no longer be placed on the market unless it is recyclable within grades A or B as described in Table 3 of Annex II of Regulation 2025/40.

2.2.4 Content of the measure

All packaging placed on the market must be recyclable: firstly, packaging must be designed for material recycling, which enables the use of resulting secondary raw materials that are of sufficient quality when compared to the original material that they can be used to substitute primary raw materials¹², while, secondly, all packaging placed on the market must be recyclable in the sense that when it becomes waste, it can be separately collected and sorted into specific waste streams without compromising the recyclability of other waste streams and recycled at scale^{13 15}.



¹²

Article 6, paragraph 2, point (a) of Regulation 2025/40.

¹³

Article 6, paragraph 2, point (b) of Regulation 2025/40.

¹⁴

Paragraph 4 of Article 6 stipulates that by 1 January 2028, the EU Commission shall supplement Regulation 2025/40 by providing for:

- (a) design for recycling criteria and recyclability performance grades based on Table 3 of Annex II and the parameters listed in Table 4 of Annex II for packaging categories listed in Table 1 of Annex II;
- (b) how to perform recyclability performance assessment and express its result in recyclability performance grades per packaging unit, in terms of weighting, including material-specific criteria and sorting efficiency, to determine whether packaging is to be considered recyclable under paragraph 2;
- (c) a description, for each packaging category listed in Table 1 of Annex II, of the conditions for compliance with their respective recyclability performance grades;
- (d) a framework concerning the modulation of financial contributions to be paid by producers to comply with their extended producer responsibility obligations set out in Article 45, paragraph 1, based on the packaging recyclability performance grades.

¹⁵

According to Article 3, “packaging waste recycled at scale” means packaging waste which is collected separately, sorted and recycled in installed infrastructure, using established processes proven in an operational environment which ensure, at Union level, an annual quantity of recycled material under each packaging category listed in Table 2 of Annex II equal to or greater than 30% for wood and 55% for all other materials; it includes packaging waste that is exported from the Union for the purpose of waste management and which can be considered to meet the requirements of Article 53, paragraph 11.

¹⁶

Article 6, paragraph 4 of Regulation 2025/40.

¹⁷

Article 6, paragraph 5 of Regulation 2025/40.

¹⁸

Article 6, paragraph 2, points (a) and (b) of Regulation 2025/40.

However, several delegated acts are expected from the EU Commission, which shall establish:

- › by 1 January 2028, the design for recycling criteria and the recyclability performance grades. These criteria shall be defined taking into account the standards developed by European standardisation organisations¹⁶;
- › by 1 January 2030, the methodology for assessing recycled material at scale by packaging category.¹⁶

Therefore, from 1 January 2030, packaging that complies with the delegated acts relating to design for recycling criteria and recyclability performance grades¹⁶ can be considered to comply with the condition set out in Article 6, paragraph 2, point (a) of Regulation 2025/40, and can therefore be placed on the market.

Packaging that complies with the delegated acts relating to design for recycling criteria and recyclability performance grades¹⁶, as well as with the implementing acts establishing the methodology for assessing recycled content at scale by packaging category¹⁷, is deemed to comply with both conditions¹⁸ and can therefore be placed on the market because: it has been designed for material recycling which enables the use of resulting secondary raw materials that are of sufficient quality when compared to the original material that they can be used to substitute primary raw materials; it can be separately collected and sorted into specific waste streams without compromising the recyclability of other waste streams and recycled at scale.

The packaging manufacturer must then assess the recyclability of packaging on the basis of the delegated acts prepared by the EU Commission; packaging recyclability shall be expressed in the recyclability performance grades A, B or C as described in Table 3 of Annex II to Regulation 2025/40.

Recyclability performance is based on design for recycling criteria. Those criteria shall ensure the circularity of the use of the resulting secondary raw materials of sufficient quality to substitute the primary raw materials.

The recyclability assessment based on the design for recycling criteria shall be carried out for each packaging category listed in Table 1 of Annex II of Regulation 2025/40, taking into account the methodology defined in Article 6, paragraph 4 of Regulation 2025/40, and the related delegated acts, as well as the parameters established in Table 4 of Annex II of Regulation 2025/40. After assessing compliance with the design criteria, which must be done for each packaging unit, it will be classified into categories A, B or C. When a packaging unit's recyclability performance grade is below 70%, it is considered to be non-compliant with the recyclability performance grades and therefore the packaging will be considered technically non-recyclable and its placing on the market will be prohibited.

From 2035, a new factor will be added to the assessment of the packaging recyclability, which is the “recycled at scale” assessment. Consequently, a new assessment shall be carried out based on the quantity (weight) of the material effectively recycled from each of the packaging categories in accordance with the methodology established in the implementing acts adopted under Article 6, paragraph 5. The thresholds related to the annual recycled packaging materials for compliance with the recycled-at-scale assessment shall be defined taking into account the targets set in Article 3, paragraph 1, point (39) of Regulation 2025/40.



NOTE

From 2030 onwards, the rules for modulating the EPR Fee by the EPR systems of individual Member States shall take into account the classification of packaging into grades A, B, and C.

2.2.5 Exemptions from the measure



The recyclability requirements until 2035 will not apply to:

- › the primary packaging of medicinal products for human consumption, defined as “the container or other form of packaging immediately in contact with the medicinal product” (Article 1, paragraph 23, [Directive 2001/83/EC](#));
- › the primary packaging of veterinary medicinal products, defined as “the container or any other form of packaging that is in direct contact with the veterinary medicinal product” (Article 4, paragraph 25, [Regulation 2019/6](#));
- › contact-sensitive plastic packaging used for medical devices governed by [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council and for in vitro diagnostic medical devices referred to in [Regulation \(EU\) 2017/746](#) of the European Parliament and of the Council;
- › outer packaging of medicinal products for human use, meaning the packaging in which the immediate packaging is placed (Article 1, paragraph 24, [Directive 2001/83/EC](#)) and outer packaging of veterinary medicinal products, meaning the packaging in which the immediate packaging is placed (Article 4, paragraph 26, [Regulation 2019/6](#)) in cases where such packaging is necessary to comply with specific requirements to preserve the quality of the medicinal product;
- › contact-sensitive packaging for infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes (Article 1, paragraph 1, points (a), (b) and (c) of [Regulation 609/2013](#));
- › packaging used for the transport of dangerous goods referred to in [Directive 2008/68/EC](#);
- › sales packaging made from lightweight wood, cork, textile, rubber, ceramic, or porcelain (however, Article 8, paragraph 6 of Regulation 2025/40 shall still apply).

By 2035, the Commission shall reassess the above categories of exempted packaging.

2.2.6 Means of verification – EU declaration of conformity



The packaging manufacturer must assess the recyclability of packaging on the basis of EU delegated acts issued on: design for recycling criteria, recyclability performance grades ¹⁶ and methodology for assessing the achievement of the target for recycled content at scale, set for the packaging category covered in Table 3 of Annex II to Regulation 2025/40, which includes the packaging in question.

Compliance with the recyclability requirements ¹⁹ shall be demonstrated in the technical documentation for packaging as provided in Annex VII of Regulation 2025/40, which shall be drawn up by the packaging manufacturer itself (see Chapter 4.1 on the conformity assessment procedure). Where a unit of packaging includes integrated components ²⁰, the assessment of conformity with the design for recycling criteria and with the requirements for recyclability at scale shall include all integrated components. A separate assessment shall then be carried out for integrated components that can become separated from each other as a result of mechanical stress during transportation or sorting, or that may be disposed of separately in the packaging waste collection system: in this case, the definition of “separate components” shall apply ²¹.

¹⁹

Paragraphs 2 and 3 of Article 6 of Regulation 2025/40.

²⁰

A single recyclability assessment must be provided in the case of packaging consisting of a single component or a set of integrated components (e.g. bottle with cap and label), while it must be provided for each component in the case of packaging consisting of separate components. “Integrated component” (Article 3, paragraph 43 of Regulation 2025/40) means “a packaging component, whether or not of the same material as, or distinct from, the main body of the packaging unit, that is integral to the packaging unit and its functioning, that does not need to be separated from the main body of the packaging unit in order to ensure the functionality of the packaging unit and that is typically discarded at the same time as the main body of the packaging unit, although not necessarily via the same disposal route”.

²¹

“Separate component” means a packaging component, whether or not from the same material as the main body of the packaging unit, that is distinct from the main body of the packaging unit, that needs to be disassembled completely and permanently from the main body of the packaging unit and that is typically discarded prior to and separately from the main body of the packaging unit, including packaging components that can be separated from each other simply through mechanical stress during transportation or sorting (Article 3, paragraph 44 of Regulation 2025/40).

²²

Packaging categories that do not reach a rate of 55% for recycling at scale at European level by 1 January 2035 will no longer be allowed on the European market.

2.2.7 Summary table



Recyclable packaging

Regulatory reference

Article 6.

Obligated party

Manufacturers.

Deadline (by when)

- › From 1 January 2030, all packaging must be designed for recycling of sufficient quality to enable the production of secondary raw materials of sufficient quality compared to the original material, and those that are not recyclable according to grades A, B or C may not be placed on the market.
- › From 1 January 2035, packaging must be recyclable and compatible with separate collection without compromising other recycling streams and recycled at scale. ²²
- › By 1 January 2038, only recyclable packaging belonging to grades A or B may be placed on the market.

Obligation

All packaging placed on the EU market must be recyclable.

Criterion

Future delegated and implementing acts by the EU Commission shall establish:

- › design for recycling criteria and recyclability performance grades (Article 6, paragraph 4);
- › methodology for assessing recycled material at scale by packaging category (Article 6, paragraph 5).



Means of verification

The packaging manufacturer must assess the recyclability of packaging on the basis of EU delegated acts and provide evidence of this through technical documentation in accordance with the procedure set out in [Annex VII](#).

Exemptions

- › Primary packaging and outer packaging of medicinal products for human use and veterinary medicinal products;
- › Contact-sensitive plastic packaging used for medical and medical diagnostic devices;
- › Contact-sensitive packaging for infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes;
- › Packaging used for transporting dangerous goods;
- › Sales packaging made from lightweight wood, cork, textile, rubber, ceramic or porcelain.

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

2.2.8

FAQ

Recyclable packaging



Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 – FAQ](#)):

2.2|F1

Are there already technical protocols for assessing the recyclability of flexible plastic packaging that can be used to meet regulatory requirements?

2.2|F2

Can PET trays that use a peelable heat-sealed PET film that is not recyclable continue to use this type of film, given that it accounts for a minimal percentage of the plastic?

2.2|F3

What tests are used to demonstrate the recyclability of a packaging material?

2.2|F4

“Recyclability grades” have been defined: how does the criterion for this classification work? How is it calculated?

2.2|F5

What are the criteria for considering packaging recyclable (grades A, B and C) until provisions are established? Is it already possible to define it as such? Is it mandatory or optional to declare the percentage of recycled plastic?

2.3 Minimum recycled content in plastic packaging

The text of this section refers to the content of Article 7 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulatory reference

Article 7.

Delegated acts or implementing acts

Deadlines for businesses



From 1 January

% Any plastic parts of the packaging:

SUP	30%
Contact-sensitive	
PET	30%
Other	10%
Other	35%

From 1 January

% Any plastic parts of the packaging:

SUP	65%
Contact-sensitive	
PET	50%
Other	25%
Other	65%

2026

2030

2032

2040

By 31 December

By 12 February

- Methodology for calculating and verifying the percentage of recycled content – **implementing act**;
- Definition of sustainability criteria for plastic recycling technologies – **delegated act**;
- Definition of the methodology for assessing, verifying and certifying the equivalence of **standards applied to post-consumer plastic waste** recycled or collected outside the EU – **implementing act**

- The Commission will assess:
- the feasibility of **achieving the 2040 targets**;
 - the use of recycled materials in non-plastic packaging and, if appropriate, propose new measures or targets.

Timetable for the European Commission



Design requirement



RECYCLED CONTENT
Minimum recycled material content for plastic packaging

2.3.1 Objective

To encourage an increase in the amount of recycled material in the plastic part of packaging and to promote the market for secondary raw materials.

2.3.2 Scope

All plastic parts of packaging placed on the EU market.

2.3.3 Deadlines and timeframes

By 1 January 2030 (or three years after the entry into force of the implementing act establishing the methodology for calculating and verifying the percentage of recycled content, whichever is later, see paragraph 8 of article 7 of Regulation 2025/40), all plastic parts of packaging placed on the market must comply with the minimum percentages of recycled content from post-consumer plastic waste indicated in Article 7, paragraph 1 of Regulation 2025/40.

By 1 January 2040, all plastic parts of packaging placed on the market must contain the minimum percentages of recycled material specified in Article 7, paragraph 2 of Regulation 2025/40.

2.3.4 Content of the measure

By 1 January 2030 (or three years after the date of entry into force of the implementing act referred to in paragraph 8 of Article 7, whichever is later), all plastic parts of packaging placed on the market shall contain a specific minimum percentage of recycled material obtained from post-consumer plastic waste, by type and format of packaging, as listed in Table 1 of Annex II to Regulation 2025/40.

The percentage is calculated as an average per manufacturing plant and per year:

- a. 30% for contact-sensitive packaging made from polyethylene terephthalate (PET) as the major component, except single-use plastic beverage bottles;
- b. 10% for contact-sensitive packaging made from plastic materials other than PET, except single-use plastic beverage bottles;
- c. 30% for single-use plastic beverage bottles;
- d. 35% for plastic packaging other than those referred to in points (a), (b) and (c) ²³.

By 1 January 2040, any plastic part of packaging placed on the market shall contain a specific minimum percentage of recycled material obtained from post-consumer plastic waste, per packaging type and format as referred to in Table 1 of Annex II of Regulation 2025/40, calculated as an average per manufacturing plant and year:

- a. 50% for contact-sensitive packaging made from PET as the major component, except single-use plastic beverage bottles;
- b. 25% for contact-sensitive packaging made from plastic materials other than PET, except single-use plastic beverage bottles;
- c. 65% for single-use plastic beverage bottles;
- d. 65% for plastic packaging other than those referred to in points (a), (b) and (c) ²⁴.

2.3.5 Exemptions from the measure

The minimum recycled content percentages will not apply to:

- a. primary packaging as defined in Article 1, paragraph 23 of Directive 2001/83/EC and Article 4, paragraph 25 of Regulation (EU) 2019/6;
- b. contact-sensitive plastic packaging of medical devices, devices exclusively destined for research use and investigational devices covered by Regulation (EU) 2017/745;
- c. contact-sensitive plastic packaging of in vitro diagnostic medical devices covered by Regulation (EU) 2017/746;
- d. outer packaging as defined in Article 1, paragraph 24 of Directive

²³

Article 7, paragraph 1 of Regulation 2025/40.

²⁴

Article 7, paragraph 2 of Regulation 2025/40.

2001/83/EC and outer packaging as defined in Article 4, paragraph 26 of Regulation (EU) 2019/6 in cases where such packaging is necessary to comply with specific requirements to preserve the quality of the medicinal product;

e. compostable plastic packaging;

f. packaging used for the transport of dangerous goods in accordance with Directive 2008/68/EC;

g. contact-sensitive plastic packaging for food that is intended only for infants and young children, food for special medical purposes and packaging for drinks and food typically used for young children as referred to in Article 1, paragraph 1, points (a), (b) and (c), of Regulation (EU) 609/2013;

h. packaging of supplies, components and immediate packaging components for the manufacturing of medicinal products in accordance with Directive 2001/83/EC and veterinary medicinal products in accordance with Regulation (EU) 2019/6, where such packaging is needed to be in line with the quality standards of the medicinal product;

i. plastic packaging that is intended to come into contact with food where the quantity of recycled content poses a threat to human health and results in non-compliance of packaged products with Regulation (EC) 1935/2004;

j. any plastic part representing less than 5% of the total weight of the whole packaging unit.

2.3.6 Means of verification – EU declaration of conformity



Compliance with the requirements regarding the minimum content of recycled material in plastic packaging shall be demonstrated by manufacturers or importers in the technical information on packaging referred to in Annex VII to Regulation 2025/40 (see Chapter 4.1 on the conformity assessment procedure).



NOTE

- › The recycled material content must originate from post-consumer plastic waste that:
 - a. has been collected within the Union on the basis of Regulation 2025/40 and, where applicable, national rules transposing Directive (EU) 2019/904 and Directive 2008/98/EC, or has been collected in a third country in accordance with separate collection rules aimed at promoting high-quality recycling equivalent to those referred to in Regulation 2025/40, Directive (EU) 2019/904 and Directive 2008/98/EC, as applicable; and
 - b. where applicable, has been recycled in an installation located in the Union to which Directive 2010/75/EU applies, or has been recycled in an installation located in a third country to which rules on the prevention and reduction of emissions into air, water and land associated with recycling operations apply; those rules are equivalent to those concerning emissions limits and environmental performance levels established in accordance with Directive 2010/75/EU and applicable to an installation established in the Union carrying out the same activity; the above condition shall only apply where such limits and levels would be applicable to an installation located in the Union and carrying out the same activity as a similar installation located in a third country.
- › By 31 December 2026, the Commission shall adopt implementing acts to establish the methodology for calculating and verifying the percentage of recycled content recovered from post-consumer plastic waste recycled and recovered within the Union, and the format of the technical documentation referred to in Annex VII to Regulation 2025/40. For that purpose, the Commission shall take into account the use of secondary raw materials that are of sufficient quality when compared to the original material that they can be used to substitute primary raw materials. ²⁵

²⁵

Article 7, paragraph 8 of Regulation 2025/40.

- › **By 1 January 2029** (or 24 months after the date of entry into force of the implementing act, whichever is later), the calculation and verification of the percentage of recycled material content in packaging shall comply with the rules laid down in the implementing act. ²⁶
- › **By 31 December 2026**, the Commission shall, on the basis of the assessment referred to in the second sub-paragraph of paragraph 8, adopt delegated acts (pursuant to Article 6, paragraph 4 of Regulation 2025/40) supplementing Regulation 2025/40 by establishing sustainability criteria for plastic recycling technologies. ²⁷ For the purposes of Article 7 of Regulation 2025/40, recycled content shall be recovered from post-consumer plastic waste that has been recycled either in:
 - a. installations located within the Union using recycling technologies which meet such sustainability criteria established pursuant to Article 7, paragraph 9 of Regulation 2025/40; or
 - b. installations located in a third country using recycling technologies in accordance with standards equivalent to the sustainability criteria developed under the delegated acts.
- › **By 31 December 2026**, the Commission shall adopt an implementing act establishing the methodology for assessing, verifying and certifying, including through third-party audit, the equivalence of the rules applied in cases where the recycled content obtained from post-consumer plastic waste is recycled or collected outside the Union.
- › **By 1 January 2028**, the Commission shall assess the need for derogations from the minimum recycled content percentage referred to in Article 7, paragraph 1, points (b) and (d), for specific plastic packaging, or the revision of the list of exceptions in Article 7, paragraph 4 for specific plastic packaging, adjusting the scope and timing accordingly.
- › **Where justified by the unavailability or excessive prices of specific recycled plastics, which make it excessively difficult to comply with the minimum recycled content percentages, the Commission shall be empowered to adopt a delegated act to amend paragraphs 1 and 2 of Article 7 of Regulation 2025/40, adjusting the minimum percentages accordingly. The Commis-**

²⁶

Article 7, paragraph 8 of Regulation 2025/40.

²⁷

The European Commission's intention is not to exclude any recycling technology a priori, but to assess the environmental impact of each one, favouring those with the lowest environmental impact.

sion shall adopt such a delegated act only in exceptional cases where there would be severe adverse effects for human or animal health, the security of food supply or the environment.

- › **By 12 February 2032**, taking into account the evolution of the state of the art of technology and the practical experience gained by economic operators and Member States, the Commission shall present a report reviewing the implementation of the minimum percentages of recycled material for 2030 and assessing: the extent to which those percentages lead to solutions fostering sustainable packaging that are effective and easy to implement; the feasibility of achieving the percentages set for 2040 based on the experience gained in achieving the percentages for 2030 and the evolution of circumstances; the importance of maintaining the exemptions and derogations provided for; the need or appropriateness of setting new minimum percentages of recycled material. That report shall, where appropriate, be accompanied by a legislative proposal amending Article 7 of Regulation 2025/40, in particular the 2040 minimum percentages of recycled material.
- › **By 12 February 2032**, the Commission shall review the situation regarding the use of recycled packaging materials in packaging other than plastics and, on that basis, assess the appropriateness of establishing measures, or setting targets, for increasing the use of recycled material in such other packaging, and, where appropriate, present a legislative proposal.

2.3.7 Summary table

Minimum recycled content in plastic packaging

Regulatory reference

Article 7.



Obligated party

Manufacturers or importers.

Deadline (by when)

- > By **1 January 2030** (or three years after the entry into force of the implementing act establishing the methodology for calculating and verifying the percentage of recycled content, whichever is later – see paragraph 8 of article 7) for the minimum percentages of recycled content from post-consumer plastic waste indicated in Article 7, paragraph 1:
 - a. 30% for contact-sensitive packaging made from polyethylene terephthalate (PET) as the major component, except single-use plastic beverage bottles;
 - b. 10% for contact-sensitive packaging made from plastic materials other than PET, except single-use plastic beverage bottles;
 - c. 30% for single-use plastic beverage bottles;
 - d. 35% for plastic packaging other than those referred to in points (a), (b) and (c).
- > By **1 January 2040** for the minimum percentages of recycled material indicated in Article 7, paragraph 2:
 - a. 50% for contact-sensitive packaging made from PET as the major component, except single-use plastic beverage bottles;
 - b. 25% for contact-sensitive packaging made from plastic materials other than PET, except single-use plastic beverage bottles;
 - c. 65% for single-use plastic beverage bottles;
 - d. 65% for plastic packaging other than those referred to in points (a), (b) and (c).

Obligation

All plastic parts of packaging placed on the EU market must contain the minimum percentages of recycled material obtained from post-consumer plastic waste specified in Article 7 (paragraphs 1 and 2).

Criterion

The Commission shall adopt implementing acts to establish the methodology for calculating and verifying the percentage of recycled content obtained from post-consumer plastic waste recycled and recovered within the EU.

Means of verification

The manufacturer or importer shall demonstrate compliance with the requirements on the minimum recycled content of plastic packaging in the technical information and declaration of compliance ([Annexes VII and VIII](#)) and shall declare under its responsibility that the packaging complies with the requirements on the recycled content of plastic packaging. The Commission shall establish the format of the technical documentation referred to in [Annex VII](#).

Exemptions

Please refer to section 2.3.5 “Exemptions from the measure”.

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

2.3.8

FAQ Minimum recycled content in plastic packaging



Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 – FAQ](#)):

2.3|F1

How does recycled packaging fit in with the safety assessment of cosmetics?

2.3|F2

How can the suitability of a plastic film containing recycled material be verified?

2.3|F3

In the case of plastic packaging, what are the minimum recycled content thresholds and when will they come into force?

2.3|F4

How should Article 7.5.a be interpreted with regard to packaging that poses a risk to human health?

2.4 Biobased feedstock in plastic packaging

The text of this section refers to the content of Article 8 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

2.4.1 Objective



The European Commission will evaluate a legislative proposal to establish sustainability requirements and targets to increase the use of biobased feedstock in plastic packaging.

2.4.2 Scope



Plastic packaging containing biobased feedstock.

2.4.3 Deadlines and timeframes



By **12 February 2028**, the EU Commission shall review the state of technological development and environmental performance of biobased plastic packaging based on the sustainability criteria set out in Article 29 of [Directive \(EU\) 2018/2001](#) (on the promotion of the use of energy from renewable sources).

2.4.4 Content of the measure

Based on the review of the state of technological development, the Commission shall, where appropriate, present a legislative proposal in order to:

- lay down sustainability requirements for biobased feedstock in plastic packaging;
- lay down targets to increase the use of biobased feedstock in plastic packaging;
- introduce the possibility to achieve the targets set out in Article 7, paragraphs 1 and 2 of Regulation 2025/40, on the minimum recycled material in packaging, by using biobased plastic feedstock instead of recycled content obtained from post-consumer plastic waste ²⁸ in the event that suitable recycling technologies for food-contact packaging complying with the requirements laid down in [Regulation \(EU\) 2022/1616](#) are not available;
- amend, where appropriate, the definition of biobased plastic set out in Article 3, paragraph 53.

2.4.5 Exemptions from the measure

None currently planned.

2.4.6 Means of verification – EU declaration of conformity

None currently planned.

²⁸

By 2028, the Commission shall assess the possibility of using (virgin) biobased feedstock as an alternative to recycled materials to achieve the targets set out in Article 7 of Regulation 2025/40 and shall take a decision in this regard.

2.4.7 Summary table

Regulatory reference	Article 8.
Obligated party	Manufacturers or importers.
Deadline (by when)	By 12 February 2028 , the European Commission may present a legislative proposal.
Obligation	Not currently applicable.
Criterion	Not currently applicable.
Means of verification	The manufacturer or importer shall, where necessary, demonstrate compliance with the requirements of Article 8 by including the required information in the declaration of conformity.
Exemptions	None currently planned.
Penalties	Responsibility of each EU Member State.
Checks	Responsibility of each EU Member State.

2.5 Compostable packaging

The text of this section refers to the content of Article 9 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulatory reference

Article 9.

Deadlines for businesses



From
12 February

- The following packaging *** must be compostable** (industrial composting):
- > permeable tea, coffee or other beverage bags, or soft after-use system single-serve units that contain tea, coffee or another beverage, and intended to be used and disposed of together with the product;
 - > sticky labels applied to fruit and vegetables.

*

Member States may decide to extend compostability to other types of packaging made of materials other than metal, with particular reference to non-permeable tea, coffee or other beverage system single-serve units intended for use in a machine, and used and disposed of together with the product.

2026

2028

By
12 February

The Commission will request European standardisation organisations to prepare **harmonised standards for industrial and home composting** of packaging.

Timetable for the European Commission



Design requirement



COMPOSTABILITY
Compostable packaging

2.5.1 Objective

Establish general rules for the use of compostable packaging and introduce/update uniform definitions and standards (e.g. home and industrial composting), strengthen infrastructure in Member States, and prevent cross-contamination of traditional plastic recycling streams and bio-waste collection through effective communication with citizens.

2.5.2 Scope

Packaging placed on the market that is compatible with industrial composting standards, i.e. packaging that meets the conditions set out in [Annex III to Regulation 2025/40](#). In particular, packaging included in the scope of mandatory compostability is:

- › permeable tea, coffee or other beverage bags, or soft after-use system single-serve units that contain tea, coffee or another beverage, and intended to be used and disposed of together with the product;
- › sticky labels applied to fruit and vegetables.

2.5.3 Deadlines and timeframes

By 12 February 2028.

2.5.4 Content of the measure

Packaging placed on the market as referred to in Article 3, paragraph 1, point (1)(f): **permeable tea, coffee or other beverage bags, or single-serve, single-use units that are soft after use, which contain tea, coffee or another beverage, and are intended to be used and disposed of together with the product, and sticky labels affixed to fruit and vegetables** shall be compatible with the standards for composting in industrially controlled conditions in bio-waste treatment facilities and shall be compatible, where required by the Member States, with home composting standards.

2.5.5 Exemptions from the measure

No exemptions are provided for.

2.5.6 Means of verification – EU declaration of conformity

Compliance with the requirements relating to the compostability of packaging ²⁹ shall be demonstrated in the technical information on packaging set out in [Annex VII to Regulation 2025/40](#) (see [Chapter 4.1](#) on the conformity assessment procedure). The declaration of conformity shall comply with the provisions of [Annex VIII to Regulation 2025/40](#).



NOTE

- › Member States have the (additional) power to require biodegradable and compostable packaging to comply with the home composting standards referred to in Article 9 paragraph 6 of Regulation 2025/40.
- › By 12 February 2028, packaging other than that referred to in paragraphs 1 and 2 of Regulation 2025/40, including packaging made from biodegradable plastic polymers and other biodegradable materials, shall be designed for material recycling in accordance with Article 6 of Regulation 2025/40 without compromising the recyclability of other waste streams.
- › Where Member States allow waste with similar biodegradability and compostability properties as bio-waste to be collected together with bio-waste, and where adequate collection systems and waste treatment infrastructure are in place to ensure that compostable packaging enters the bio-waste management stream, Member States may require that the following packaging shall also be made available on their market for the first time only if the packaging is compostable:
 - a. packaging consisting of non-permeable single-serve units intended for a system for the preparation of tea, coffee or other beverages, to be used in a machine and used and disposed of together with the product (referred to in

²⁹

Article 9, paragraphs 1 to 3 of Regulation 2025/40.

Article 3 paragraph 1, point (1)(g)), composed of material other than metal, very lightweight plastic carrier bags and lightweight plastic carrier bags;

b. packaging other than that referred to in the previous point for which Member States have already introduced compostability requirements prior to 12 August 2026.

- › The Commission may consider including other packaging among those that should be placed on the market only if they are compatible with industrial or home composting standards, if justified and appropriate in light of technological and regulatory developments.
- › Article 9 of Regulation 2025/40 allows Member States a certain degree of flexibility, but in accordance with the single market, this flexibility is subject to compliance with the TRIS notification procedure.
- › By 12 February 2026, the Commission shall request European standardisation organisations to prepare harmonised standards setting out the detailed technical specifications for the home compostability requirements for packaging ³⁰. By 12 February 2028, packaging other than that referred to in paragraphs 1 and 2, including packaging made of biodegradable plastic polymers and other biodegradable materials ³¹, shall be designed for material recycling in accordance with Article 6 without affecting the recyclability of other waste streams.

2.5.7 Summary table



Compostable packaging

Regulatory reference

Article 9.



Obligated party

Manufacturers or importers.

Deadline (by when)

By 12 February 2028.

Obligation

The following items must be compostable:

- › permeable tea, coffee or other beverage bags, or soft after-use system single-serve units that contain tea, coffee or another beverage, and intended to be used and disposed of together with the product;
- › sticky labels applied to fruit and vegetables.

Criterion

Please refer to [Annex VII](#).

Means of verification

The manufacturer shall complete a written declaration of conformity ([Annexes VII and VIII](#)) and declare under its responsibility that the packaging complies with the requirements for compostability of packaging.

Exemptions

No exemptions are provided for.

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

³⁰

Biodegradable waste should not lead to the presence of contaminants in the compost produced. The requirements of harmonised standard EN 13432 “Packaging – Requirements for packaging recoverable by composting and biodegradation – Test scheme and evaluation criteria for final acceptance of packaging” should be revised with regard to composting times, permissible levels of contamination and restrictions on the release of microplastic to allow those materials to be processed in bio-waste treatment facilities in an appropriate manner. In addition, a similar standard for home composting should be established in the Union.

³¹

That is, it is of such biodegradable nature that it allows the packaging to undergo physical or biological decomposition, including anaerobic digestion, resulting ultimately in conversion into carbon dioxide and water, new microbial biomass, mineral salts, and, in the absence of oxygen, methane.

2.5.8

FAQ Compostable packaging



Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 - FAQ](#)):

2.5|F1

Will capsules and bags for coffee or other beverages be subject to compostability requirements?

2.5|F2

According to Regulation 2025/40, will tea filters be considered packaging? Do we therefore need to amend all disposal tables to include disposal provisions for tea filters?

2.5|F3

Will capsules and bags for coffee or other beverages have to be compostable, or will each country in Europe be able to decide whether to make compostability mandatory, based on its own recycling chain?

2.5|F4

What are the requirements for compostable packaging?

2.5|F5

With regard to coffee bags, will the filter paper that makes up the bags be considered packaging under Regulation 2025/40?

2.5|F6

Must packaging not included in Articles 9.1 and 9.2 still be recyclable as well as compostable?

2.5|F7

How should Article 9.2 be interpreted in terms of non-compostable plastic capsules when the Member State requires compostability? Will they be banned or will the dual option of compostable and non-compostable remain?

2.6 Packaging minimisation

The text of this section refers to the content of Article 10 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulatory reference

Articles 10 and 24.

Delegated acts or implementing acts

Deadlines for businesses



From 12 February

✳️ Packaging for sale (with the exception of packaging in re-use schemes) must be **designed so that empty space is minimised.***

* _____
Filling materials – paper scraps, air cushions, bubble wraps, sponge fillers, foam fillers, wood wool, polystyrene or Styrofoam chips – are considered “empty space”.

From 1 January (or 3 years after the entry into force of the implementing act)

- ✳️ > Packaging designed to minimise weight and volume (**attention to double walls, false bottoms and unnecessary layers**);
- > Compliance must be demonstrated through technical documentation;
- > **Grouped, transport and e-commerce packaging** (with the exception of those in re-use circuits) may not have **more than 50% empty space**.

2027

2028

2030

2032

By 12 February

✳️ The European Commission will request European standardisation organisations to develop a **standard methodology for calculating compliance** with packaging minimisation requirements.



By 12 February

✳️ **Implementing acts** for the methodology for calculating the **empty space ratio** in grouped, transport and e-commerce packaging.

By 12 February

✳️ The Commission will review the empty space ratio and assess the possibility of establishing **specific proportions for retail sales**, particularly for toys, cosmetics, DIY kits and electronic products.

Timetable for the European Commission



Design requirement



REDUCTION
Packaging minimisation

2.6.1 Objective

Reduce the weight and volume of packaging to the minimum necessary to ensure its functionality, taking into account its shape and material, in order to generate less environmental impact.

2.6.2 Scope

All packaging, regardless of material, with particular attention to limiting empty the space in grouped and transport packaging, including e-commerce packaging.

2.6.3 Deadlines and timeframes

From 1 January 2030.

2.6.4 Content of the measure

The manufacturer or importer shall ensure that the packaging placed on the market is designed so that its weight and volume is reduced to the minimum necessary to ensure its functionality, taking account of the shape and material from which the packaging is made, in accordance with the performance criteria set out in [Annex IV to Regulation 2025/40 on the methodology for packaging minimisation assessment](#).

Packaging with characteristics that aim only to increase the perceived volume of the product (including double walls, false bottoms, layers not necessary to fulfil the main function) may not be placed on the market. In order to comply with the packaging minimisation requirements, particular attention should be paid to limiting the empty space in grouped and transport packaging, including e-commerce packaging.

2.6.5 Exemptions from the measure

Packaging placed on the market may not comply with the content of this measure if:

- › the packaging is protected by a Community design in accordance with [Regulation \(EC\) 6/2002 on Community designs](#), by designs falling within the scope of [Directive 98/71/EC on the legal protection of designs](#), or by international agreements having effect in one of the Member States;
- › the shape is a trademark that falls within the scope of [Regulation \(EU\) 2017/1001 on the European Union trademark](#) or [Directive \(EU\) 2015/2436 on trademarks](#), including trademarks registered under international agreements that have effect in one of the Member States. These exemptions listed in Article 10 of [Regulation 2025/40 on packaging minimisation](#) apply only to designs and trademarks protected before 11 February 2025 and only where the application of these requirements would affect:
 1. the design of the packaging in such a way as to alter its novelty or individual character, or
 2. the trademark in such a way that the trademark can no longer distinguish the trademarked good from goods of another undertaking.
- › the packaged product or beverage benefits from a geographical indication protected under Union law, such as under [Regulation \(EU\) 1308/2013 for wine](#), [Regulation \(EU\) 2019/787 for spirit drinks](#) or [Regulation \(EU\) 2023/2411 for craft and industrial products](#), or is covered by a quality scheme as referred to in [Regulation \(EU\) 2024/1143](#).

2.6.6 Means of verification – EU declaration of conformity



The conformity of packaging placed on the market with the requirements of Article 10, paragraphs 1 and 2, on packaging minimisation must be demonstrated by the technical documentation contained in [Annex VII to Regulation 2025/40](#). ³²

The technical documentation shall contain the following elements:

- a. an explanation of the technical specifications, standards and conditions used to assess the packaging against the performance criteria (Part A) and methodology (Part B) set out in [Annex IV](#);
- b. identification of the design requirements that prevent further reduction of the weight or volume of the packaging for each of the above performance criteria;
- c. any test results, studies or other relevant sources, such as modelling and simulations, used to assess the minimum necessary volume or weight of the packaging.



NOTE

By 12 February 2027, the Commission shall request the European standardisation organisations to prepare or update, as appropriate, harmonised standards laying down the methodology for the calculation and measurement of compliance with the requirements concerning packaging minimisation under Regulation 2025/40. For most common packaging types and formats, such standards should specify maximum adequate weight and volume limits, and, where appropriate, wall thickness and maximum empty space.

³²

For reusable packaging, the assessment of conformity with the requirements shall take into account the function of reusable packaging as referred to in Article 11 of Regulation 2025/40.

³³

Beware of packaging with characteristics that aim only to increase the perceived volume of the product (including double walls, false bottoms, layers not necessary to fulfil the main function) – Article 10, paragraph 2.

³⁴

For reusable packaging, point (8), Part A of [Annex IV](#) specifies that packaging minimisation must ensure reusability, recyclability and/or the inclusion of recycled content, i.e. it may be necessary to increase the weight or volume of the packaging to increase the number of movements or rotations, facilitate the inclusion of recycled material or improve recyclability.

³⁵

Article 10, paragraph 3 of Regulation 2025/40.

2.6.7 Summary table



Packaging minimisation

Regulatory reference

Article 10.

Obligated party

Manufacturers or importers.

Deadline (by when)

By 1 January 2030 . For deadlines relating to Article 24, please refer to the further reading below on “Excessive packaging”

Obligation

- › Packaging optimised in terms of weight and volume. ³³
- › Compliance with the performance criteria set out in [Annex IV](#). ³⁴

Criterion

By 12 February 2027, there will be new European standards establishing the methodology for the calculation and measurement of compliance with the requirements concerning packaging minimisation under Regulation 2025/40. ³⁵

Means of verification

The manufacturer shall:

- › draw up the technical documentation referred to in [Annex VII](#) and Article 10, paragraph 4;
- › complete a written declaration of conformity.



Exemptions

Please refer to section 2.6.5, which covers paragraph 2 of Article 10.

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

FURTHER READING ³⁶



Excessive packaging

Regulatory reference

Article 24.

Obligated party

Economic operator filling grouped packaging, transport packaging, e-commerce packaging or sales packaging.

Deadline (by when)

- › By 1 January 2030 or 3 years after the entry into force of the delegated acts (for the obligation to ensure that the empty space ratio does not exceed 50%, Article 24, paragraph 1).
- › By 12 February 2028 (for the obligation to fill packaging so that empty space is reduced to the minimum necessary, Article 24, paragraph 4).

Obligation

The empty space ratio shall not exceed 50% (Article 24, paragraph 1) and empty space shall be reduced to the minimum necessary for ensuring the packaging functionality, including product protection (Article 24, paragraph 4). ³⁷



³⁶

The provision referred to in Article 10 applies to **all types of packaging**, except for the specific exclusions provided for in the same article, and requires manufacturers or importers to place on the market packaging designed so that its weight and volume is reduced to the minimum necessary to ensure its functionality, taking account of the shape and material from which the packaging is made.

Article 24, on the other hand, requires **only** economic operators who fill grouped packaging, transport packaging or e-commerce packaging to ensure that the maximum empty space ratio, expressed as a percentage, does not exceed 50%.

³⁷

“By 12 February 2028, the Commission shall adopt implementing acts to establish the methodology for the calculation of the empty space ratio. That methodology shall take into account the special characteristics of packaging which needs to be placed in an empty space that is large enough to comply with applicable legal requirements or to protect the product, such as, in particular, packaged products of irregular shape, packaging containing more than one sales packaging or product, packaging containing liquid products, packaged products the content of which can easily be damaged and packaged products that can be damaged by larger products due to their small dimensions, and the minimum space on the transport packaging to enable shipment labels to be affixed.” – Article 24, paragraph 2 of Regulation 2025/40.

³⁸

Regulation 2025/40 establishes that **empty space** is the difference between the total volume of the grouped packaging, transport packaging or e-commerce packaging and the volume of the sales packaging contained therein; Regulation 2025/40 also provides a definition of “**empty space ratio**”: the ratio of void space to the total volume of the grouped packaging, transport packaging or e-commerce packaging.

Filling materials – paper scraps, air cushions, bubble wraps, sponge fillers, foam fillers, wood wool, polystyrene or Styrofoam chips – are considered “empty space”.

³⁹

This applies only when the same packaging used for sale is used for e-commerce packaging. This is without prejudice to the obligation for such packaging to comply with the requirements of Article 10.

Criterion

- › By 12 February 2028, implementing acts to establish the methodology for calculating the empty space ratio referred to in paragraph 1 of Article 24.
- › By 12 February 2032, review of the empty space ratio (referred to in paragraph 1 of Article 24) as well as exemptions and possibilities for establishing empty space ratios for sales packaging, particularly for toys, cosmetics, do-it-yourself kits and electronic products.

Means of verification

Pending the implementing act that will establish the methodology for the calculation of the empty space ratio. ³⁸

Exemptions

- › Sales packaging used as e-commerce packaging (Article 24, paragraph 5); ³⁹
- › Reusable packaging used as part of a re-use system (Article 24, paragraph 5).

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

2.6.8

FAQ**Packaging
minimisation**

Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 - FAQ](#)):

2.6|F1

Will it be possible to maintain the aesthetic style required by the cosmetics sector, for example the use of double-walled jars and caps?

2.6|F2

What is the criterion for determining whether packaging is disproportionate to its contents? Who should verify this and how?

2.6|F3

Which types of packaging should be strictly avoided/reduced?

2.6|F4

How can we distinguish between the requirements of Article 10 (minimisation) and those of Article 24 (empty space)? Are these two different issues?

2.6|F5

Does the obligation to minimise weight and volume apply to all packaging materials?

2.7 Reusable packaging

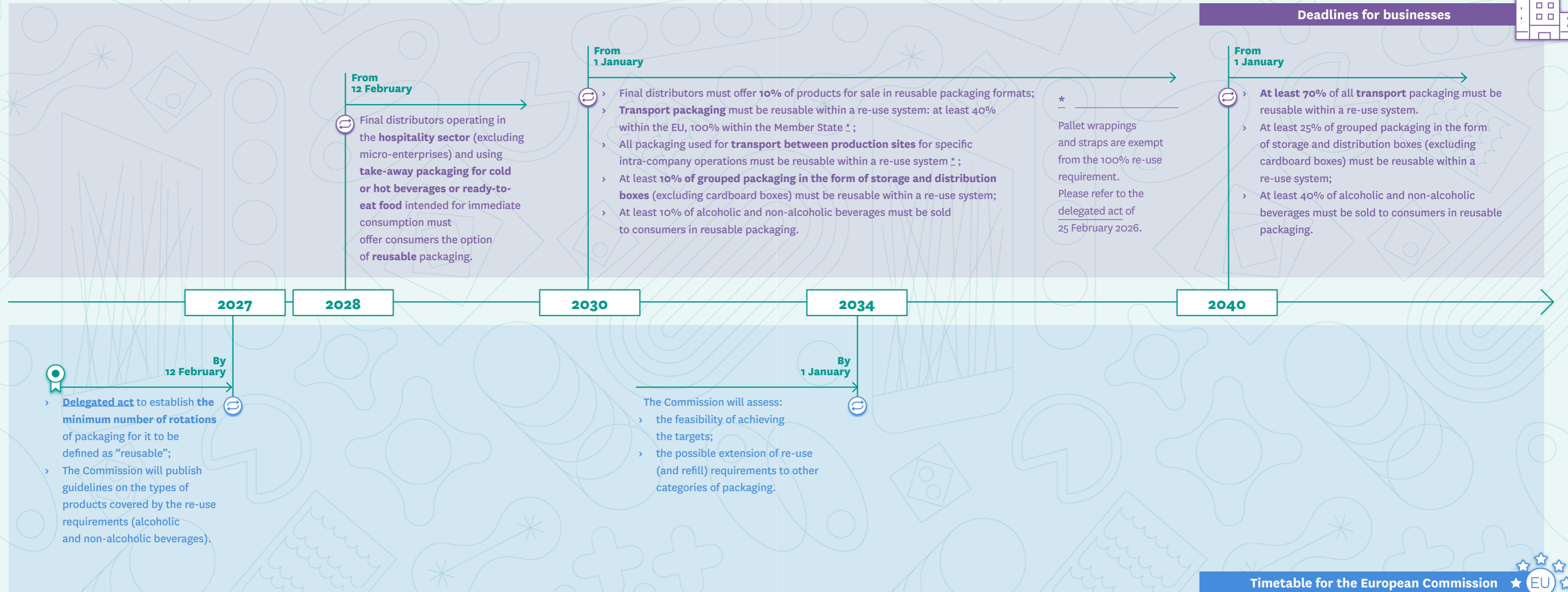
The text of this section refers to the content of Article 11 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulatory reference

Articles 11, 29, 33.

 Delegated acts or implementing acts

Deadlines for businesses



Design requirement

 **RE-USE**
Reusable packaging



2.7.1 Objective

To place reusable packaging on the market with the aim of generating less packaging waste and consequently reducing environmental impact. The concept of reusable packaging is linked both to the design of packaging – which should enable the highest possible number of rotations and maintain the safety, quality and hygiene requirements when being emptied, unloaded, refilled or reloaded – and to the existence of re-use systems that comply with the requirements set out in Articles 26 and 27 and [Annex VI](#) of Regulation 2025/40.

2.7.2 Scope

WARNING: Please note that packaging items for which re-use targets are not set have been excluded from the scope of application.

Transport packaging or sales packaging used to transport products within the EU – including through e-commerce – in the form of pallets, collapsible plastic boxes, boxes, trays, plastic crates, intermediate bulk containers, dry bulk containers, drums and jerry cans of any size and material (including flexible formats), as well as pallet wrapping and strapping for stabilising and protecting products placed on pallets during transport. ^{40 41}

Grouped packaging in the form of boxes, excluding cardboard, outside of sales packaging to group a certain number of products to create a stock-keeping or distribution unit, and packaging for the sale of alcoholic and non-alcoholic beverages.

Take-away packaging in the hotel, restaurant and catering sector containing cold or hot beverages or ready-to-eat food intended for immediate consumption without any further preparation.

⁴⁰

Article 29 of Regulation 2025/40 sets specific re-use targets for the packaging listed in the table in section 2.7.4.

⁴¹

The list of packaging referred to in Article 29 paragraph 1 has been revised by the European Commission following an [impact assessment](#) of certain types of packaging, and on 25 February 2026 the [delegated act](#) was published exempting pallet wrappings and straps from the 100% re-use requirement.

! ATTENTION

On this subject, a special regime is provided for the **take-away food and beverage sector**: by 12 February 2028, final distributors operating in the hotel, restaurant and catering sectors and who, using take-away packaging, make available on the market in the territory of a Member State cold or hot beverages or ready-to-eat food intended for immediate consumption without any further preparation, by filling a take-away container at the point of sale, shall offer consumers the option of reusable packaging as part of a re-use system ⁴².

⁴²

Article 33 of Regulation 2025/40 provides for a re-use offer system for the take-away sector.

2.7.3 Deadlines and timeframes

By 12 February 2027, the Commission shall adopt a delegated act establishing a minimum number of rotations for reusable packaging relating to the formats most frequently intended for re-use, taking into account hygiene and other requirements, such as logistics.

2.7.4 Content of the measure

Packaging placed on the market from 11 February 2025 shall be considered to be “reusable” where it fulfils all of the following requirements:

- a. it has been conceived, designed and placed on the market with the objective to be re-used multiple times;
- b. it has been conceived and designed to accomplish as many rotations as possible under normally predictable conditions of use;
- c. it fulfils applicable requirements regarding consumer health, safety and hygiene;
- d. it can be emptied or unloaded without being damaged in away that would prevent its further function and re-use;
- e. it is capable of being emptied, unloaded, refilled or reloaded

while maintaining the quality and safety of the packaged product and ensuring compliance with the applicable safety and hygiene requirements, including those on food safety;

- f. it can be reconditioned in accordance with Annex VI, Part B of Regulation 2025/40 while maintaining its ability to perform its intended function;
- g. it allows for affixing of labels and the provision of information on the properties of that product and on the packaging itself, including any relevant instructions and information for ensuring safety, adequate use, traceability and shelf-life of the product;
- h. it can be emptied, unloaded, refilled or reloaded without risk to the health and safety of those responsible for doing so; and
- i. it fulfils the requirements specific to recyclable packaging set out in Article 6 of Regulation 2025/40, so that it can be recycled when it becomes waste.

FOCUS: RE-USE TARGETS ⁴³

Targets calculated for a calendar year

Who	When	What
1. Economic operators using packaging to transport products within the EU – including through e-commerce – in the form of pallets, collapsible plastic boxes, boxes, trays, plastic crates, intermediate bulk containers, dry bulk containers, drums and jerry cans of any size and material (including flexible formats), or pallet wrapping or strapping for stabilising and protecting products placed on pallets during transport.	From 1 January 2030.	They shall ensure that at least 40% of such packaging used is packaging that can be reused within a re-use system.



Who	When	What
2. Economic operators that use the packaging referred to in point (1).	From 1 January 2040.	They must use at least 70% of the packaging referred to in point (1) in a reusable format within a re-use system.
3. Economic operators who use packaging in the formats referred to in point (1) for transport or sale used to transport products within the EU between different sites where the operator carries out its activities or between any of the sites where the operator carries out its activities and the sites of any related or associated undertakings (see point (1) of section 2.7.5 “Exemptions and derogations”).	From 1 January 2030.	They shall ensure that 100% of such packaging used is packaging that can be reused within a re-use system.
4. Economic operators who use packaging (in the formats referred to in point (1)) to deliver products to another economic operator within the same Member State (see point (2) of section 2.7.5 “Exemptions and derogations”).	From 1 January 2030.	They shall ensure that such packaging can be reused within a re-use system.
5. Economic operators who use grouped packaging in the form of boxes, excluding cardboard, used outside of sales packaging to group a certain number of products in order to create a stock-keeping or distribution unit.	From 1 January 2030.	They shall ensure that at least 10% of such packaging is packaging that can be reused within a re-use system.
6. Economic operators that use the packaging referred to in point (5).	From 1 January 2040.	They must use at least 25% of the packaging referred to in point (5) in a reusable format within a re-use system.
7. Final distributors who make alcoholic and non-alcoholic beverages in sales packaging available to consumers on the territory of a Member State.	From 1 January 2030.	They must ensure that at least 10% of such products are made available in packaging that can be reused within a re-use system.



Who	When	What
8. Economic operators who make alcoholic and non-alcoholic beverages available to consumers in packaging for sale on the market within the territory of a Member State.	From 1 January 2040.	They must make at least 40% of such products available in packaging that can be reused within a re-use system.
9. Final distributors operating in the hotel, restaurant and catering sector that use take-away packaging (Article 33, paragraph 5 of Regulation 2025/40).	From 2030.	They must offer 10% of products for sale in a reusable packaging format.

2.7.5 Exemptions from the measure



EXEMPTIONS AND DEROGATIONS

- By way of derogation from the re-use target set out in point (1) of the table “Focus: Re-use targets”:

! ATTENTION:

This derogation is equivalent to a 100% re-use target.

- economic operators using packaging for transport or packaging for sale used for the transport of the products listed in point (1) of the table above, within the EU between different sites where the operator carries out its activities or between the sites where the operator carries out its activities and the sites of any other related or associated company, (as defined in Article 3 of the Annex to Recommendation 2003/361/CE) from 1 January 2030, shall ensure that such packaging is reusable within a re-use system ^{44 45} ;
- economic operators using transport packaging or sales packaging referred to in point (1) of the table “Focus: Re-use targets”, in order to deliver products to another economic operator within the same Member State, from 1 January 2030, shall ensure that such packaging is reusable within a re-use system ⁴⁶ .

⁴⁴

Please refer to Article 29, paragraph 2 of Regulation 2025/40.

⁴⁵

The delegated act of 25 February 2026 exempted stretch wrappings and straps used to secure loads on pallets for transport from the 100% re-use requirement originally established in Regulation 2025/40 for specific intra-company and domestic operations.

⁴⁶

Please refer to Article 29, paragraph 3 of Regulation 2025/40.

- The re-use obligations for transport or sales packaging used for transport will not apply to packaging:
 - used for the transport of dangerous goods within the meaning of Directive 2008/68/EC;
 - used for the transportation of large-scale machinery, equipment and commodities for which packaging is custom-designed to fit the individual requirements of the economic operator that made the order;
 - in flexible format that is used for transport and that is in direct contact with food and feed as defined in Article 2 and in Article 3, point (4) of Regulation (EC) 178/2002, or with food ingredients as defined in Article 2, paragraph 2, point (f) in Regulation (EU) 1169/2011;
 - in the form of cardboard boxes ⁴⁷ .
- The re-use targets set for alcoholic and non-alcoholic beverage packaging will not apply to ⁴⁸ :
 - beverages considered highly perishable in accordance with Article 24 of Regulation (EU) 1169/2011, as well as to milk and milk products listed in Annex I, Part XVI, of Regulation (EU) 1308/2013 and plant-based milk substitutes falling within CN codes 2202 9911 and 2202 9915 of the Combined Nomenclature set out in Annex I to Regulation (EEC) 2658/87;
 - the categories of grapevine products listed in points (1), (3) to (9), (11), (12), (15), (16) and (17) of Part II of Annex VII to Regulation (EU) 1308/2013;
 - aromatised wine products as defined in Regulation (EU) 251/2014;
 - products that are similar to wine products and aromatised wine products and that are obtained from fruit other than grapes and vegetables, and other fermented beverages falling within CN code 2206 00;
 - alcohol-based spirituous beverages corresponding to CN heading 2208.
- Final distributors of alcoholic and non-alcoholic beverage packaging will be exempt from achieving the reuse targets if, during a calendar year, they have a sales area of no more than

⁴⁷

Please refer to Article 29, paragraph 4 of Regulation 2025/40.

⁴⁸

Please refer to Article 29, paragraph 7 of Regulation 2025/40.

100 m². On the basis of the special conditions of final distribution and some manufacturing sectors, even at national level, the Commission is empowered to adopt delegated acts to amend the sales area threshold ⁴⁹.

› Member States may exempt final distributors from the obligation to achieve the reuse targets for packaging of alcoholic and non-alcoholic beverages if their sales area is located on an island with fewer than 2,000 inhabitants or in a municipality with a population density of less than 54 inhabitants/km². However, these obligations apply to all settlements/localities with more than 5,000 inhabitants. ⁵⁰

› Member States may allow final distributors to form pools for the purpose of meeting the re-use obligations.

› Economic operators shall be exempt from the obligation to meet the re-use targets if, during that calendar year, they:

- made not more than 1,000 kg of packaging available on the market within the territory of a Member State; and
- fall within the definition of micro-enterprise in accordance with the rules set out in Recommendation 2003/361/EC applicable on 11 February 2025. ⁵¹

On the basis of the special conditions of final distribution and of some manufacturing sectors, including at national level, the Commission is empowered to adopt delegated acts to amend the threshold set out in point (a).

› Member States may exempt economic operators from the re-use obligations for a period of 5 years under the following conditions:

a. the exempting Member State reaches 5 percentage points above the targets for recycling of packaging waste per material to be achieved by 2025 and is expected to reach 5 percentage points above the 2030 target according to the report published by the Commission 3 years before that date;

b. the Member State granting the exemption is on track to achieve its waste prevention targets set out in Article 43

⁴⁹

Please refer to Article 29, paragraph 10 of Regulation 2025/40.

⁵⁰

Please refer to Article 29, paragraph 11 of Regulation 2025/40.

⁵¹

Please refer to Article 29, paragraph 13 of Regulation 2025/40.

and can demonstrate that it has achieved at least 3% waste prevention by 2028 compared to the 2018 baseline scenario;

c. economic operators have adopted a waste prevention and recycling business plan that contributes to the achievement of the waste prevention and recycling targets.

The 5-year period may be renewed by the Member State where the conditions are met ⁵².

2.7.6 Means of verification – EU declaration of conformity



In order to demonstrate that packaging is “reusable”, it will be necessary to comply with the requirements set out in the delegated act to be adopted by 12 February 2027, which will establish a minimum number of rotations.

Compliance with the requirements on “re-use” shall be demonstrated by the technical information on packaging set out in Annex VII to Regulation 2025/40 (see Chapter 4.1 on the conformity assessment procedure).



NOTE

› Economic operators who make reusable packaging available for the first time in the territory of a Member State shall ensure the existence of a system for the re-use of such packaging, including an incentive to ensure collection in that Member State, which meets the requirements set out in Annex VI to Regulation 2025/40. This provision may be considered to be met by existing re-use systems that may already be in place and operational in Member States ⁵³.

› Economic operators that make use of reusable packaging shall participate in one or more re-use systems and shall ensure that the re-use systems within which the reusable packaging can be re-used comply with the requirements laid down in Part A of Annex VI to Regulation 2025/40 (Requirements for re-use systems) and that such packaging is reconditioned in accor-

⁵²

Please refer to Article 29, paragraph 14 of Regulation 2025/40.

⁵³

Article 26 of Regulation 2025/40 establishes obligations regarding reusable packaging.

dance with Part B of [Annex VI to Regulation 2025/40](#) prior to offering it again for use by end users (**Reconditioning**)⁵⁴.

- › Economic operators that make use of reusable packaging may appoint a third party to be responsible for one or more mutualised re-use systems.
- › Where economic operators have appointed a third party as referred to in the previous point, the obligations set out in Article 27 shall be met by that third party on their behalf.
- › Economic operators that make use of reusable packaging in closed loop systems in accordance with the requirements in [Annex VI](#) of Regulation 2025/40 shall be required to return the packaging to one or more of the collection points identified by the system participants and approved by the system operator.
- › Final distributors operating in the hotel, restaurant and catering sector who use take-away packaging for hot/cold beverages or ready-to-eat food intended for immediate consumption shall also inform final consumers at the point of sale, by means of clearly visible and legible information panels or signs, of the possibility of obtaining the goods in reusable packaging and shall offer the goods intended to fill reusable packaging at prices not higher and under conditions not less favourable than the sales unit consisting of the same goods and single-use packaging.
- › The final distributors referred to in the previous points are exempt from the application of Article 33 of Regulation 2025/40 if they fall within the definition of micro-enterprises set out in [Commission Recommendation 2003/361/EC](#).

⁵⁴

Article 27 of Regulation 2025/40 establishes obligations relating to re-use systems.

2.7.7 Summary table

Reusable packaging

Regulatory reference

Article 11.

Obligated party

Manufacturers or importers or distributors.

Deadline (by when)

From 11 February 2025.

Obligation

Reusable packaging.

Criterion

Please refer to Article 11, paragraph 1 of Regulation 2025/40.

Means of verification

Annex VII – The manufacturer shall complete a written declaration of conformity. Please refer to section 2.7.6.

Exemptions

Please refer to section 2.7.5 “Exemptions and derogations”.

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

FURTHER READING**Re-use targets****Regulatory reference**

Article 29 – Re-use targets.

Obligated party

Economic operators who use transport packaging or sales packaging used to transport products or who use grouped packaging in the form of boxes to group a certain number of products to create a stock-keeping or distribution unit, and final distributors who make alcoholic and non-alcoholic beverages available to consumers in sales packaging.

Deadline (by when)

From 1 January 2030 and 1 January 2040, as applicable (see table “Focus: Re-use targets”).

Obligation

The economic operators shall ensure that packaging is reusable as part of a re-use system.

Criterion

Please refer to Article 11 of Regulation 2025/40.

Means of verification

Annex VII – The manufacturer shall complete a written declaration of conformity. Please refer to [Chapter 4.1](#) “Declaration of conformity”.

Exemptions

Please refer to section 2.7.5 “Exemptions and derogations”.

**Penalties**

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

FURTHER READING**Re-use for the take-away sector****Regulatory reference**

Article 33 – Re-use offer obligation for the take-away sector.

Obligated party

Final distributors operating in the hotel, restaurant and catering sector who provide hot or cold beverages and products intended for immediate consumption.

Deadline (by when)

- > From 12 February 2028, they shall offer consumers the option of obtaining products in reusable packaging as part of a re-use system;
- > From 2030, they must offer 10% of the products they sell in a reusable packaging format.

Obligation

Ensure that packaging is reusable as part of a re-use system.



Criterion

Please refer to Article 11 of Regulation 2025/40.

Means of verification

Annex VII – The manufacturer shall complete a written declaration of conformity. Please refer to [Chapter 4.1](#) “Declaration of conformity”.

Exemptions

Micro-enterprises.

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

2.7.8 **FAQ** Reusable packaging



Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 – FAQ](#)):

2.7|F1 *Are there incentives for reusable packaging? If so, what are they?*

2.7|F2 *Is there a re-use requirement for “contact-sensitive” materials, such as flexible plastic packaging intended to come into contact with food?*

2.7|F3 *What will be the targets and obligations for the use of reusable packaging in Italy? And by when?*

2.7|F4 *How should Article 29.6 on re-use targets be interpreted? Are vending machines included or excluded? If included, how will those offering hot drinks in paper cups be managed?*

2.7|F5 *Article 29, paragraphs 1, 2 and 3, sets out certain re-use obligations for transport or sales packaging used to transport products. Considering the technological challenges associated with the solutions currently available and in line with the need to ensure stringent quality KPIs, have further considerations been made regarding the “achievability” of these targets?*

2.7|F6

Article 29, paragraph 6, sets stringent re-use targets for “final distributors” from 1 January 2030, as well as aspirational targets for “economic operators” from 1 January 2040. In this context, Article 29 paragraph 14 highlights the possibility for Member States to exempt “economic operators” from the obligations laid down. Should this possibility of exemption be interpreted as applicable to all the above targets, or only to those valid from 1 January 2040?

2.7|F7

Which articles of Regulation 2025/40 concern the issue of “Re-use”?

2.8 Refill

The text of this section refers to the content of Articles 28 and 32 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulatory reference

Article 28.

Deadlines for businesses

From
12 February

Final distributors in the hotel sector (excluding micro-enterprises), restaurant sector and catering sector that use take-away packaging shall provide consumers with a system that allows them to bring their own container **to be filled with cold or hot beverages or ready-prepared food.**

2027

From
1 January

Final distributors with a **sales area of more than 400 m²** shall endeavour to allocate **10%** of that sales area to refill stations for both food and non-food products.

2030

Design requirement



REFILL
Refill

Timetable for the European Commission



2.8.1 Objective

In order to encourage the prevention of packaging waste, the refilling of packaging should be understood as a specific waste prevention measure that counts towards, and is necessary for, meeting the prevention targets set out in Regulation 2025/40.

2.8.2 Scope

The measure applies to final distributors with a sales area of more than 400 m² in relation to refill stations for both food and non-food products.

! ATTENTION: This measure does not apply to all economic operators.

Specific refill obligations are also established for final distributors operating in the take-away food and beverage sector and carrying out commercial activities in the hotel, restaurant and catering sector using take-away packaging.

2.8.3 Deadlines and timeframes

From 1 January 2030, final distributors with a sales area of more than 400 m² shall endeavour to allocate 10% of that sales area to refill stations for both food and non-food products ⁵⁵.

By 12 February 2027:

- a. final distributors that conduct their business activity in the hotel, restaurant and catering sector and that make cold or hot beverages in take-away packaging available on the territory of a specific EU Member State shall provide a system for consumers to bring their own container to be filled;
- b. final distributors that conduct their business activity in the hotel, restaurant and catering sector and that make ready-prepared food in take-away packaging available on the territory of a Member State shall provide a system for consumers to bring their own container to be filled ⁵⁶.

⁵⁵

Please refer to Article 28, paragraph 5 of Regulation 2025/40.

⁵⁶

Please refer to Article 32, paragraph 1 of Regulation 2025/40.

Final distributors shall offer the goods intended to fill the container brought by the consumer at prices no higher and on terms no less favourable than the sales unit consisting of the same goods and single-use packaging, and shall also inform final consumers at the point of sale, by means of clearly visible and legible information panels or signs, of the possibility of obtaining the goods in a refillable container provided by the consumer.

2.8.4 Content of the measure

Where economic operators offer the possibility to purchase products through refill, they shall inform end users of:

- a. the types of containers that can be used to purchase the products on offer through refill;
- b. the hygiene standards for refill;
- c. the responsibility of the end user in relation to health and safety regarding the use of the containers referred to in point (a).

The rules for refill shall be regularly updated and be either clearly displayed on the premises or otherwise provided to end users.

Economic operators who offer the possibility to purchase products through refill shall ensure that refill stations comply with the requirements laid down in Part C of Annex VI of Regulation 2025/40 (Requirements for refill) and with any requirements laid down in other Union legal acts for the sale of products through refill.

Economic operators who offer the possibility to purchase products through refill shall ensure that if packaging or containers are offered to the end users at refill stations, that packaging and those containers are not provided free of charge if they do not meet the requirements laid down in Annex VI of Regulation 2025/40 or are provided as apart of a deposit and return system.

Economic operators may refuse to fill a container provided by the end user if it does not comply with the requirements communicated by the economic operator, in particular if they consider it unhygienic or unsuitable for the food or drink sold.

Economic operators shall bear no liability for any hygiene or food safety issues that arise from the use of containers provided by the end user.

2.8.5 Exemptions from the measure

There are no exemptions for the “Refill” sustainability measure because, unlike other measures, it is **not** mandatory for all economic operators.

2.8.6 Means of verification

Refilling is **not** covered by the conformity assessment procedure.



NOTE

- › Where consumers bring their own container to be filled, final distributors (who conduct their business activity in the hotel, restaurant and catering sector) shall offer them the products at no higher cost and under no less favourable conditions than when selling the sales unit consisting of the same product and single-use packaging. ⁵⁷
- › Final distributors shall inform consumers at the point of sale, through clearly visible and legible information boards or signs, about the possibility of obtaining the goods in a refillable container provided by the consumer ⁵⁷.
- › Where economic operators offer the possibility to purchase products through a refill system, they should ensure that their refill stations meet certain requirements in order to ensure the health and safety of consumers. In this context, where the consumers use their own containers, the economic operators should inform consumers about the conditions for the safe refill and use of those containers. In order to encourage refill, economic operators should not provide packaging that is free of charge or that is not part of a deposit and return system at the refill stations. Economic operators should be exempt from liability for food safety problems that could arise from the use of containers provided by consumers ⁵⁸.

⁵⁷

Please refer to Article 32, paragraph 2 of Regulation 2025/40.

⁵⁸

Please refer to Recital 90 of Regulation 2025/40.

REQUIREMENTS FOR REFILL

Refill stations shall satisfy the following requirements:

- a. the refill stations must display clear and precise information on:
 1. the hygiene rules that the end user’s container must comply with in order to use the refill station;
 2. the types and features of containers that can be used to purchase products through refill;
 3. the contact details of the final distributor to ensure compliance with hygiene standards under applicable law;
- b. the refill stations must contain a measuring device or provide similar means to ensure that the end user purchases a specific quantity of product;
- c. the price paid by end users does not include the weight of the container ⁵⁹.

⁵⁹

Please refer to Annex VI, Part C, of Regulation 2025/40.

2.8.7 Summary table



Refill

Regulatory reference

Article 28 Refill obligations; Article 32 Refill obligation for the take-away food and beverage sector

Obligated party

Final distributors.

Deadline (by when)

- › From 1 January 2030, final distributors with a sales area of more than 400 m² shall endeavour to allocate 10% of that sales area to refill stations for both food and non-food products;
- › By 12 February 2027, final distributors who conduct their business activity in the hotel, restaurant and catering sector and offering hot or cold beverages or ready-made food shall provide a system for consumers to bring their own container to be filled.

Obligation

Refillable packaging and refill station obligation.

Criterion

Please refer to the point above: “Requirements for refill” within the “Note” area.

Penalties

Responsibility of each EU Member State.

Checks

Responsibility of each EU Member State.

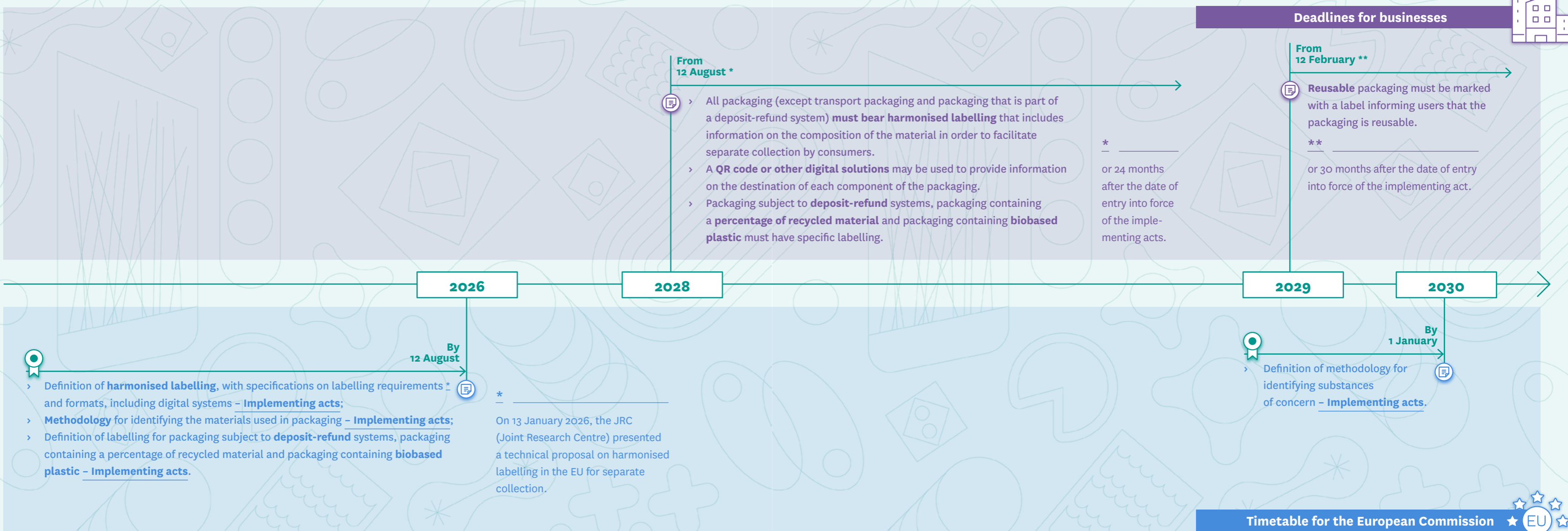
3 Other obligations

3.1 Labelling of packaging

The text of this section refers to the content of Article 12 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulatory reference
Article 12.

Delegated acts or implementing acts



Design requirement

LABELLING
Labelling of packaging



3.1.1 Objective

To facilitate the correct disposal of packaging waste by consumers through harmonised labelling of packaging at European level.

3.1.2 Scope

All packaging placed on the market, except for the exemptions indicated in section 3.1.5.

3.1.3 Deadlines and timeframes

The obligation will take effect on 12 August 2028, provided that the following implementing acts are adopted by 12 August 2026:

- › act defining a **harmonised label** and harmonised specifications for labelling requirements and formats;
- › act defining a methodology for identifying the materials of which packaging is composed using **digital marking technologies**.

In the event of a delay in the adoption of the aforementioned implementing acts, the labelling obligation shall apply 24 months after the entry into force of those acts.

3.1.4 Content of the measure

Packaging placed on the market must be marked with a label containing information on the materials it is made of, with the aim of facilitating the correct disposal of packaging waste by consumers. The label shall consist of pictograms (to be defined in the relevant implementing act) and be easily understandable, even for people with disabilities. For **compostable packaging** ⁶⁰, the label shall indicate that the material is compostable, that it is not suitable for home composting, and that compostable packaging must not be disposed of in nature.

⁶⁰

Referred to in Article 9, paragraph 1 and, where applicable, paragraph 2 of Regulation 2025/40.

⁶¹

Please refer to Article 12, paragraph 1 of Regulation 2025/40.

⁶²

Please refer to Article 12, paragraph 6 of Regulation 2025/40.

⁶³

Please refer to Article 12, paragraph 7 of Regulation 2025/40.

With the exception of e-commerce packaging, this obligation shall not apply to transport packaging or packaging that is part of a deposit and return system.

In addition to the harmonised label, economic operators may affix a **QR code or other type of digital data carrier** to the packaging containing information on the **destination of each separate component** of the packaging in order to facilitate sorting by consumers. ⁶¹

By 12 August 2026, the EU Commission shall adopt implementing acts to define:

- › a harmonised label and harmonised specifications for labelling requirements and formats, including when provided by digital means ⁶²;
- › a methodology for identifying the materials of which packaging is composed using digital marking technologies. ⁶³

Packaging placed on the market and containing substances of concern shall be marked using standardised, open digital marking technologies in accordance with the methodology to be defined by the Commission by 1 January 2030 through specific implementing acts. That methodology shall ensure that the marking includes at least the name and concentration of the substance of concern present in each material in a packaging unit.

3.1.5 Exemptions from the measure

The labelling requirements shall not apply to immediate or outer packaging as defined in Regulations (EU) 2017/745 on medical devices, (EU) 2017/746 on in vitro diagnostic medical devices, (EU) 2019/6 on veterinary medicinal products, and Directive 2001/83/EC on medicinal products for human use, if there is no space on the packaging due to other labelling requirements defined in those legal acts, or if the labelling of the packaging could jeopardise the safe use of medicinal products for human use or of veterinary medicinal products.

Furthermore, transport packaging and packaging that is part of a deposit and return system shall not be marked with the label containing information on the materials of composition.

3.1.6 Means of verification – EU declaration of conformity



None currently planned.



NOTE

- › Packaging subject to deposit and return systems shall be marked with a clear and unambiguous label. In addition to the national label, packaging may be marked with a harmonised colour label established in the relevant implementing act adopted pursuant to paragraph 6. Member States may require that packaging that is subject to deposit and return systems be marked with that harmonised colour label, provided that does not lead to distortions on the internal market or trade barriers for products from other Member States (Article 12, paragraph 1).
- › Reusable packaging placed on the market from 12 February 2029 or 30 months from the date of entry into force of the implementing act adopted pursuant to paragraph 6, whichever is the latest, shall bear a label informing users that the packaging is reusable. Further information on reusability – including the availability of a local, national or Union-wide re-use system and information on collection points – may be made available through a QR code or other type of standardised, open, digital data carrier that facilitates the tracking of the packaging and the calculation of trips and rotations (or, if that calculation is not feasible, an average estimation). In addition, reusable sales packaging shall be clearly identified at the point of sale and appropriately distinguished from single-use packaging (Article 12, paragraph 2).
- › The requirement to carry a label and QR code, or other type of open and standardised digital data carrier, shall not apply to open-loop systems (i.e. a re-use system in which reusable packaging circulates amongst an unspecified number of system participants and the ownership of the packaging changes at one or more points in the re-use process) which do not have a system operator in accordance with Annex VI, i.e. a natural or legal person who participates in and operates a re-use system.

- › If plastic packaging with a minimum content of recycled material is placed on the market from 12 August 2028⁶⁴ and is marked with a label containing information on the share of recycled content, that label – and, where applicable, the QR code or other type of digital data carrier – shall comply with the specifications set out in the relevant implementing act adopted by the EU Commission on the harmonised label⁶⁵, and shall be based on the methodology for calculating and verifying the share of recycled content.⁶⁶ Where packaging is marked with a label containing information on the share of biobased plastic content, that label shall comply with the specifications set out in the relevant implementing act adopted by the EU Commission on the harmonised label adopted in accordance with Article 12, paragraph 6.⁶⁷
- › Packaging labels and QR codes, or other types of open and standardised digital data carriers, shall be affixed, printed or engraved visibly, legibly and firmly on the packaging, so that they cannot be easily erased. The information shall also be available to end users before they purchase the product in online sales. Where such affixing, printing or engraving is not possible or not warranted on account of the nature and size of the packaging, the label, QR code or other standardised, open, digital data carrier may be affixed to the grouped packaging. Where this is not possible or not warranted on account of the nature and size of the packaging or where it is relevant to provide for non-discriminatory access to information for vulnerable groups (particularly visually impaired persons), the labels may be provided via a single electronically readable code or other type of data carrier.
- › The information contained in the labels and QR codes or other types of digital data carriers governed by Article 12 shall be made available in one or more languages easily understood by end users, as determined by the Member State in which the packaging is to be made available on the market.
- › Where information is provided by electronic means the following requirements shall apply:
 - a. adequate and relevant personal data shall be collected only for the limited purpose of giving the user access to relevant compliance information referred to in paragraphs 1, 2 and

⁶⁴

In the event of delay in the adoption of the implementing act referred to in Article 12, paragraph 6, the labelling requirement shall apply 24 months after the entry into force of that act.

⁶⁵

In accordance with Article 12, paragraph 6 of Regulation 2025/40.

⁶⁶

Referred to in Article 7, paragraph 8 of Regulation 2025/40.

⁶⁷

Please refer to Article 12, paragraph 4 of Regulation 2025/40.

4 of Article 12 in respect of Article 5, paragraph 1, of [Regulation \(EU\) 2016/679](#);

b. the information shall not be displayed with other information intended for sales or marketing purposes.

- › Where Union law requires information on the packaged product to be provided via a data carrier, a single data carrier shall be used for providing the information required for the packaged product and for the packaging, and both shall be easily distinguishable.
- › Without prejudice to requirements concerning other harmonised EU labels, economic operators shall not provide or display labels, marks, symbols or inscriptions that are likely to **mislead or confuse consumers or other end users** with respect to the **sustainability requirements for packaging**, other packaging characteristics or packaging waste management options for which harmonised labelling has been laid down in Regulation 2025/40. The Commission shall, where appropriate, adopt guidelines in order to clarify aspects that are likely to mislead or confuse consumers or other end users.
- › By 12 February 2027, packaging included in an **extended producer responsibility scheme** may be identified throughout the territory of the Member States in which that scheme or system applies. Such identification shall be achieved only by means of a corresponding symbol in a QR code or other standardised, open, digital-marking technology in order to indicate that the producer fulfils its extended producer responsibility obligations. That symbol shall be clear and unambiguous and shall not mislead consumers or other end users as to the recyclability or reusability of the packaging.
- › Packaging covered by a deposit and return system (other than that referred to in Article 50, paragraph 1 of Regulation 2025/40, concerning single-use plastic beverage bottles and single-use metal beverage containers) may, under national law, be identified by means of a corresponding symbol throughout the territory in which that scheme or system applies. That symbol shall be clear and unambiguous and shall not mislead consumers or end users about the packaging recyclability and reusability in

the Member States where it is returned. Member States shall not prohibit the affixing of labels related to deposit and return systems in place in other Member States.

- › Packaging referred to in Article 12 of Regulation 2025/40 which is manufactured or imported before the expiry of the deadlines specified in paragraphs 1, 2 and 4, and which does not comply with those paragraphs, may be placed on the market for up to 3 years from the date of entry into force of the labelling requirements laid down in paragraphs 1, 2 and 4.

3.1.7 **FAQ** Labelling of packaging



Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 - FAQ](#)):

3.1|F1

What is different compared to the environmental labelling of packaging intended for the B2C channel currently required in Italy?

3.2 Restrictions on use of certain packaging formats

The text of this section refers to the content of Article 25 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulatory reference

Article 25.

Deadlines for businesses



From 1 January

- G The following **single-use plastic packaging will be prohibited**:
 - › multipack packaging for bottles, cans, tins, jars and containers (excluding those intended to facilitate handling). FOR EXAMPLE: **film**;
 - › for unprocessed fruit and vegetables weighing less than 1.5 kg. FOR EXAMPLE: **nets, bags, trays**;
 - › for food and beverages filled and consumed in the catering/hospitality sector. Non-plastic flexible packaging is exempt. FOR EXAMPLE: **sachets, tubs, trays**;
 - › for individual portions, used in the catering sector. FOR EXAMPLE: **individual portion packaging for condiments, preserves, sauces or sugar**;
 - › in the hospitality and accommodation sectors for products intended for individual bookings. FOR EXAMPLE: **shower gel bottles and sachets**

2027

2030

2032

By 12 February

Publication of **guidelines** clarifying the content of Annex V, with concrete examples of exemptions to the restrictions.

By 12 February

- The European Commission will assess:
- › the positive environmental impact of the restrictions and derogations;
 - › the need to review the provisions and Annex V;
 - › the appropriateness of introducing new restrictions and/or modifying existing ones.

Timetable for the European Commission



Design requirement

G **RESTRICTIONS**
Restrictions on use of certain packaging formats

3.2.1 Objective

To prohibit the placing on the market of certain packaging formats and materials in relation to particular uses.

Economic operators may not place on the market packaging in the formats and materials and for the uses listed in [Annex V to Regulation 2025/40](#).

3.2.2 Scope

Single-use plastic grouped packaging; single-use plastic packaging for fresh, unprocessed fruit and vegetables; single-use plastic packaging for food and beverages, condiments, preserves, sauces, coffee creamer and sugar in the hotel, restaurant and catering sector; ultra-lightweight plastic bags; single-use packaging for cosmetics and hygiene products in the hospitality sector.

3.2.3 Deadlines and timeframes

From 1 January 2030, economic operators will not be able to place packaging on the market in the formats and for the uses listed in [Annex V of Regulation 2025/40](#) shown in the table below in section 3.2.4 “Content of the measure”.

3.2.4 Content of the measure

Restrictions on the use of certain packaging formats are detailed in [Annex V of Regulation 2025/40](#), according to the table below:

ANNEX V RESTRICTIONS ON USE OF CERTAIN PACKAGING FORMATS

	Packaging format	Restricted use	Illustrative example
1.	Single-use plastic grouped packaging	Single-use plastic packaging used at the point of sale to group goods sold in bottles, cans, tins, pots, tubs, and packets designed as convenience packaging to enable or encourage consumers to purchase more than one product. This excludes grouped packaging necessary to facilitate handling.	Collation films, shrink wrap
2.	Single-use plastic packaging for unprocessed fresh fruit and vegetables	Single-use plastic packaging for less than 1,5 kg pre-packed fresh fruit and vegetables. Member States may set up exemptions in respect of this restriction if there is a demonstrated need to avoid water loss, or turgidity loss, microbiological hazards or physical shocks, oxidation, or if there is no other possibility to avoid commingling of organic fruits and vegetables with non-organic fruits and vegetables in compliance with requirements in Regulation (EU) 2018/848 of the European Parliament and of the Council ⁽¹⁾ on certification or labelling, without entailing disproportionate economic and administrative costs.	Nets, bags, trays, containers
3.	Single-use plastic packaging	Single-use plastic packaging for foods and beverages filled and consumed within the premises in the HORECA sector, which include all eating areas inside and outside a place of business, covered with tables and stools, standing areas, and eating areas offered to the end users jointly by several economic operators or a third party for the purpose of food and drinks consumption. Establishments in the HORECA sector that do not have access to drinking water are exempted.	Trays, disposable plates and cups, bags, boxes
4.	Single-use plastic packaging for condiments, preserves, sauces, coffee creamer, sugar, and seasoning in HORECA sector	Single-use plastic packaging in the HORECA sector, containing individual portions or servings, used for condiments, preserves, sauces, coffee creamer, sugar and seasoning, except in the following cases: (a) such packaging is provided together with take-away ready-prepared food intended for immediate consumption without the need of any further preparation; (b) such packaging is required to ensure safety and hygiene in establishments where there is a medical requirement for individualised care, such as hospitals, clinics or nursing homes.	Sachets, tubs, trays, boxes

⁽¹⁾ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

	Packaging format	Restricted use	Illustrative example
5.	Single-use accommodation sector packaging intended for an individual booking	Single-use packaging for cosmetics, hygiene and toiletry products for the use in the accommodation sector, as described in NACE Rev. 2 – Statistical classification of economic activities, intended for an individual booking only and intended to be discarded before the next guest arrives.	Shampoo bottles, hand and body lotion bottles, sachets around bar soap
6.	Very lightweight plastic carrier bags	Very lightweight plastic carrier bags, except for very lightweight plastic carrier bags required for hygiene reasons or provided as sales packaging for loose food when this helps to prevent food wastage.	Very thin bags provided for bulk groceries

Member States may:

- › maintain restrictions adopted before 1 January 2025 on the placing on the market of packaging in the formats and for the uses listed in [Annex V](#) but made from materials not listed in [Annex V](#);
- › exempt compostable packaging from these prohibitions.

3.2.5 Exemptions from the measure



The above restrictions on use shall not apply to packaging for which Member States have already introduced compostability requirements prior to 12 August 2026.

Member States may exempt micro-enterprises as defined in [Recommendation 2003/361/EC](#) applicable on 11 February 2025 from the application of [Annex V](#), point (3) of Regulation 2025/40, if it has been demonstrated that it is not technically feasible to forego packaging or to obtain access to the infrastructure that is necessary for the functioning of a re-use system.

3.2.6 Means of verification



None currently planned.



NOTE

- › By 12 February 2027, the Commission shall publish guidelines, in consultation with Member States and the European Food Safety Authority, which explain [Annex V](#) of Regulation 2025/40 in more detail, including examples of the packaging formats in scope, and any exemptions from the restrictions, and provide a non-exhaustive list of fruits and vegetables that are excluded from point (2) of [Annex V](#) of Regulation 2025/40.
- › By 12 February 2032, the Commission shall assess the positive environmental impact of the restrictions and derogations of such exemptions from such restrictions, and shall take into account the availability of alternative packaging solutions that meet safety and hygiene requirements applicable to contact-sensitive packaging. On the basis of that assessment, the Commission shall, with the objective of reducing packaging waste, review the provisions of Article 25 and [Annex V](#) of Regulation 2025/40 to adapt them to technical and scientific progress. On the basis of that review, the Commission shall assess the appropriateness of establishing new restrictions on the use of specific packaging formats and the relevance of maintaining the derogations and exemptions set out in Article 25 of Regulation 2025/40, and, where appropriate, shall present a legislative proposal.

3.2.7

FAQ**Restrictions on use of certain packaging formats**

Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 – FAQ](#)):

3.2|F1

Does the ban on using plastic for packaging fruit and vegetables weighing less than 1.5 kg also apply to recycled/recyclable plastics, such as PET, R-PET? Will there be any exceptions to the use of plastics in fruit and vegetables for packaging weighing less than 1.5 kg?

3.2|F2

With regard to the timetable for compliance with the reduction in packaging, which single-use materials will be prohibited?

3.2|F3

With regard to single-use products/hotel amenities (shampoo and shower gel bottles and sachets, sewing kits, shower caps, etc.) intended for the hospitality sector, are there any restrictions, limits or bans on marketing/production? If so, from when?

3.2|F4

Restrictions in Annex V: what is meant by “facilitate handling”? Does this also apply to consumers? Will the restriction also apply to plastic film for multipacks?

3.2|F5

Can single-dose sachets used in cosmetics outside the hospitality sector continue to be marketed?

3.2|F6

For fresh fruit and vegetables, plastic packaging is to be abolished. When will this come into force?

3.2|F7

Article 25 of Regulation 2025/40 provides for restrictions on the use of certain packaging formats, referring to a list of packaging formats and uses that may not be placed on the market from 1 January 2030, as set out in Annex V. Among these, single-use plastic grouped packaging is excluded if it is “necessary to facilitate handling”. Is it possible to have further information on which plastic films for multipacks will be subject to this prohibition?

4 Further reading

4.1 EU declaration of conformity

Objective



The EU declaration of conformity certifies that **compliance with the sustainability and labelling requirements set out in Articles 5 to 12 of Regulation 2025/40** has been demonstrated: ⁶⁸

- > Requirements for substances in packaging (Article 5);
- > Recyclable packaging (Article 6);
- > Minimum recycled content in plastic packaging (Article 7);
- > Biobased feedstock in plastic packaging (Article 8);
- > Compostable packaging (Article 9);
- > Packaging minimisation (Article 10);
- > Reusable packaging (Article 11);
- > Labelling of packaging (Article 12).

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Please note that no declaration of conformity is required for refilling requirements and restrictions on the use of certain packaging formats.

Content and timeline – Declaration of conformity

Requirements set out in Regulation 2025/40	Required from	Notes – Next steps
Requirements for substances in packaging – Article 5	2026	Report on the presence of substances of concern in packaging.
Recyclable packaging – Article 6	2030	Pending delegated acts by 2028.
Minimum recycled content in plastic packaging – Article 7	2030	Pending implementing acts by 2026.
Biobased feedstock in plastic packaging – Article 8	TBD – Pending details from the EU Commission	By 2028, the EU Commission will consider introducing a legislative proposal to establish sustainability requirements for biobased feedstock in plastic packaging.
Compostable packaging – Article 9	2028	Pending harmonised standards in 2026.
Packaging minimisation – Article 10	2030	Pending harmonised standards in 2027.
Reusable packaging – Article 11	2025 ⁶⁹	Pending the delegated act by 2027.
Labelling of packaging – Article 12	2028	Pending implementing acts by 2026.

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Attention: This is not a regulation that is already “in force” as we must wait for the delegated act of the European Commission, which will be published by 2027. 2025 is the deadline established by Article 11, paragraph 1 of Regulation 2025/40.

Contents



The EU declaration of conformity:

- › shall be drawn up in accordance with the structure set out in [Annex VIII to Regulation 2025/40](#) ⁷⁰;
- › shall contain the elements specified in the form set out in [Annex VIII to Regulation 2025/40](#);
- › shall be continuously updated;
- › shall be translated into the language or languages required by the Member State in whose market the packaging is placed or made available.

In particular, the documentation referred to in [Annex VII of Regulation 2025/40](#) shall allow for the assessment of:

- a. a general description of the packaging and its intended use;
- b. conceptual design, manufacturing drawings and materials of components;
- c. descriptions and explanations necessary for understanding the drawings, schemes and operation of the packaging;
- d. a list of:
 1. the harmonised standards referred to in Article 36, applied in whole or in part: packaging complying with harmonised standards shall be considered to comply with the requirements of Articles 5 to 12 and Articles 24 and 26;
 2. the common specifications referred to in Article 37, applied in whole or in part;
 3. other relevant technical specifications used for measurement or calculation purposes;
 4. in the event of partly applied harmonised standards and/or common specifications, an indication of the parts which have been applied;
 5. in the event of harmonised standards and/or common specifications not being applied, a description of the solutions adopted to meet the requirements referred to in point (1);
- e. a qualitative description of the how the assessments provided for in Article 6 (recyclability), 10 (packaging minimisation) and 11 (reusability);
- f. test reports.

⁷⁰

The declaration of conformity must be prepared by the operator concerned. Regulation 2025/40 does not provide for a specific or official form or facsimile to be used but indicates, in [Annex VIII](#), the contents of such a document. The economic operator is therefore free to use the format it considers most appropriate for its compilation, subject to any different provisions that may be established by the European Commission.

⁷¹

Based on information that the subject may obtain from the supplier.

By drawing up the EU declaration of conformity, the manufacturer assumes responsibility for the compliance of the packaging with the requirements laid down Regulation 2025/40.

Competent authorities shall control the accuracy of at least part of the declarations of conformity per year, assessed on a risk-based approach and shall take the necessary measures to address non-compliance, such as the withdrawal of non-compliant products from the market.

Summary of the main obligations relating to the declaration of conformity incumbent on the manufacturer, authorised representative, importer and distributor

Obligation	Obligated parties			
	Manufacturer	Authorised representative	Importer	Distributor
Carrying out the conformity assessment procedure and drafting the technical documentation ⁷¹				
Completing the EU declaration of conformity				
Retaining technical documentation and EU declaration of conformity: for 5 years from the date the single-use packaging was placed on the market, and 10 years from the date the reusable packaging was placed on the market				
Submitting all relevant information and documentation to the national authority, to demonstrate the conformity of packaging with the applicable requirements set out in Articles 5 to 12.				

Exemptions and derogations



- › The procedure for assessing the conformity of packaging with the provisions of Regulation 2025/40 shall not apply to **customised transport packaging for medical devices and configurable medical systems** that are to be used in industrial and healthcare environments.
- › In the case of transport packaging, reusable packaging, primary production packaging, grouped packaging, sales packaging or service packaging, where the natural or legal person who has the packaging **designed or manufactured** under their own name or trademark falls within the **definition of a micro-enterprise** set out in [Recommendation 2003/361/EC](#) as applicable on 11 February 2025, and the supplier of the packaging is located in the European Union, **the supplier of the packaging shall be considered the manufacturer** and is therefore subject to the obligations of the manufacturer defined in Article 15 of Regulation 2025/40.
- › **Importers or distributors** shall be considered manufacturers and therefore subject to the obligations of the manufacturer if they **place packaging on the market under their own name or trademark or modify packaging** already placed on the market in a way that it could affect its compliance with the relevant requirements of Regulation 2025/40.



FAQ EU declaration of conformity

Questions related to this section are listed below. The answers, together with the full list of questions, can be found in the dedicated chapter ([Chapter 6 - FAQ](#)):

4.1|F1

Is it correct that the manufacturer of a semi-finished product (PE film for packaging, which will subsequently be laminated to one or more materials by a converter) is NOT required to issue the declaration of conformity required by the Regulation?

4.1|F2

Declaration of conformity: who must draw it up? Must the end user (the packager) request it from the supplier?

4.1|F3

Will companies have to issue a declaration of conformity regarding compliance with the requirements of Regulation 2025/40? Is this also required for medical devices and medicines?

4.1|F4

Will the declaration of conformity to be drawn up in accordance with Annex VII be mandatory from 12 August 2026 (18 months after the entry into force of Regulation 2025/40)?

4.1|F5

The manufacturer “shall only place packaging on the market that complies with the requirements of Articles 5 to 12, following a conformity assessment procedure”. Nevertheless, the definition of “manufacturer” includes anyone who manufactures or has manufactured packaging or packaged products. In the case of a company that places packaged products on the market, is it therefore not necessary to draw up a declaration of conformity?

4.1|F6

In the case of finished products, such as branded products, it is not clearly defined who should be considered the “manufacturer” for the purposes of drawing up the declaration of conformity for packaging. Is it possible to have clarification on this point?

4.1|F7

Who is responsible for checking and verifying the accuracy of declarations of conformity? This is particularly relevant in the specific case of secondary raw materials from outside the EU.

4.2 Plastic carrier bags

Objective

In view of the consistently high levels of consumption of plastic bags and their potential for littering the environment, as well as the inefficient use of resources, it is appropriate to maintain provisions aimed at achieving a consolidated reduction in their consumption, as already provided for in [Directive 94/62/EC](#).

Content of the measure

Member States shall take measures to achieve a sustained reduction in the consumption of lightweight plastic carrier bags on their territory.

A sustained reduction is considered to be achieved if **the annual consumption does not exceed 40 lightweight plastic carrier bags per person**, or the equivalent target in weight, by 31 December 2025 and subsequently by 31 December each year thereafter.

Measures to be taken by Member States to meet such objectives shall take into consideration the environmental impact of lightweight plastic carrier bags when they are manufactured, recycled or disposed of, and their composting properties, durability or specific intended use. Such measures may also include marketing restrictions, provided that they are proportionate and non-discriminatory. Member States may exclude from the obligations very lightweight plastic carrier bags which are required for hygiene purposes or provided as sales packaging for loose food to prevent food wastage. ⁷²

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In order to transpose [Directive 2015/720/EU](#) on the reduction of the use of lightweight plastic carrier bags and to harmonise Italian legislation on the subject, Law 123 of 3 August 2017 amended Part IV of [Legislative Decree 152/2006](#). For further information, please refer to Article 218 paragraph 1; 226 bis and 226 ter of [Legislative Decree 152/2006](#) and the CONAI briefing: <https://www.etichetta-conai.com/documenti/nota-informativa-borse-di-plastica>

4.3 Definition of “micro-enterprise”

Regulation 2025/40 repeatedly exempts “micro-enterprises” from the obligations incumbent on operators. The term “micro-enterprises” is to be understood, pursuant to Article 2 of the Annex to Recommendation 2003/361/EC, as referring to enterprises which:

- › employ fewer than 10 persons and
- › have either an annual turnover or an annual balance sheet total not exceeding €2 million.



In summary, the main exemptions ⁷³ applicable to micro-enterprises are as follows:

- › Exemption from the status of “manufacturer” for micro-enterprises that have packaging or packaged products manufactured or designed by another entity located in the same Member State;
- › Exemption from compliance with the re-use targets set out in Article 29, in the case of micro-enterprises that have made available no more than 1,000 kg of packaging in the territory of a Member State in a calendar year;
- › Exemption from the obligation to offer re-use for the take-away sector set out in Article 33 for micro-enterprises that conduct their business activity in the hotel, restaurant, and catering sectors and that use take-away packaging;

It is also provided that Member States may allow micro-enterprises to place packaging on the market in the formats and for the uses listed in Annex V, point (3), of Regulation 2025/40, otherwise prohibited, where it has been demonstrated that it is not technically feasible not to use such packaging or to obtain access to infrastructure that is necessary for the functioning of a re-use system.

! ATTENTION

To be defined as a “micro-enterprise”, both conditions must be met.

⁷³

Non-exhaustive list of exemptions; please refer to the individual articles and, where applicable, to secondary legislation.

4.4 Difference between “delegated acts” and “EU implementing acts”

For a more accurate reading of Regulation 2025/40, it is necessary to clarify the difference between a delegated act and an EU implementing act. This mainly concerns the level of discretion and the type of competence that are transferred to the Commission:

Delegated acts

A delegated act is an act adopted by the Commission to supplement or amend certain non-essential elements of a legislative act. They can only be of a general nature and must be adopted on the basis of a delegation granted in the text of EU legislation. Essentially, they allow for greater flexibility and speed in the application of detailed regulations without having to amend the primary law each time.

Implementing acts

An implementing act is an act adopted by the Commission to ensure the uniform application of Union legislation in all Member States. They can be of general or individual scope and are adopted to implement European legislation in practice, establishing precise operating procedures.

In concrete terms, they cannot add to, delete or amend anything in the basic act, and can only implement its content without changing its substance.

5 Definitions

The text of this section refers to the content of Article 3 of Regulation 2025/40; other regulatory references will be duly indicated in a note.

Regulation 2025/40 has reformulated the following definitions with respect to [Directive 94/62/EC](#).

The definition of packaging given in Regulation 2025/40 is as follows:

“PACKAGING”: an item, irrespective of the materials from which it is made, that is intended to be used by an economic operator for the containment, protection, handling, delivery or presentation of products to another economic operator or to an end user, and that can be differentiated by packaging format based on its function, material and design, including:

- a. an item that is necessary to contain, support or preserve a product throughout its lifetime, without being an integral part of the product, and which is intended to be used, consumed or disposed of together with the product;
- b. a component of, and ancillary element to, an item referred to in point (a) that is integrated into the item;
- c. an ancillary element to an item referred to in point (a) that is hung directly on, or attached to, the product and that performs a packaging function, without being an integral part of the product, and which is intended to be used, consumed or disposed of together with the product;
- d. an item that is designed and intended to be filled at the point of sale in order to dispense the product, which is also referred to as “service packaging”;
- e. a disposable item that is sold and filled or designed and intended to be filled at the point of sale and which performs a packaging function;
- f. a permeable tea, coffee or other beverage bag, or soft after-use system single-serve unit that contains tea, coffee or another beverage, and which is intended to be used and disposed of together with the product;

g. a non-permeable tea, coffee or other beverage system single-serve unit intended for use in a machine and which is used and disposed of together with the product.

“SALES PACKAGING”: packaging conceived so as to constitute a sales unit consisting of products and packaging to the end user at the point of sale.

“GROUPED PACKAGING”: packaging conceived so as to constitute a grouping of a certain number of sales units at the point of sale, irrespective of whether that grouping of sales units is sold as such to the end user or whether it serves as a means to facilitate the restocking of shelves at the point of sale or to create a stock-keeping or distribution unit, and which can be removed from the product without affecting its characteristics.

“TRANSPORT PACKAGING”: packaging conceived so as to facilitate the handling and transport of one or more sales units or a grouping of sales units, in order to prevent damage to the product from handling and transport, but which excludes road, rail, ship and air containers.

Regulation 2025/40, in its recitals, specifies that cups, food containers, sandwich bags or other items which can perform a packaging function should not be considered to be packaging where they are designed and intended to be sold empty by the final distributor. Such items should only be considered to be packaging where they are designed and intended to be filled at the point of sale – in which case they should be considered to be “service packaging” – or sold by the final distributor containing food and beverages, provided that they perform a packaging function.

Specific indications are also provided by Regulation 2025/40 with regard to **tea bags and coffee bags or single-serve units intended for use in tea or coffee preparation systems**. As a rule, an item which is an integral part of a product and is necessary to contain, support or preserve that product throughout its lifetime and where all elements of that item are intended to be used, consumed or disposed of together should not be considered to be packaging given that its functionality is intrinsically linked to it being part of the product. However, in light of the disposal behaviour of consumers regarding tea and coffee bags as well as coffee or tea system single-serve units, which, in practice, are disposed of together with the product residue, leading to the contamination of compostable and recycling streams, those specific items should be treated as packaging, as specified in the definition of “packaging” provided by Regulation 2025/40.

Paints, inks, varnishes, lacquers and adhesives that have been applied directly on a product should not, however, be included in the definition of packaging. In any case, **labels hung directly on or attached to a product**, including sticky labels attached to fruits and vegetables, are included in the definition of packaging.

Regulation 2025/40 introduces, with respect to [Directive 94/62/EC](#), additional terms and definitions to those listed above for “packaging”:

“TAKE-AWAY PACKAGING”: *service packaging filled at attended points of sale with beverages or ready-prepared food that are packaged for transportation and immediate consumption at another location without the need for any further preparation and are typically consumed from the packaging.*

“PRIMARY PRODUCTION PACKAGING”: *an item designed and intended to be used as packaging for unprocessed products from primary production as defined in Regulation (EC) 178/2002.*

The definition of primary production packaging⁷⁴ should not entail an expansion of products being considered to be packaging under Regulation 2025/40. The introduction of this definition and its use in the definition of “producer” ensures that the natural or legal

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Please refer to Recital 12 of Regulation 2025/40.

person making that kind of packaging available for the first time is considered to be the producer under Regulation 2025/40, and not the primary sector businesses (such as farmers) who use it.

“E-COMMERCE PACKAGING”: *transport packaging used to deliver products in the context of sale online or through other means of distance sales to the end user.*

“INNOVATIVE PACKAGING”: *a form of packaging that is manufactured using new materials, resulting in a significant improvement in the functions of the packaging, such as the containment, protection, handling, or delivery of products, and in overall demonstrable environmental benefits, with the exception of packaging that is the result of modification to existing packaging for the main purpose of improving the presentation of products and marketing.*

“SINGLE-USE PACKAGING”: *packaging which is not reusable packaging.*

“CONTACT-SENSITIVE PACKAGING”: *packaging that is intended to be used for products falling within the scope of [Regulations \(EC\) 1831/2003 of the European Parliament and of the Council](#), [\(EC\) 1935/2004](#), [\(EC\) 767/2009 of the European Parliament and of the Council](#), [\(EC\) 1223/2009 of the European Parliament and of the Council](#), [\(EU\) 2017/745](#), [\(EU\) 2017/746](#), [\(EU\) 2019/4 of the European Parliament and of the Council](#) or [\(EU\) 2019/6](#), or of [Directives 2001/83/EC](#), [2002/46/EC of the European Parliament and of the Council](#) or [2008/68/EC](#), or for products as defined in Articles 1 and 2 of [Decision \(EU\) 2023/1809 of the Commission](#).*

“COMPOSITE PACKAGING”: *a unit of packaging made of two or more different materials which are part of the weight of the main packaging material and cannot be separated manually and therefore form a single integral unit, unless one of the materials constitutes an insignificant part of the packaging unit and in any event no more than 5% of the total mass of the*

packaging unit and excluding labels, varnishes, paints, inks, adhesives and lacquers. This provision is without prejudice to [Directive \(EU\) 2019/904](#).

Therefore, if a given material represents only an insignificant part of a packaging unit, and in any event no more than 5% of its total mass, such a packaging unit should not be considered to be composite packaging. The definition of composite packaging in Regulation 2025/40 should not exempt single-use packaging partially made of plastics, regardless of the threshold level, from the requirements of [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.

“INTEGRATED COMPONENT”: *a packaging component, whether or not of the same material as, or distinct from, the main body of the packaging unit, that is integral to the packaging unit and its functioning, that does not need to be separated from the main body of the packaging unit in order to ensure the functionality of the packaging unit and that is typically discarded at the same time as the main body of the packaging unit, although not necessarily via the same disposal route.*

“SEPARATE COMPONENT”: *a packaging component, whether or not from the same material as the main body of the packaging unit, that is distinct from the main body of the packaging unit, that needs to be disassembled completely and permanently from the main body of the packaging unit and that is typically discarded prior to and separately from the main body of the packaging unit, including packaging components that can be separated from each other simply through mechanical stress during transportation or sorting.*

“PACKAGING UNIT”: *a unit, including integrated or separate components, which together perform a packaging function, such as containing, protecting, handling, delivering, storing, transporting or presenting products, and which includes individual units of grouped packaging or packaging for transport when they are discarded before the point of sale.*

“PACKAGING PRESENTING A RISK”: *packaging that, by not complying with a requirement set out in or pursuant to Regulation 2025/40, other than those requirements listed in Article 62, paragraph 1, could adversely affect the environment, health or other public interests protected by that requirement.*

“PACKAGING PRESENTING A SERIOUS RISK”: *packaging presenting a risk for which, based on an assessment, the degree of the relevant non-compliance or the associated harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the non-compliance are not immediate.*

Regulation 2025/40 aims to prevent the production of packaging waste and reduce its quantity. It establishes specific measures to prevent packaging waste, which are defined as follows:

“PACKAGING WASTE PREVENTION”: *measures that are taken before any packaging or packaging material has become packaging waste and that reduce the quantity of packaging waste, so that less or no packaging is required to contain, protect, handle, deliver or present products, including measures as regards the re-use of the packaging and measures to extend the life of the packaging before it becomes waste.*

The measures governed by Regulation 2025/40 include:

- > measures aimed at packaging minimisation;
- > restrictions on use of certain packaging formats;
- > measures for the re-use of packaging;
- > measures relating to the refilling of packaging;
- > measures relating to the recyclability/compostability of packaging;
- > measures aimed at reducing the consumption of plastic bags.

The following definitions apply in this regard:

“RE-USE”: *any operation by which reusable packaging is used again multiple times for the same purpose for which it was conceived.*

“RE-USE SYSTEM”: the organisational, technical or financial arrangements, together with incentives, that allow re-use either in a closed loop or open loop system, including a deposit and return system that ensures that packaging is collected for re-use.

“RECONDITIONING”: any operation listed in Part B of Annex VI necessary to restore reusable packaging to a functional state for the purpose of its re-use.

“REFILL”: an operation by which a container that fulfils the packaging function, and that is either owned by the end user or purchased by the end user at the point of sale of the final distributor is filled by the end user or by the final distributor with one or several products purchased by the end user from the final distributor.

“REFILL STATION”: a place where a final distributor offers to end users products that can be purchased through refill.

“DESIGN FOR RECYCLING”: the design of packaging, including individual components of packaging, that ensures the recyclability of the packaging with established collection, sorting and recycling processes proven in an operational environment.

“RECYCLABILITY”: the compatibility of packaging with the management and processing of waste by design, based on separate collection, sorting in separate streams, recycling at scale and the use of recycled materials to replace primary raw materials.

“COMPOSTABLE PACKAGING”: packaging that biodegrades in industrially controlled conditions or that is capable of undergoing biological decomposition in such conditions, including through anaerobic digestion, but not necessarily in a home-composting environment, combined, if necessary, with physical treatment, resulting ultimately in the conversion of the packaging into carbon dioxide or, in the absence of oxygen, methane, and mineral salts, biomass and water, and

that does not hinder or jeopardise the separate collection and the composting and anaerobic digestion process.

“HOME COMPOSTABLE PACKAGING”: packaging that can biodegrade in non-controlled conditions that are not industrial-scale composting facilities and the composting process of which is performed by private individuals with the aim of producing compost for their own use.

“PLASTIC”: a material consisting of a polymer as defined in Article 3, paragraph 5, of Regulation (EC) 1907/2006, to which additives or other substances may have been added, and which is capable of functioning as a main structural component of packaging, with the exception of natural polymers that have not been chemically modified.

“BIOBASED PLASTICS”: plastics made from biological resources, such as biomass feedstock, organic waste or by-products, and irrespective of whether the plastics are biodegradable or non-biodegradable.

“PLASTIC CARRIER BAGS”: carrier bags, with or without a handle, made of plastic, which are supplied to consumers at the point of sale of products.

“LIGHTWEIGHT PLASTIC CARRIER BAGS”: plastic carrier bags with a wall thickness below 50 microns.

“VERY LIGHTWEIGHT PLASTIC CARRIER BAGS”: plastic carrier bags with a wall thickness below 15 microns.

“THICK PLASTIC CARRIER BAGS”: plastic carrier bags with a wall thickness between 50 and 99 microns.

“VERY THICK PLASTIC CARRIER BAGS”: plastic carrier bags with a wall thickness above 99 microns.

With regard to the parties subject to the obligations arising from the application of Regulation 2025/40, the relevant definitions are set out below:

“ECONOMIC OPERATOR”: the manufacturer, the supplier, the importer, the distributor, the authorised representative, the final distributor and the fulfilment service provider.

“MANUFACTURER”: any natural or legal person that manufactures packaging or a packaged product. However:

- a) subject to point (b), where a natural or legal person has packaging or a packaged product designed or manufactured under its own name or trademark, regardless of whether any other trademark is visible on the packaging or on the packaged product, “manufacturer” means that natural or legal person;
- b) where the natural or legal person that has the packaging or packaged product designed or manufactured under its own name or trademark falls within the definition of micro-enterprise set out in [Recommendation 2003/361/EC](#) as applicable on 11 February 2025, and the natural or legal person that supplies the packaging to the natural or legal person that has the packaging designed or manufactured under its own name or trademark is located in the same Member State, “manufacturer” means the natural or legal person that supplies the packaging.

“PRODUCER”: any manufacturer, importer or distributor to whom, irrespective of the selling technique used, including by means of distance contracts, one of the following applies:

- a) the manufacturer, importer or distributor is established in a Member State and makes available for the first time from within the territory of that Member State and on that same territory transport packaging, service packaging, or primary production packaging, whether as single-use packaging or as reusable packaging; or
- b) the manufacturer, importer or distributor is established in a Member State and makes available for the first time from within the territory of that Member State and on that same territory products packaged in packaging other

- than those referred to in point (a); or
- c) the manufacturer, importer or distributor is established in a Member State or in a third country and makes available for the first time on the territory of another Member State, directly to end users, transport packaging, service packaging or primary production packaging, whether as single-use packaging or as reusable packaging; or
- d) the manufacturer, importer or distributor is established in a Member State or in a third country and makes available for the first time on the territory of another Member State, directly to end users, products packaged in packaging other than those referred to in point (c); or
- e) the manufacturer, importer or distributor is established in a Member State and unpacks packaged products without being an end user, unless another person is the producer as defined in point (a), (b), (c) or (d).

“SUPPLIER”: any natural or legal person that supplies packaging or packaging material to a manufacturer.

“IMPORTER”: any natural or legal person established within the Union that places packaging from a third country on the market.

“DISTRIBUTOR”: any natural or legal person in the supply chain, other than the manufacturer or importer, that makes packaging available on the market.

“AUTHORISED REPRESENTATIVE”: any natural or legal person established in the Union that has received a written mandate from the manufacturer to act on that manufacturer’s behalf in relation to specified tasks with regard to the manufacturer’s obligations under Regulation 2025/40.

“FINAL DISTRIBUTOR”: the natural or legal person in the supply chain that delivers packaged products, including through re-use, or products that can be purchased through refill to the end user.

“CONSUMER”: any natural person who is acting for purposes which are outside their trade, business or profession.

“END USER”: any natural or legal person that resides or is established in the Union to whom a product has been made available either as a consumer or as a professional end user in the course of its industrial or professional activities, and that does not make that product further available on the market in the form supplied to it.

6 FAQ

UPDATED AS OF 30 SEPTEMBER 2025

This section contains frequently asked questions (FAQs) relating to Regulation 2025/40. The questions and answers are organised by topic, following the structure of the main document.

There is also an “Other” section, which contains cross-cutting or general questions that do not refer to a specific measure but are nevertheless relevant for the understanding and application of the Regulation.

All answers are updated as of 30 September 2025; any subsequent additions and/or changes will be made available with an indication of the new publication date.

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2.1 Requirements for substances in packaging

2.1|F1

Should analyses of chemical content (PFAS) be repeated for each production batch? Even if the same types of raw materials or components are used, but from different suppliers?

Article 5 of Regulation 2025/40 does not provide specific guidance on this matter. However, delegated acts are expected both for hazardous substances in general and specifically for PFAS, which may include information of this kind.

Regulation 2025/40 stipulates that compliance with the requirements relating to substances contained in packaging must be demonstrated in the documentation drawn up in accordance with [Annex VII](#) to the Regulation, whereby “The manufacturer shall take all measures necessary so that the manufacturing process and the monitoring thereof ensure compliance of the manufactured packaging”.

For this reason, analyses relating to the content of “hazardous” substances, such as PFAS, must be repeated as often as necessary to ensure compliance with the limits set out in Regulation 2025/40. The manufacturer must therefore declare, under its sole responsibility, that the packaging concerned complies with the requirements.

Will there be a definitive list of PFAS substances subject to restrictions under the PPWR or will reference be made to existing regulatory frameworks (e.g. REACH/POP)?

Pursuant to Article 5, paragraph 5 of Regulation 2025/40, from 12 August 2026, food-contact packaging shall not be placed on the market if it contains per- and polyfluoroalkyl substances (PFAS) in a concentration equal to or above the following limit values, unless another Union legal act already prohibits the placing on the market of such packaging:

- a. 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFAS excluded from quantification);
- b. 250 ppb for the sum of PFAS measured as the sum of targeted PFAS analysis, where applicable with prior degradation of precursors (polymeric PFAS excluded from quantification); and
- c. 50 ppm for PFAS (including polymeric PFAS); if total fluorine exceeds 50 mg/kg the manufacturer, importer or downstream user as defined respectively in Article 3, points (9), (11) and (13) of Regulation (EC) 1907/2006 shall, upon request, provide to the manufacturer or the importer as defined respectively in Article 3, paragraph 1, points (13) and (17) of Regulation 2025/40, proof of the quantity of fluorine measured as content of either PFAS or non-PFAS in order for them to draw up the technical documentation as referred to in Annex VII to Regulation 2025/40.

“PFAS” means any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it), except substances that only contain the following structural elements: CF₃-X or X-CF₂-X', where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-).

By 12 August 2030, the Commission shall carry out an evaluation to assess whether to amend or repeal paragraph 5, in order to avoid overlaps with restrictions or prohibitions on the use of PFAS laid down in accordance with Regulations (EC) 1935/2004, (EC) 1907/2006, or (EU) 2019/1021.

2.1|F2

2.1|F3

Is it correct to say that there are no transitional measures for PFAS? There is mention of the placing on the market of packaging containing PFAS, but no mention of the placing on the market of finished products containing them. What should companies do?

There are no transitional measures for the ban on the marketing of packaging that exceeds the PFAS content limits. Regulation 2025/40 does not lay down provisions on the concentration of PFAS in products contained in packaging.



2.2 Recyclable packaging

Are there already technical protocols for assessing the recyclability of flexible plastic packaging that can be used to meet regulatory requirements?

With regard to technical protocols related to recyclability, it will be necessary to wait for the delegated acts of the EU Commission. These acts are expected by **1 December 2028** and will apply from **1 January 2030**, when all packaging must be recyclable, i.e. designed for recycling (the acts will define the design for recycling criteria, the recyclability performance grades and the methodologies for defining the grades).

From 1 January 2035, all packaging must be recyclable on a large scale. The relevant methodology and criteria for assessment will be the subject of delegated acts expected by 1 January 2030.

Therefore, the criteria to be considered in view of the 2030 and 2035 recyclability targets have not yet been defined. CEN is working on design for recycling guidelines, which will take into account existing European guidelines.

However, it is known that the D4R guidelines and the methodology for defining recyclability grades will consider all integrated components of the packaging system and take into account factors such as the quality of secondary raw materials obtained from recycling processes, existing infrastructure and the presence of hazardous substances.

For guidance purposes only, and pending further clarification on these aspects with the publication of CEN standards and delegated acts, here are some existing European guidelines for plastic packa-

2.2|F1

ging that may be useful for analysing and assessing recyclability:

- › for flexible packaging, for example, the [CEFLEX Design for Recycling Guidelines](#);
- › for all plastic packaging, the [Recyclclass guidelines](#);
- › for plastic bottles, the [EPBP Guidelines](#).

For paper packaging, on the other hand, the existing references are the Aticelca Assessment System, the CEPI 4evergreen method. CONAI but provides the “[Progettare Riciclo](#)” (Design for Recycling) platform, a tool that offers design guidelines aimed at improving the recyclability of aluminium, steel, paper, and plastic packaging. For further information on voluntary communication on recyclability, please refer to page 19 of the [Guidelines For Voluntary Environmental Labelling by CONAI](#). However, it should also be noted that once recyclability becomes a legal requirement, it will no longer be possible to claim this characteristic as a distinctive feature of packaging. For further information, please consult the [Summary Guide to the new European Directive 2024/825/EU](#).

2.2|F2

Can PET trays that use a peelable heat-sealed PET film that is not recyclable continue to use this type of film, given that it accounts for a minimal percentage of the plastic?

Article 7 (paragraphs 1 and 2) of Regulation 2025/40 contains requirements for minimum recycled content in plastic packaging; however, paragraph 5 states that “any plastic part representing less than 5% of the total weight of the whole packaging unit” is exempt from these requirements, therefore if the film remains below the 5% threshold, it is exempt.

What tests are used to demonstrate the recyclability of a packaging material?

In order to demonstrate the recyclability of a material, it will be necessary to wait for the adoption of the Commission's delegated acts.

Specifically, by 1 January 2028, the Commission must adopt a delegated act setting out, among other things, how to perform recyclability performance assessment and express its result in recyclability performance grades per packaging unit, in terms of weighting, including material-specific criteria and sorting efficiency, to determine whether packaging is to be considered recyclable.

“Recyclability grades” have been defined: how does the criterion for this classification work? How is it calculated?

The recyclability grades are indicated in Table 3 of [Annex II](#) (Recyclability performance grades). Article 6 of Regulation 2025/40 stipulates that, from 1 January 2030, packaging placed on the market must be recyclable according to grades A, B and C indicated in the table. However, it is necessary to wait for the Commission (by 1 January 2028) to supplement Regulation 2025/40 with delegated acts establishing the design for recycling criteria and the recyclability performance grades.

What are the criteria for considering packaging recyclable (grades A, B, and C) until specific provisions are established? Is it already possible to define it as such? Is it mandatory or optional to declare the percentage of recycled plastic?

Article 6 of Regulation 2025/40 stipulates that from 1 January 2030 (or, if the delegated acts referred to in paragraph 4 of Ar-

2.2|F3

2.2|F4

2.2|F5

ticle 6 are adopted after 1 January 2028, the obligation will take effect 24 months after the entry into force of those acts) packaging placed on the market must be recyclable in accordance with grades A, B and C of Table 3 of [Annex II](#) (Recyclability performance grades). However, it is necessary to wait for the Commission (by 1 January 2028) to supplement Regulation 2025/40 with delegated acts establishing design for recycling criteria and recyclability performance grades based on the provisions of Table 3 of [Annex II](#). Compliance with these recyclability requirements must be clearly stated in the declaration of conformity referred to in [Annex VII](#). With regard to the minimum content of recycled material in plastic packaging, Article 7 of Regulation 2025/40 stipulates that by 1 January 2030, all plastic parts of packaging must contain a minimum percentage of recycled content recovered from post-consumer plastic waste. Compliance with this obligation must also be demonstrated by the manufacturer or importer in the technical information on packaging referred to in [Annex VII](#).

For further information on voluntary communication on recyclability, please refer to page 19 of the [Guidelines For Voluntary Environmental Labelling by CONAI](#). However, it should be noted that once recyclability becomes a legal requirement, it will no longer be possible to claim this characteristic as a distinctive feature of packaging in order to avoid the risk of greenwashing. For further information, please consult the [Summary Guide to the new European Directive 2024/825/EU](#).



2.3 Minimum recycled content in plastic packaging

How does recycled packaging fit in with the safety assessment of cosmetics?

Regulation 2025/40 does not regulate or provide for specific exemptions regarding the minimum content of recycled plastic in cosmetic packaging. However, the implementing acts of Article 7, which will establish the methodology for calculating and verifying the percentage of recycled content recovered from post-consumer waste, may provide guidance in this regard.

In any case, it should be noted that, as provided for in Article 2, Regulation 2025/40 is without prejudice to European Union regulatory requirements “relating to the safety, quality, health protection and hygiene of packaged products”.⁷⁵

How can the suitability of a plastic film containing recycled material be verified?

In order to verify the suitability of packaging in accordance with the requirements of Article 7 of Regulation 2025/40, “*minimum recycled content in plastic packaging*”, it will be necessary to wait

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For further information on the safety of cosmetic products, please refer to Regulation (EC) 2009/1223, specifically Article 10 and Annex I, point (4).

2.3|F2

for the Commission to adopt implementing acts by 31 December 2026, aimed at establishing the methodology for calculating and verifying the percentage of recycled content.

2.3|F3

In the case of plastic packaging, what are the minimum recycled content thresholds and when will they come into force?

Article 7 of Regulation 2025/40 establishes specific minimum recycled content requirements for plastic packaging:

1. By 1 January 2030 (or three years after the date of entry into force of the implementing act referred to in paragraph 8 of Article 7, if later) any plastic part of packaging placed on the market shall contain the following minimum percentage of recycled content recovered from post-consumer plastic waste, per packaging type and format as referred to in Table 1 of Annex II, calculated as an average per manufacturing plant and year:
 - a. 30% for contact-sensitive packaging made from polyethylene terephthalate (PET) as the major component, except single-use plastic beverage bottles;
 - b. 10% for contact-sensitive packaging made from plastic materials other than PET, except single-use plastic beverage bottles;
 - c. 30% for single-use plastic beverage bottles;
 - d. 35% for plastic packaging other than those referred to in points (a), (b) and (c).
2. By 1 January 2040, any plastic part of packaging placed on the market shall contain the following minimum percentage of recycled content recovered from post-consumer plastic waste, per packaging type and format as referred to in Table 1 of Annex II, calculated as an average per manufacturing plant and year:
 - a. 50% for contact-sensitive packaging made from PET as the major component, except single-use plastic beverage bottles;

- b. 25% for contact-sensitive packaging made from plastic materials other than PET, except single-use plastic beverage bottles;
- c. 65% for single-use plastic beverage bottles;
- d. 65% for plastic packaging other than those referred to in points (a), (b) and (c).

How should Article 7.5.a be interpreted with regard to packaging that poses a risk to human health?

Compliance with [Regulation \(EC\) 1935/2004](#) remains a prerequisite for materials and articles intended to come into contact with food, which cannot be waived in order to comply with the requirements of Regulation 2025/40.

Therefore, the amount of recycled content in plastic packaging intended to come into contact with foods must not pose a threat to human health.

Article 7, paragraph 5, point (a) of Regulation 2025/40 stipulates that the minimum recycled content requirements for plastic packaging (set out in paragraphs 1 and 2 of the same regulation) do not apply to plastic packaging that is intended to come into contact with food where the quantity of recycled content poses a threat to human health and results in non-compliance of packaged products with [Regulation \(EC\) 1935/2004](#) on materials and articles intended to come into contact with foods. Therefore, the application of this exclusion must be assessed with specific reference to the above-mentioned Regulation, as well as to [Regulation \(EU\) 2022/1616](#) on recycled plastic materials and articles intended to come into contact with foods.

2.3|F4



2.5 Compostable packaging

2.5|F1

Will capsules and bags for coffee or other beverages be subject to compostability requirements?

For non-permeable single-serve units, compostability is at the discretion of each Member State when specific conditions apply at national level. Depending on the type of capsule, there are different provisions in Regulation 2025/40:

- › According to Article 3, paragraph 1, point (f), the definition of packaging includes “a permeable tea, coffee or other beverage bag, or soft after-use system single-serve unit that contains tea, coffee or another beverage, and which is intended to be used and disposed of together with the product”. With regard to those items, Article 9 of Regulation 2025/40 stipulates that, by 12 February 2028, such packaging must be compostable under industrial composting conditions. Member States may also require compatibility with home composting, if provided for in national legislation.
- › With regard to non-permeable single-serve units (Article 3, paragraph 1, point (g)), compostability is not mandatory at EU level, but may be required by Member States, provided that adequate collection and treatment systems for bio-waste waste exist.

For permeable tea bags, coffee bags or bags for other beverages, or single-serve, single-use units that are soft after use, which con-

tain tea, coffee or another beverage, and are intended to be used and disposed of together with the product, there is a general compostability requirement from 2028.

According to Regulation 2025/40, will tea filters be considered packaging? Do we therefore need to amend all disposal tables to include disposal provisions for tea filters?

The filters in question fall within the category of packaging. In particular, a permeable tea, coffee or other beverage bag, or soft after-use system single-serve unit that contains tea, coffee or another beverage, and which is intended to be used and disposed of together with the product, will be considered packaging from 12 August 2026 and will therefore be subject to environmental labelling requirements.

They must bear the identification code pursuant to [Decision 129/97/EC](#) referring to the material composition of the wrapping.

With regard to disposal instructions, compostable capsules, bags and sachets in accordance with UNI 13432 these will be destined for separate collection for bio-waste and must bear all the mandatory information required for items with these characteristics (for further details, please refer to page 32 of the [Guidelines on the labelling of packaging pursuant to Article 219, paragraph 5 of Legislative Decree 152/2006](#) as amended). The use of digital channels is always possible to convey this information in accordance with the procedures already set out in the official guidelines.

It should also be noted that the above-mentioned environmental labelling requirements for packaging will be subject to change, as Regulation 2025/40 stipulates that from 12 August 2028, packaging must bear a harmonised label for all Member States in accordance with the implementing acts to be adopted by the European Commission by 12 August 2026.

2.5|F2

2.5|F3

Will capsules and bags for coffee or other beverages have to be compostable, or will each country in Europe be able to decide whether to make compostability mandatory, based on its own recycling chain?

Compostability with regard to compatibility with the standards for composting in industrially controlled conditions in bio-waste treatment facilities will be mandatory, pursuant to Article 9 of Regulation 2025/40.

The introduction of the requirement for compatibility with home composting standards is, however, at the discretion of each Member State. With regard to non-permeable coffee capsules (defined by Article 3, point (g) of Regulation 2025/40), it will be up to each Member State to impose compostability requirements; it should be noted that, in accordance with the single market as highlighted in Article 4 of Regulation 2025/40, this flexibility is subject to compliance with the [TRIS notification procedure](#). See Article 9, paragraph 2, point (a): “By way of derogation from Article 6, paragraph 1, where Member States allow waste with similar biodegradability and compostability properties as bio-waste pursuant to Article 22, paragraph 1 of [Directive 2008/98/EC](#) to be collected together with bio-waste, and appropriate waste collection schemes and waste treatment infrastructure are available to ensure that compostable packaging enters the bio-waste management stream, Member States may require that the following packaging shall be made available on their territory for the first time only if the packaging is compostable:

a) packaging referred to in Article 3, paragraph 1, point (1)(g), composed of material other than metal, very lightweight plastic carrier bags and lightweight plastic carrier bags (...).”

2.5|F4

What are the requirements for compostable packaging?

Compostable packaging is defined as “packaging that biodegrades in industrially controlled conditions or that is capable of undergoing biological decomposition in such conditions, including

through anaerobic digestion, but not necessarily in a home-composting environment, combined, if necessary, with physical treatment, resulting ultimately in the conversion of the packaging into carbon dioxide or, in the absence of oxygen, methane, and mineral salts, biomass and water, and that does not hinder or jeopardise the separate collection and the composting and anaerobic digestion process”.

To date, the reference standard for compostable packaging is EN 13432.

Then, by 12 February 2026, it will be up to European standardisation organisations to prepare harmonised standards with technical specifications for industrial and home composting.

With regard to coffee bags, will the filter paper that makes up the bags be considered packaging under Regulation 2025/40?

Yes, the reference is made by Article 3, paragraph 1 of Regulation 2025/40, which includes in the definition of packaging in point (f) the “permeable tea, coffee or other beverage bag, or soft after-use system single-serve unit that contains tea, coffee or another beverage, and which is intended to be used and disposed of together with the product”.

Must packaging not included in Articles 9.1 and 9.2 still be recyclable as well as compostable?

By 12 February 2028, packaging other than that referred to in paragraphs 1 and 2 of Article 9 of Regulation 2025/40, including packaging made from biodegradable plastic polymers and other biodegradable materials, must be designed for the recycling of the reference materials, as must all other packaging placed on the market, in accordance with Article 6 of Regulation 2025/40 and without compromising the recyclability of other waste streams. Reci-

2.5|F5

2.5|F6

tal 53 reads: “As the proper disposal route for compostable plastic packaging is becoming increasingly confusing for consumers, it is justified and necessary to lay down clear and common rules on the use of compostable plastic packaging, mandating it only when its use brings a clear benefit for the environment or for human health.” Therefore, only the packaging indicated in paragraphs 1 and 2 may be compostable. The Commission may consider the possibility of including other packaging in paragraph 1 or paragraph 2, point (a).

2.5|F7

How should Article 9.2 be interpreted in terms of non-compostable plastic capsules when the Member State requires compostability? Will they be banned or will the dual option of compostable and non-compostable remain?

Article 9, paragraph 1 of Regulation 2025/40 stipulates that each Member State may require that non-permeable single-serve units intended for use in a system for preparing tea, coffee or other beverages (intended for use in a machine and used and disposed of together with the product) also be compostable (if made of material other than metal). Where the Member State imposes this obligation, non-permeable single-serve capsules may also only be placed on the market if they are compostable. However, in accordance with the single market, this flexibility is subject to compliance with the [TRIS notification procedure](#).

Each Member State may decide, by August 2026, to introduce a compostability requirement for plastic capsules placed on its territory, provided that there is an infrastructure for the collection and recycling of the organic fraction.



2.6 Packaging minimisation

Will it be possible to maintain the aesthetic style required by the cosmetics sector, for example the use of double-walled jars and caps?

In general, no, because Regulation 2025/40 imposes specific obligations regarding packaging reduction. By 1 January 2030, the manufacturer or importer must ensure that the packaging placed on the market is designed so that its weight and volume is reduced to the minimum necessary to ensure its functionality, taking account of the shape and material from which the packaging is made. The manufacturer or importer must therefore ensure that packaging which does not comply with the performance criteria set out in [Annex IV](#) of Regulation 2025/40 (Methodology for packaging minimisation assessment) and packaging with characteristics that aim only to increase the perceived volume of the product, including double walls, false bottoms and unnecessary layers, is not placed on the market. These obligations do not apply only if, as specified in Article 10 of Regulation 2025/40, the packaging design is protected, prior to 11 February 2025, by a Community design and only if the application of the requirements set out in Article 10 affects:

1. the design of the packaging in such a way as to alter its novelty or individual character, or
2. the trademark in such a way that the trademark can no longer distinguish the trademarked good from goods of another undertaking.

2.6|F1

2.6|F2

What is the criterion for determining whether packaging is disproportionate to its contents? Who should verify this and how?

There is currently no defined criterion for this. This criterion will be established by 12 February 2027, as European standardisation organisations will develop or update specific harmonised standards on the methodology for calculating and measuring compliance with packaging reduction requirements, specifying maximum limits for weight, volume, material thickness (where applicable) and empty space for the most common types and formats of packaging.

However, it is already stipulated that compliance with the packaging minimisation requirements must be demonstrated in the technical documentation referred to in [Annex VII](#) to Regulation 2025/40, while each Member State will define the relevant verification and control mechanisms.

In particular, pursuant to Article 10 of Regulation 2025/40, by 1 January 2030, manufacturers or importers must ensure that packaging placed on the market is designed in such a way that its weight and volume are reduced to the minimum necessary to ensure its functionality, taking account of the shape and material from which the packaging is made, in accordance with the performance criteria set out in [Annex IV](#) to Regulation 2025/40 on the methodology for packaging minimisation assessment.

Furthermore, by 1 January 2030, economic operators who fill grouped packaging, transport packaging or e-commerce packaging must ensure that the maximum empty space ratio, expressed as a percentage, does not exceed 50%.

2.6|F3

Which types of packaging should be strictly avoided/reduced?

Article 25 of Regulation 2025/40 (Restrictions on use of certain packaging formats) provides that, as of 1 January 2030, economic operators must not place on the market packaging in the formats and for the uses listed in [Annex V](#) of Regulation 2025/40. In addition, it should be noted that, by 1 January 2030, the manufacturer

or importer must ensure that the packaging placed on the market is designed so that its weight and volume is reduced to the minimum necessary to ensure its functionality, taking account of the shape and material from which the packaging is made (no double walls, false bottoms or unnecessary layers).

How can we distinguish between the requirements of Article 10 (minimisation) and those of Article 24 (empty space)? Are these two different issues?

Yes, they are two different issues.

The provision referred to in Article 10 of Regulation 2025/40 **applies to all types of packaging**, except for the specific exclusions provided for in the same article, and requires manufacturers or importers to place on the market packaging designed so that its weight and volume is reduced to the minimum necessary to ensure its functionality, taking account of the shape and material from which the packaging is made.

Article 24 of Regulation 2025/40 requires economic operators who fill grouped packaging, transport packaging or e-commerce packaging to ensure that the maximum empty space ratio, expressed as a percentage, does not exceed 50%; with regard to sales packaging, they must ensure that empty space is reduced to the minimum necessary for ensuring the packaging functionality, including product protection.

Does the obligation to minimise weight and volume apply to all packaging materials?

The requirements regarding the need to minimise the weight and volume of packaging set out in Article 10 of Regulation 2025/40 apply to all packaging, regardless of the material.

2.6|F4

2.6|F5



2.7 Reusable packaging

Are there incentives for reusable packaging? If so, what are they?

2.7|F1

Regulation 2025/40 does not provide for any incentives for the creation of reusable packaging. The creation and marketing of reusable packaging within a re-use system is a legal obligation.

Is there a re-use requirement for “contact-sensitive” materials, such as flexible plastic packaging intended to come into contact with food?

2.7|F2

No, because the re-use requirements set out in Article 29 of Regulation 2025/40 for transport or sales packaging used for transport do not apply, among other things, to packaging in flexible format that is used for transportation and that is in direct contact with food and feed as defined in Article 2 and in Article 3, point (4), of Regulation (EC) 178/2002 or with food ingredients as defined in Article 2, paragraph 22, point (f) in Regulation (EU) 1169/2011 of the European Parliament and of the Council.

The references refer to the general definition of “food”, “feed” and “food ingredients” and not to specific types.

Food means “any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans”.

Feed means “any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals”.

Ingredient means “any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as ingredients”.

2.7|F3

What will be the targets and obligations for the use of reusable packaging in Italy? And by when?

For both Italy and the other Member States of the European Union, the re-use targets are set out in Article 29 of Regulation 2025/40 and have different deadlines.

RE-USE TARGETS

	2030	2040		
Economic operators who use transport packaging	40%	70%	EXCLUSIONS: Packaging used: <ul style="list-style-type: none"> > for transporting dangerous goods; > for the transportation of large machinery, equipment and products for which customised packaging is designed; > in flexible form in direct contact with food, feed or food ingredients; > in the form of cardboard boxes. 	
Economic operators who use grouped packaging in the form of boxes used to group a certain number of products in order to create a stock-keeping or distribution unit.	10%	25%		EXCLUSIONS: Paper packaging.
Final distributors who make alcoholic and non-alcoholic beverages available to consumers in sales packaging.	10%	40%		EXCLUSIONS: <ul style="list-style-type: none"> > beverages considered highly perishable; > milk, dairy products, plant-based milk substitutes; > wine products, alcoholic beverages.

Economic operators shall participate in one or more re-use systems and shall report data on the achievement of re-use targets to the competent authority.

- › The report shall be submitted within six months of the end of the reporting year for which the data are collected.
- › The first reporting period shall cover the calendar year starting on 1 January 2030.
- › The competent authorities shall establish electronic systems through which data shall be reported to them and specify the formats to be used.

ADDITIONAL OBLIGATIONS REGARDING REUSE ACCORDING TO REGULATION 2025/40:

- › Final distributors operating in the hospitality sector and using take-away packaging for cold or hot beverages or ready-to-eat food intended for immediate consumption, by filling a take-away container at the point of sale, shall offer consumers the option of reusable packaging within a re-use system by 12 February 2028;
- › From 2030, final distributors shall endeavour to offer 10% of products for sale in a reusable packaging format.

ADDITIONAL REFILL OBLIGATIONS ACCORDING TO REGULATION 2025/40:

- › From 1 January 2030, final distributors with a sales area of more than 400 m² shall endeavour to allocate 10% of that sales area to refill stations for both food and non-food products.
- › Final distributors operating in the hospitality sector and using take-away packaging for cold or hot beverages or ready-to-eat food intended for immediate consumption, by filling a take-away container at the point of sale, shall provide consumers with a system that allows them to bring their own container to be refilled by 12 February 2027.

2.7|F4

How should Article 29.6 on re-use targets be interpreted? Are vending machines included or excluded? If included, how will those offering hot drinks in paper cups be managed?

Article 29, paragraph 6 of Regulation 2025/40 stipulates that from 1 January 2030, final distributors that make alcoholic and non-alcoholic beverages in sales packaging available on the territory of a Member State to consumers shall ensure that at least 10% of those products are made available in reusable packaging within a re-use system. However, the regulation establishes several exemptions from this re-use requirement: for example, paragraph 7 stipulates that the re-use targets shall not apply to beverages considered highly perishable, as well as milk and milk products and plant-based milk substitutes. In addition, paragraph 10 of the regulation stipulates that if, in a given calendar year, a final distributor has a sales area of no more than 100 m², that final distributor shall be exempt from the obligation to meet the targets set out in paragraph 6. There are therefore exemptions related to the type of product or the size of the sales area, but no further exemptions are provided for. Therefore, the general rules of Regulation 2025/40 should also apply to final distributors operating through vending machines. This is without prejudice to the publication by the Commission, by February 12, 2027, of guidelines on the types of beverages that may be subject to the re-use obligations referred to in paragraph 6.

Article 29, paragraphs 1, 2 and 3, sets out certain re-use obligations for transport or sales packaging used to transport products. Considering the technological challenges associated with the solutions currently available and in line with the need to ensure stringent quality KPIs, have further considerations been made regarding the “achievability” of these targets?

Currently, there are no ongoing considerations by the Commission on the feasibility of these objectives.

On this point, however, paragraph 19 of Article 29 provides that “By 1 January 2034, taking into account the evolution of the state of the art of technology and the practical experience gained by economic operators and Member States, the Commission shall present a report reviewing the implementation of the 2030 targets set out in Article 29. In that report, it shall evaluate, including from the perspective of the life-cycle assessment of single-use and re-use packaging, the following:

- a. the extent to which the 2030 targets have led to solutions fostering sustainable packaging that are effective and easy to implement;
- b. the feasibility of the achievement of the 2040 targets on the basis of the experience in achieving the 2030 targets and the evolving circumstances;
- c. the relevance of maintaining the exemptions and derogations set out in Article 29; and
- d. the necessity or pertinence of setting new targets for the re-use and refill of other packaging categories.”

Article 29, paragraph 6, sets stringent re-use targets for “final distributors” from 1 January 2030, as well as aspirational targets for “economic operators” from 1 January 2040. In this context, Article 29 paragraph 14 highlights the possibility for Mem-

2.7|F5

2.7|F6

ber States to exempt “economic operators” from the obligations laid down. Should this possibility of exemption be interpreted as applicable to all the above targets, or only to those valid from 1 January 2040?

The exemption provided for in paragraph 14 applies to all the obligations of Article 29 and not only to those of paragraph 6.

2.7|F7

Which articles of Regulation 2025/40 concern the issue of “Re-use”?

The main articles of Regulation 2025/40 concerning “re-use” are:

- › Article 11 – Reusable packaging;
- › Article 26 – Obligations in relation to reusable packaging;
- › Article 27 – Obligation relating to re-use systems;
- › Article 29 – Re-use targets;
- › Article 30 – Rules on the calculation of the achievement of the re-use targets;
- › Article 31 – Reporting to the competent authorities on re-use targets;
- › Article 33 – Re-use offer obligation for the take-away sector.

2.7|F8

Will the re-use requirements also apply to stretch wrappings and straps for pallets?

No, in a delegated act adopted on 25 February 2026, the European Commission excluded stretch wrappings and straps used to secure loads on pallets during transport from the 100% re-use requirement originally set out in Regulation 2025/40 for specific intra-company and domestic operations.



3.1 Labelling of packaging

What is different compared to the environmental labelling of packaging intended for the B2C channel currently required in Italy?

3.1|F1

According to current Italian legislation, the mandatory information for the environmental labelling of packaging intended for the end consumer is the **identification code of the packaging material according to [Decision 129/97/EC](#) and collection instructions**. The phrase “Check your local municipal guidelines” is optional.

With regard to Regulation 2025/40, currently and until **11 August 2028**, it is possible to maintain environmental labelling in its current form.

From 12 August 2028, based on the provisions of Article 70 of Regulation 2025/40:

› [Decision 129/97/EC](#) will be repealed.

From 12 August 2028, or at the latest 24 months after the date of entry into force of the implementing acts planned for 2026, based on the provisions of Article 12, paragraph 1 of Regulation 2025/40:

› packaging, excluding packaging for transport (except for e-commerce) or subject to a deposit, shall bear the harmonised label in accordance with the following implementing acts (paragraphs 6 and 7 of Article 12):

1. act defining a harmonised label and harmonised specifications for labelling requirements and formats;

2. act defining a methodology for identifying the materials of which packaging is composed using digital marking technologies.

In summary:

The current rules apply until 11 August 2028, or, as regards collection instructions, until the implementing acts come into force. By 12 August 2026, the European Commission shall publish the delegated acts that will define the new harmonised rules in detail, giving companies two years to adapt. If the delegated acts are delayed, the date of 12 August 2028 will be postponed accordingly, in order to maintain the two-year adaptation period.



3.2 Restrictions on the use of certain packaging formats

Does the ban on using plastic for packaging fruit and vegetables weighing less than 1.5 kg also apply to recycled/recyclable plastics, such as PET, R-PET? Will there be any exceptions to the use of plastics in fruit and vegetables for packaging weighing less than 1.5 kg?

Single-use, non-processed plastic packaging used for fruit and vegetables weighing less than 1.5 kg will be prohibited from being placed on the market from 1 January 2030. Regulation 2025/40 does not specify whether this applies to recycled or virgin plastic, so the prohibition applies regardless. The only exceptions provided for are in Article 25 of Regulation 2025/40: By 12 February 2027, the Commission shall publish guidelines, in consultation with Member States and the European Food Safety Authority, which explain [Annex V](#) in more detail, including examples of the packaging formats in scope, and any exemptions from the restrictions, and provide a non-exhaustive list of fruits and vegetables that are excluded from point (2) of [Annex V](#). In addition, point (2) of [Annex V](#) provides that Member States may set up exemptions in respect of such a restriction if there is a demonstrated need to avoid water loss, or turgidity loss, microbiological hazards or physical shocks, oxidation, or if there is no other possibility to avoid commingling of organic fruits and vegetables with non-organic fruits and vegetables in com-

3.2|F1

pliance with requirements in [Regulation \(EU\) 2018/848](#) of the European Parliament and of the Council on certification or labelling, without entailing disproportionate economic and administrative costs.

3.2|F2

With regard to the timetable for compliance with the reduction in packaging, which single-use materials will be prohibited?

Pursuant to Article 10, paragraph 1, by 1 January 2030 at the latest, manufacturers or importers must ensure that the packaging placed on the market is designed so that its weight and volume is reduced to the minimum necessary to ensure its functionality, taking account of the shape and material from which the packaging is made.

Single-use packaging listed in [Annex V](#) will be prohibited for the uses specified therein. However, this is without prejudice to the derogations provided for in Article 25.

3.2|F3

With regard to single-use products/hotel amenities (shampoo and shower gel bottles and sachets, sewing kits, shower caps, etc.) intended for the hospitality sector, are there any restrictions, limits or bans on marketing/production? If so, from when?

Yes, there are. Article 25 of Regulation 2025/40 stipulates that, from 1 January 2030, economic operators shall not place packaging on the market in the formats and for the uses listed in [Annex V](#), which contains certain restrictions on the use of certain packaging formats, including:

- › single-use plastic packaging in the hotel, restaurant and catering sector, containing individual portions or servings, used for condiments, preserves, sauces, coffee creamer, sugar and seasoning, except in the following cases:
 - a. such packaging is provided together with take-away ready-prepared food intended for immediate consumption without the need of any further preparation;
 - b. such packaging is required to ensure safety and hygiene in establishments where there is a medical requirement for individualised care, such as hospitals, clinics or nursing homes.
- › single-use packaging for cosmetics, hygiene and toiletry products for the use in the accommodation sector, as described in NACE Rev. 2 – Statistical classification of economic activities, intended for an individual booking only and intended to be discarded before the next guest arrives.

However, it is expected that, by 12 February 2027, the Commission will publish guidelines, in consultation with Member States and the European Food Safety Authority, to explain [Annex V](#) in more detail, including examples of the packaging formats in scope, and any exemptions from the restrictions.

Restrictions in Annex V: what is meant by “facilitate handling”? Does this also apply to consumers? Will the restriction also apply to plastic film for multipacks?

On this point, it is expected that, by 12 February 2027, the Commission will publish guidelines, in consultation with Member States and the European Food Safety Authority, to explain [Annex V](#) of Regulation 2025/40 in more detail, including examples of the packaging formats in scope, and any exemptions from the restrictions, and provide a non-exhaustive list of fruits and vegetables that are excluded from point (2) of [Annex V](#).

3.2|F4

3.2|F5

Can single-dose sachets used in cosmetics outside the hospitality sector continue to be marketed?

[Annex V](#) of Regulation 2025/40 (Restrictions on use of packaging formats) provides for a restriction on the use of single-use packaging for cosmetics, hygiene and toiletry products for the use in the accommodation sector, as described in NACE Rev. 2. Therefore, outside of this sector, no specific restrictions are envisaged.

3.2|F6

For fresh fruit and vegetables, plastic packaging is to be abolished. When will this come into force?

Regulation 2025/40 stipulates that from 1 January 2030, single-use plastic packaging for unprocessed fresh fruit and vegetables, such as nets, bags and trays, shall no longer be placed on the market.

3.2|F7

Article 25 of Regulation 2025/40 provides for restrictions on the use of certain packaging formats, referring to a list of packaging formats and uses that may not be placed on the market from 1 January 2030, as set out in Annex V. Among these, single-use plastic grouped packaging is excluded if it is “necessary to facilitate handling”. Is it possible to have further information on which plastic films for multipacks will be subject to this prohibition?

Regulation 2025/40 does not provide further guidance on this point, but Article 25, paragraph 6 provides that “by 12 February 2027, the Commission shall publish guidelines, in consultation with Member States and the European Food Safety Authority, which explain [Annex V](#) in more detail, including examples of the packaging formats

in scope, and any exemptions from the restrictions, and provide a non-exhaustive list of fruits and vegetables that are excluded from point (2) of Annex V”. We therefore await guidance from the Commission by 12 February 2027.



4.1 EU declaration of conformity

4.1|F1

Is it correct that the manufacturer of a semi-finished product (PE film for packaging, which will subsequently be laminated to one or more materials by a converter) is NOT required to issue the declaration of conformity required by the Regulation?

The declaration of conformity must be drawn up by the packaging manufacturer (see Article 15 of Regulation 2025/40: “Before placing packaging on the market, manufacturers shall carry out the conformity assessment procedure referred to in Article 38 or have it carried out on their behalf, and shall draw up the technical documentation referred to in Annex VII. Where compliance of packaging with the applicable requirements has been demonstrated by the conformity assessment procedure referred to in Article 38, manufacturers shall draw up an EU declaration of conformity in accordance with Article 39”).

Regulation 2025/40 defines “manufacturer” as any natural or legal person that manufactures packaging or a packaged product.

It is then specified that:

- a. subject to point (b), where a natural or legal person has packaging or a packaged product designed or manufactured under its own name or trademark, regardless of whether any other trademark is visible on the packaging or on the packaged product, “manufacturer” means that natural or legal person;
- b. where the natural or legal person that has the packaging or packaged product designed or manufactured under its own name or trademark falls within the definition of micro-enter-

prise set out in [Recommendation 2003/361/EC](#) as applicable on 11 February 2025, and the natural or legal person that supplies the packaging to the natural or legal person that has the packaging designed or manufactured under its own name or trademark is located in the same Member State, “manufacturer” means the natural or legal person that supplies the packaging.

However, in the case presented, it would appear that the company qualifies not as a manufacturer but as a “supplier”, i.e. any natural or legal person that supplies packaging or packaging material to a manufacturer.

Declaration of conformity: who must draw it up? Must the end user (the packager) request it from the supplier?

The EU declaration of conformity certifies that compliance with the sustainability and labelling requirements established by Regulation 2025/40 has been demonstrated. In particular, it is a document that demonstrates compliance with the requirements relating to:

- › Requirements for substances in packaging (Article 5);
- › Recyclable packaging (Article 6);
- › Minimum recycled content in plastic packaging (Article 7);
- › Biobased feedstock in plastic packaging (Article 8);
- › Compostable packaging (Article 9);
- › Packaging minimisation (Article 10);
- › Reusable packaging (Article 11);
- › Labelling of packaging (Article 12);

It must be drawn up by the manufacturer and must be requested and checked by importers.

4.1|F2

4.1|F3

Will companies have to issue a declaration of conformity regarding compliance with the requirements of Regulation 2025/40? Is this also required for medical devices and medicines?

Based on the provisions of Article 15 of Regulation 2025/40, it is the responsibility of packaging manufacturers, before placing packaging on the market, to carry out (or have carried out on their behalf) the procedure for assessing the conformity of the packaging with the requirements of Regulation 2025/40 (provided for in Article 38) and draw up the technical documentation referred to in [Annex VII](#). Where compliance of packaging with the applicable requirements has been demonstrated by the conformity assessment procedure referred to in Article 38 of Regulation 2025/40, manufacturers shall draw up an EU declaration of conformity (provided for in Article 39 of Regulation 2025/40).

Specific exemptions are provided for certain types of packaging for medical devices and medicinal products.

Article 6, which stipulates that all packaging must be recyclable, does not apply to:

- › contact-sensitive packaging of medical devices covered by [Regulation \(EU\) 2017/745](#);
- › contact-sensitive packaging of in vitro diagnostic medical devices covered by [Regulation \(EU\) 2017/746](#);
- › contact-sensitive packaging for infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes defined in Article 1, paragraph 1, points (a), (b) and (c), of [Regulation \(EU\) 609/2013](#).

Paragraphs 1 and 2 of Article 7, which impose a minimum recycled content in plastic packaging, do not apply to:

- › contact-sensitive plastic packaging of medical devices, devices exclusively destined for research use and investigational devices covered by [Regulation \(EU\) 2017/745](#);
- › contact-sensitive plastic packaging of in vitro diagnostic medical devices covered by [Regulation \(EU\) 2017/746](#);

- › packaging of supplies, components and immediate packaging components for the manufacturing of medicinal products covered by [Directive 2001/83/EC](#) and veterinary medicinal products covered by [Regulation 2019/6](#), where such packaging is needed to be in line with the quality standards of the medicinal product.

Paragraphs 2 and 3 of Article 15 of Regulation 2025/40 do not apply to custom-made transport packaging for configurable medical devices and medical systems that are to be used in industrial and healthcare environments. These paragraphs refer, in particular, to the obligation to carry out the conformity assessment procedure for packaging (referred to in Article 38) and to draw up and keep the technical documentation referred to in [Annex VII](#).

Article 12 of Regulation 2025/40, which lays down requirements for labelling, does not apply to immediate or outer packaging as defined in Regulations [\(EU\) 2017/745](#), [\(EU\) 2017/746](#) and [\(EU\) 2019/6](#) and [Directive 2001/83/EC](#), if there is no space on the packaging due to other labelling requirements as defined in those Union legislative acts or if the labelling of the packaging could jeopardise the safe use of medicinal products for human use or of veterinary medicinal products.

Will the declaration of conformity to be drawn up in accordance with Annex VII be mandatory from 12 August 2026 (18 months after the entry into force of Regulation 2025/40)?

Yes, the declaration of conformity must be drawn up from 12 August 2026 (date of application of Regulation 2025/40 as established by Article 71).

4.1|F4

4.1|F5

The manufacturer “shall only place packaging on the market that complies with the requirements of Articles 5 to 12, following a conformity assessment procedure”. Nevertheless, the definition of “manufacturer” includes anyone who manufactures or has manufactured packaging or packaged products. In the case of a company that places packaged products on the market, is it therefore not necessary to draw up a declaration of conformity?

The manufacturer is not only the person who manufactures packaging but also the person who has packaging or a packaged product designed or manufactured **under its own name or trademark**, regardless of whether any other trademark is visible on the packaging or on the packaged product, except where the person who has had packaging or a packaged product designed or manufactured falls within the definition of a micro-enterprise.

4.1|F6

In the case of finished products, such as branded products, it is not clearly defined who should be considered the “manufacturer” for the purposes of drawing up the declaration of conformity for packaging. Is it possible to have clarification on this point?

Pursuant to the provisions of Article 21 of Regulation 2025/40, “Where an importer or a distributor places packaging on the market under its own name or trademark or modifies packaging already placed on the market in a way that could affect compliance with the relevant requirements of this Regulation, that importer or distributor shall be considered to be a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer under Article 15”.

Therefore, in the case of branded products, the company that affixes its trademark to the packaging is considered the “manufacturer”. Consequently, it is the latter that must provide the declaration of conformity.

Who is responsible for checking and verifying the accuracy of declarations of conformity? This is particularly relevant in the specific case of secondary raw materials from outside the EU.

Article 39 of Regulation 2025/40 provides that “Competent authorities shall endeavour to control the accuracy of at least part of the declarations of conformity per year, assessed on a risk-based approach and shall take the necessary measures to address non-compliance, such as the withdrawal of non-compliant products from the market”.

For a precise definition of the competent authorities, it will be necessary to wait for the internal national implementing act of Regulation 2025/40.

4.1|F7



Other

The questions collected in this section concern cross-cutting issues that are not directly related to a single measure of Regulation 2025/40, but are nevertheless relevant to its proper understanding and application. Each FAQ is accompanied by one or more tags allowing for quick identification of the subject area.

The macro-categories identified are as follows:

- > **OBLIGATED PARTIES;**
- > **RESPONSIBILITY;**
- > **SCOPE OF APPLICATION;**
- > **DEPOSITS;**
- > **PACKAGING FOR MEDICAL DEVICES;**
- > **PENALTIES.**

OBLIGATED PARTIES

RESPONSIBILITY

What are the differences between the obligations of the manufacturer and those of the importer?

Regulation 2025/40 defines the “manufacturer” as “any natural or legal person that manufactures packaging”, while the “importer” is “any natural or legal person established within the Union that places packaging from a third country on the market”.

On the basis of the provisions of Article 15 of Regulation 2025/40, manufacturers must only place packaging on the market that complies with the requirements set out in Articles 5 to 12 (sustainability and labelling requirements for packaging) and, before placing the packaging on the market, they must carry out (or have carried out on their behalf) the conformity assessment procedure for the

packaging by drawing up the technical documentation referred to in [Annex VII](#).

Importers must also ensure that only packaging that complies with the requirements set out in Articles 5 to 12 of Regulation 2025/40 is placed on the EU market and that the manufacturer has carried out the conformity assessment procedure, that the technical documentation has been drawn up and that all the mandatory information necessary to identify the manufacturer is indicated on the packaging.

Furthermore, Article 21 of Regulation 2025/40 identifies specific cases in which the obligations of manufacturers apply to importers and distributors; the regulation stipulates that where an importer or a distributor places packaging on the market under its own name or trademark or modifies packaging already placed on the market in a way that could affect compliance with the relevant requirements of Regulation 2025/40, that importer or distributor shall be considered to be a manufacturer for the purposes of Regulation 2025/40 and shall be subject to the obligations of the manufacturer under Article 15. Where an importer or a distributor falls within the definition of micro-enterprise set out in [Recommendation 2003/361/EC](#) as applicable on 11 February 2025, and the natural or legal person that supplies the packaging to the importer or distributor is located in the Union, the natural or legal person that supplies the packaging shall be considered to be the manufacturer for the purposes of Article 15.

As a packaging manufacturer, what information do you need to request from your suppliers to ensure compliance with the Regulation?

Pursuant to Article 16, suppliers must provide the manufacturer with all the information and documentation necessary for the manufacturer to demonstrate the conformity of the packaging and the packaging materials with Regulation 2025/40, including the technical documentation referred to in [Annex VII](#).

OBLIGATED PARTIES

RESPONSIBILITY

OBLIGATED PARTIES

RESPONSIBILITY

What are the obligations of packaging producers?

The term “producer” in Regulation 2025/40 means any manufacturer, importer or distributor to whom, irrespective of the selling technique used, including by means of distance contracts, one of the following applies:

- a. the manufacturer, importer or distributor is established in a Member State and makes available for the first time from within the territory of that Member State and on that same territory transport packaging, service packaging, or primary production packaging, whether as single-use packaging or as reusable packaging; or
- b. the manufacturer, importer or distributor is established in a Member State and makes available for the first time from within the territory of that Member State and on that same territory products packaged in packaging other than those referred to in point (a); or
- c. the manufacturer, importer or distributor is established in a Member State or in a third country and makes available for the first time on the territory of another Member State, directly to end users, transport packaging, service packaging or primary production packaging, whether as single-use packaging or as reusable packaging; or
- d. the manufacturer, importer or distributor is established in a Member State or in a third country and makes available for the first time on the territory of another Member State, directly to end users, products packaged in packaging other than those referred to in point (c); or
- e. the manufacturer, importer or distributor is established in a Member State and unpacks packaged products without being an end user, unless another person is the producer as defined in point (a), (b), (c) or (d).

In order to correctly outline the obligations and responsibilities of the entity, it is necessary to understand whether it identifies itself as a manufacturer, importer or distributor of packaging.

According to Regulation 2025/40, the definition of manufacturer is “any natural or legal person that manufactures packaging or a packaged product”. My company manufactures automation systems for microbiology laboratories. These automation systems are shipped by sea or air and are placed in wooden crates, made by a carpenter (who supplies the materials) to our specific dimensions and who carries out the packing at our premises. In this case, do we fall under the category of “packaged products”, meaning that we must also consider ourselves manufacturers of the packaging? Our automation systems are IVDs (according to Regulation 2017/746), so are they excluded from the application of Regulation 2025/40?

Pursuant to Article 3, paragraph 1, point (13)(a) “where a natural or legal person has packaging or a packaged product designed or manufactured under its own name or trademark, regardless of whether any other trademark is visible on the packaging or on the packaged product, “manufacturer” means that natural or legal person”.

In light of this definition, if the automation company affixes its name to the packaging it has had designed, it would appear to fall within the category of “manufacturer” and the carpenter within that of “supplier”.

Packaging sensitive to contact with in vitro diagnostic medical devices referred to in [Regulation \(EU\) 2017/746](#) is expressly excluded from the obligations set out in Article 6, which stipulates that all packaging must be recyclable, and Article 7, paragraphs 1 and 2, which impose a minimum recycled content in plastic packaging, as well as, under certain conditions, those referred to in Article 12, which lays down requirements for labelling.

When is an industry considered a “manufacturer” of packaging?

Regulation 2025/40 defines “manufacturer” as any natural or legal person that manufactures packaging or a packaged product.

OBLIGATED PARTIES

RESPONSIBILITY

OBLIGATED PARTIES

RESPONSIBILITY

It is then specified that:

- f. subject to point (b), where a natural or legal person has packaging or a packaged product designed or manufactured under its own name or trademark, regardless of whether any other trademark is visible on the packaging or on the packaged product, “manufacturer” means that natural or legal person;
- g. where the natural or legal person that has the packaging or packaged product designed or manufactured under its own name or trademark falls within the definition of micro-enterprise set out in [Recommendation 2003/361/EC](#) as applicable on 11 February 2025, and the natural or legal person that supplies the packaging to the natural or legal person that has the packaging designed or manufactured under its own name or trademark is located in the same Member State, “manufacturer” means the natural or legal person that supplies the packaging.

OBLIGATED PARTIES

RESPONSIBILITY

Do the responsibilities (and, consequently, the penalties) also apply to traders or “only” to customers and producers?

Regulation 2025/40 does not establish penalties for breaches of the obligations laid down therein; it will be up to the individual Member States to define them. Article 68 of Regulation 2025/40 stipulates that by 12 February 2027, Member States must lay down rules on penalties applicable to infringements of Regulation 2025/40 and take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

With regard to responsibilities, Regulation 2025/40 imposes obligations, in general, on economic operators identified as “the manufacturer, the supplier, the importer, the distributor, the authorised representative, the final distributor and the fulfilment service provider”.

Does the new Regulation 2025/40 also apply to users or only to packaging manufacturers?

Regulation 2025/40 imposes obligations on both the “packaging producer”, identified as the manufacturer, importer or distributor of the packaging, and the final distributor, i.e. the entity in the supply chain that delivers packaged products, including through re-use, or products that can be purchased through refill to the end user. No obligations are imposed on the end user, i.e. any natural or legal person that resides or is established in the Union to whom a product has been made available either as a consumer or as a professional end user in the course of its industrial or professional activities, and that does not make that product further available on the market in the form supplied to it.

Does the new Regulation 2025/40 apply to both manufacturers and users of packaging?

Yes, Regulation 2025/40 imposes obligations on both the “packaging producer”, identified as the manufacturer, importer or distributor of the packaging, and the final distributor, i.e. the entity in the supply chain that delivers packaged products, including through re-use, or products that can be purchased through refill to the end user. No obligations are imposed on the end user, i.e. any natural or legal person that resides or is established in the Union to whom a product has been made available either as a consumer or as a professional end user in the course of its industrial or professional activities, and that does not make that product further available on the market in the form supplied to it.

OBLIGATED PARTIES

RESPONSIBILITY

OBLIGATED PARTIES

RESPONSIBILITY

OBLIGATED PARTIES

RESPONSIBILITY

SCOPE OF APPLICATION

What is the role of a company that sells a PET bottle supplied by a manufacturer based in a non-EU country?

Under Regulation 2025/40, such a trader is considered an “importer”, defined as “any natural or legal person established within the Union that places packaging from a third country on the market” and is primarily subject to the obligations set out in Article 18 of Regulation 2025/40.

SCOPE OF APPLICATION

Does packaging already subject to other regulations, including those on the transport of dangerous goods, fall within the scope of Regulation 2025/40?

Yes, as specified in Article 2, Regulation 2025/40 generally applies to:

- › all packaging, regardless of the material used;
- › all packaging waste, regardless of the context in which it is used or from which it originates: industry, other manufacturing, retail or distribution, offices, services or private households.

In any case, the measure does not affect EU provisions on packaging and safety/quality/health protection/hygiene of packaged products, hazardous waste, and transport.

However, specific types of packaging may be exempted from the application of certain specific provisions.

Packaging used for the transport of dangerous goods in accordance with [Directive 2008/68/EC](#) is not subject to Article 6 on “recyclable packaging”, Article 7 on “minimum recycled content in plastic packaging”, Article 29 on “re-use targets,” and Article 12 on “labelling” with regard to the indication of the material composition of packaging.

Furthermore, Article 2 specifies that “where this Regulation conflicts with [Directive 2008/68/EC](#), [Directive 2008/68/EC](#) shall prevail”.

Although this is a European Regulation, it is likely that some practical and implementation measures will be necessary at national level. Will Italy simply apply the provisions at European level or will it exercise discretion in implementing the measures?

Regulation 2025/40 is directly applicable in all Member States and therefore does not require a national Italian legislative act to be transposed. Italy will exercise its powers within the limits granted to individual Member States by Regulation 2025/40.

Does the term “contact-sensitive packaging” refer only to primary packaging?

The definition of contact-sensitive packaging is given in Article 3, paragraph 1, point (49) of Regulation 2025/40.

Contact-sensitive packaging is primary packaging intended for use with products covered by the following regulations, directives and decisions:

- › [Regulation \(EC\) 1831/2003](#) on additives for use in animal nutrition;
- › [Regulation \(EC\) 1935/2004](#) on materials and articles intended to come into contact with food;
- › [Regulation \(EC\) 767/2009](#) on the placing on the market and use of feed;
- › [Regulation \(EC\) 1223/2009](#) on cosmetic products;
- › [Regulation \(EU\) 2017/745](#) on medical devices, amending [Regulation \(EU\) 2017/746](#) on in vitro diagnostic medical devices;
- › [Regulation \(EU\) 2019/4](#) on the manufacture, placing on the market and use of medicated feed;
- › [Regulation \(EU\) 2019/6](#) on veterinary medicinal products;
- › [Directive 2001/83/EC](#) on the Community code relating to medicinal products for human use;
- › [Directive 2002/46/EC](#) on the approximation of the laws of the Member States relating to food supplements;
- › [Commission Decision \(EU\) 2023/1809](#) establishing the EU Eco-

SCOPE OF APPLICATION

SCOPE OF APPLICATION

label criteria for absorbent hygiene products and for reusable menstrual cups (for the products defined in Articles 1 and 2).

SCOPE OF APPLICATION

We have many production sites in Europe: the UK, Finland, Germany, Spain, as well as Italy. Will the same rules apply in all these countries?

European regulations are directly applicable in all EU Member States. In non-EU countries, however, Regulation 2025/40 will not apply, so there may be different provisions in the UK.

SCOPE OF APPLICATION

When does Regulation 2025/40 enter into force?

Regulation 2025/40 entered into force on 11 February 2025, but its provisions will apply from 12 August 2026, with different obligations and deadlines depending on the measures envisaged. For further details, please refer to the [timeline](#) in the foreword.

SCOPE OF APPLICATION

SUP Directive and PPWR: are there any unified guidelines with regard to areas of overlap?

At present, there are no guidelines on areas of overlap between the two regulations.

In summary, it should be noted that, as the SUP Directive is special legislation, it should take precedence over Regulation 2025/40 with regard to its scope of application.

However, it should be noted that the marketing ban established by Article 25 of Regulation 2025/40 for the specific types of goods listed in [Annex V](#) prevails over any national derogations provided for in relation to the ban referred to in Article 5 of the SUP Directive

(transposed in Italy by Article 5 of [Legislative Decree 196 of 8 November 2021](#)).

An example of a measure in the SUP Directive that prevails over Regulation 2025/40 is the provision in Article 5 on restrictions on placement on the market, transposed in Italy by Article 5 of [Legislative Decree 196 of 8 November 2021](#)).

Specifically, the measure provides for a general ban on placing on the market (without prejudice to the derogation referred to in Article 5, paragraph 3, of [Legislative Decree 196 of 8 November 2021](#)) for a list of single-use plastic goods, including certain packaging such as, for example, food containers made of expanded polystyrene, i.e. receptacles such as boxes, with or without a cover, used to contain food which:

- a. is intended for immediate consumption, either on-the-spot or take-away;
- b. is typically consumed from the receptacle; and
- c. is ready to be consumed without any further preparation, such as cooking, boiling or heating, including food containers used for fast food or other meal ready for immediate consumption, except beverage containers, plates and packets, and wrappers containing food.

Such packaging, while meeting all the sustainability requirements of Regulation 2025/40, cannot be marketed in any case, as it is subject to a specific ban under the SUP Directive.

Furthermore, the Directive sets out certain additional requirements specific to those established by Regulation 2025/40 for certain categories of packaging.

In this regard, we can mention the marking requirements set out in Article 7, which also apply to beverage cups, and the requirement that caps remain attached to containers, which applies to bottles and composite beverage packaging.

SCOPE OF APPLICATION

Does the same regulation apply outside Italy (Europe and non-EU countries)?

Regulation 2025/40 is directly applicable in all EU Member States.

SCOPE OF APPLICATION

Article 67, paragraph 5 of the new Regulation 2025/40 is expected to amend the SUP Directive 2019/904, extending the list of single-use plastic packaging formats banned from being placed on the market from February 2029. These include plastic rings for multipacks, used as grouped packaging. However, the regulation does not specify the ban for materials other than PET, suggesting that the use of R-PET or similar recycled plastics may remain permitted. Can you confirm this?

The amendments made by Regulation 2025/40 to the SUP Directive do not affect the scope of the Directive, which prohibits the marketing of certain single-use plastic products regardless of whether the plastic they are made of is recycled.

The only exemption is that set out in paragraph 3 of Article 5 of Legislative Decree 196 of 8 November 2021 (which transposed the SUP Directive into Italian law), which provides that “The prohibition referred to in paragraph 1 shall not apply to the placing on the market of products made of biodegradable and compostable material, certified as complying with the European standard UNI EN 13432 or UNI EN 14995, with a percentage of renewable raw material equal to or greater than 40% and, from 1 January 2024, greater than at least 60%, in the following cases:

- a. where it is not possible to use reusable alternatives to single-use plastic products intended to come into contact with foods listed in Part B of the Annex;
- b. where use is intended in controlled circuits that routinely and consistently deliver waste to the public collection service through separate collection, such as canteens, healthcare or social care facilities and residences;

- c. where such alternatives, in view of the specific circumstances of time and place, do not provide adequate guarantees in terms of hygiene and safety;
- d. in view of the particular type of food or drink;
- e. in circumstances where there are large numbers of people present;
- f. where the environmental impact of the reusable product is worse than that of biodegradable and compostable single-use alternatives, based on a life cycle analysis by the manufacturer.”

I would like more information about the measures in place or to be implemented at national level for the implementation of Regulation 2025/40. Of particular interest is the issue of Deposit Return Scheme (DRS) mechanisms provided for in the PPWR and not currently present in the Italian market.

The “deposit and return system” is defined as “a system in which a deposit is charged to the end user when purchasing a packaged or filled product covered by that system, and redeemed when the deposit bearing packaging is returned through one of the collection channels that are authorised for that purpose by the national authorities”.

Regulation 2025/40 requires Member States to establish deposit and return systems by 1 January 2029, with particular reference to achieving the target of at least 90% separate collection for:

- a. single-use plastic beverage bottles with a capacity of up to three litres; and
- b. single-use metal beverage containers with a capacity of up to 3 litres.

On a voluntary basis, Member States are encouraged to establish and maintain deposit and return systems for other types of packaging, in particular for single-use glass beverage bottles and beverage cartons.

SCOPE OF APPLICATION

DEPOSITS

OBLIGATED PARTIES

RESPONSIBILITY

SCOPE OF APPLICATION

PACKAGING FOR MEDICAL DEVICES

Annex X to the Regulation 2025/40 sets out the minimum requirements for deposit systems and for the labelling of packaging that is part of a deposit system. This labelling will be defined in an implementing act.

In order to avoid the obligation to establish a deposit system for packaging under points (a) and (b), Member States must achieve a separate collection rate of at least 80% by 2028 and submit a request for a derogation, accompanied by a plan to achieve the 90% target by 2030.

If the derogation is granted, it will lapse if the separate collection rate falls below 90% for three consecutive years.

At present, it is not possible to know what national measures will be taken to comply with these requirements.

Does Regulation 2025/40 also apply to medical devices?

As specified in Article 2, Regulation 2025/40 applies to all packaging, regardless of the material used, and to all packaging waste, regardless of the context in which the packaging is used or the origin of the packaging waste. However, specific exemptions are provided for certain types of packaging for medical devices and medicinal products.

Article 6 of Regulation 2025/40, which stipulates that all packaging must be recyclable, does not apply to:

- › contact-sensitive packaging of medical devices covered by Regulation (EU) 2017/745;
- › contact-sensitive packaging of in vitro diagnostic medical devices covered by Regulation (EU) 2017/746;
- › contact-sensitive packaging for infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes defined in Article 1, paragraph 1, points (a), (b) and (c), of Regulation (EU) 609/2013.

Paragraphs 1 and 2 of Article 7 of Regulation 2025/40, which impose a minimum recycled content in plastic packaging, do not apply to:

- › contact-sensitive plastic packaging of medical devices, devices exclusively destined for research use and investigational devices covered by [Regulation \(EU\) 2017/745](#);
- › contact-sensitive plastic packaging of in vitro diagnostic medical devices covered by [Regulation \(EU\) 2017/746](#);
- › packaging of supplies, components and immediate packaging components for the manufacturing of medicinal products covered by [Directive 2001/83/EC](#) and veterinary medicinal products covered by [Regulation \(EU\) 2019/6](#), where such packaging is needed to be in line with the quality standards of the medicinal product.

Paragraphs 2 and 3 of Article 15 of Regulation 2025/40 do not apply to custom-made transport packaging for configurable medical devices and medical systems that are to be used in industrial and healthcare environments. These paragraphs refer, in particular, to the obligation to carry out the conformity assessment procedure for packaging (referred to in Article 38) and to draw up and keep the technical documentation referred to in [Annex VII](#).

Article 12 of Regulation 2025/40, which lays down requirements for labelling, does not apply to immediate or outer packaging as defined in [Regulations \(EU\) 2017/745](#), [\(EU\) 2017/746](#) and [\(EU\) 2019/6](#) and [Directive 2001/83/EC](#) relating respectively to medical devices, in vitro diagnostic medical devices, veterinary medicinal products and medicinal products for human use, if there is no space on the packaging due to other labelling requirements as defined in those Union legislative acts, or if the labelling of the packaging could jeopardise the safe use of medicinal products for human use or of veterinary medicinal products.

OBLIGATED PARTIES

RESPONSIBILITY

SCOPE OF APPLICATION

PACKAGING FOR MEDICAL DEVICES

Does “contact-sensitive packaging” refer to all primary packaging for cosmetics, medical devices and food supplements?

Contact-sensitive packaging is primary packaging intended for use with products covered by the following regulations, directives and decisions:

- › [Regulation \(EC\) 1831/2003](#) on additives for use in animal nutrition;
- › [Regulation \(EC\) 1935/2004](#) on materials and articles intended to come into contact with food;
- › [Regulation \(EC\) 767/2009](#) on the placing on the market and use of feed;
- › [Regulation \(EC\) 1223/2009](#) on cosmetic products;
- › [Regulation \(EU\) 2017/745](#) on medical devices, amending [Regulation \(EU\) 2017/746](#) on in vitro diagnostic medical devices;
- › [Regulation \(EU\) 2019/4](#) on the manufacture, placing on the market and use of medicated feed;
- › [Regulation \(EU\) 2019/6](#) on veterinary medicinal products;
- › [Directive 2001/83/EC](#) on the Community code relating to medicinal products for human use;
- › [Directive 2002/46/EC](#) on the approximation of the laws of the Member States relating to food supplements;
- › [Commission Decision \(EU\) 2023/1809](#) establishing the EU Eco-label criteria for absorbent hygiene products and for reusable menstrual cups (for the products defined in Articles 1 and 2).

RESPONSIBILITY

PACKAGING FOR MEDICAL DEVICES

Does the new Regulation 2025/40 apply to all product categories or are there specific exemptions (e.g. distributors of medical devices)?

Regulation 2025/40 applies in general to all packaging; however, for certain categories of packaging, there are some exemptions from the obligations set out in Regulation 2025/40. For example, the recyclability requirements set out in Article 6 of Regulation

2025/40 do not apply to medical device packaging, nor do the minimum recycled content requirements for plastic packaging set out in Article 7 of Regulation 2025/40. Furthermore, medical devices are not subject to the obligation to carry out the conformity assessment procedure for packaging (referred to in Article 38) and to draw up and keep the technical documentation referred to in [Annex VII](#).

What is the deadline beyond which packaging that does not comply with Regulation 2025/40 can no longer be placed on the market? Are there penalties for those who do not comply with the new requirements?

The content of Regulation 2025/40 applies, in general, from 12 August 2026; however, some specific obligations established by Regulation 2025/40 will apply to operators in the sector at a later date, in order to allow operators to comply with the new rules. Therefore, in order to identify the individual deadlines, reference should be made to the various measures contained therein.

Article 68 of Regulation 2025/40 stipulates that, by 12 February 2027, Member States must establish the penalties to be applied in the event of infringements of the requirements.

For further details on the timetable for the European Commission and deadlines for businesses, please refer to the [timeline](#) in the foreword.

PENALTIES

7 Reference annexes

This chapter contains only the annexes to Regulation 2025/40 that are expressly referred to in the Handbook and are relevant for the purposes of analysing the sustainability and labelling requirements considered in the document.

The following annexes are listed below:

- › **ANNEX II**
Categories and parameters for assessment of recyclability of packaging
- › **ANNEX III**
Compostable packaging
- › **ANNEX IV**
Methodology for packaging minimisation assessment
- › **ANNEX V**
Restrictions on use of packaging formats
- › **ANNEX VI**
Requirements specific to re-use systems and refill stations
- › **ANNEX VII**
Conformity assessment procedure
- › **ANNEX VIII**
EU declaration of conformity
- › **ANNEX X**
Minimum requirements for deposit and return systems

ANNEX II

Categories and parameters for assessment of recyclability of packaging

Table 1

Indicative list of packaging materials, types and categories referred to in Article 6

Category No	Predominant packaging material	Packaging type	Format (illustrative and non-exhaustive)	Colour / Optical transmittance
1	Glass	Glass and composite packaging, of which the majority is glass	Bottles, jars, flacons, cosmetics pots, tubs, ampoules, vials made of glass (soda lime silica), aerosol cans	—
2	Paper/cardboard	Paper/cardboard packaging	Boxes, trays, grouped packaging, flexible paper packaging (e.g. films, sheets, pouches, lidding, cones, wrappers)	—
3	Paper/cardboard	Composite packaging of which the majority is paper/cardboard	Liquid packaging board, and paper cups (i.e. laminated with polyolefin and with or without aluminium), trays, plates and cups, metallised or plastic laminated paper/cardboard, paper/cardboard with plastic liners/windows	—
4	Metal	Steel and composite packaging of which the majority is steel	Rigid formats (aerosols cans, cans, paint tins, boxes, trays, drums, tubes) made of steel, including tinplate and stainless steel	—
5	Metal	Aluminium and composite packaging of which the majority is aluminium – rigid	Rigid formats (food and beverage cans, bottles, aerosols, drums, tubes, cans, boxes, trays) made of aluminium	—
6	Metal	Aluminium and composite packaging of which the majority is aluminium – semi-rigid and flexible	Semi rigid and flexible formats (containers and trays, tubes, foils, flexible foil) made of aluminium	—
7	Plastic	PET – rigid	Bottles and flasks	Transparent clear / coloured, opaque
8	Plastic	PET – rigid	Rigid formats other than bottles and flasks (including pots, tubs, jars, cups, mono- and multilayer trays and containers, aerosol cans)	Transparent clear / coloured, opaque
9	Plastic	PET – flexible	Films	Natural / coloured
10	Plastic	PE – rigid	Containers, bottles, trays, pots and tubes	Natural / coloured
11	Plastic	PE – flexible	Films, including multilayer and multi-material packaging	Natural / coloured
12	Plastic	PP – rigid	Containers, bottles, trays, pots and tubes	Natural / coloured
13	Plastic	PP – flexible	Films, including multilayer and multi-material packaging	Natural / coloured

Category No	Predominant packaging material	Packaging type	Format (illustrative and non-exhaustive)	Colour / Optical transmittance
14	Plastic	HDPE and PP – rigid	Crates and pallets, corrugated board plastic	Natural / coloured
15	Plastic	PS and XPS – rigid	Rigid formats (including dairy packaging, trays, cups and other food containers)	Natural / coloured
16	Plastic	EPS – rigid	Rigid formats (including fish boxes / white goods and trays)	Natural / coloured
17	Plastic	Other rigid plastics (e.g. PVC, PC) including multi-materials – rigid	Rigid formats, including intermediate bulk containers, drums	—
18	Plastic	Other flexible plastics including multi-materials – flexible	Pouches, blisters, thermoformed packaging, vacuum packaging, modified atmosphere/modified humidity packaging, including flexible intermediate bulk containers, bags, stretch films	—
19	Plastic	Biodegradable plastics ⁽¹⁾ – rigid (e.g. PLA, PHB) and flexible (e.g. PLA)	Rigid and flexible formats	—
20	Wood, cork	Wooden packaging, including cork	Pallets, boxes, crates	—
21	Textile	Natural and synthetic textile fibres	Bags	—
22	Ceramics or porcelain stoneware	Clay, stone	Pots, containers, bottles, jars	—

⁽¹⁾ Please note that this category contains plastics that are readily biodegradable (meaning a proven ability to convert >90 % of the original material into CO₂, water and minerals by biological processes within 6 months) and regardless of the feedstock used for their production. Biobased polymers that are not readily biodegradable are covered under the other relevant plastic categories.

Table 2

Indicative list of packaging materials and categories referred to in Article 6

Materials	Categories	Link to Table 1, Annex II
Plastic	PET rigid	categories 7, 8
	PE rigid, PP rigid, HDPE and PP rigid	categories 10, 12, 14
	Films/flexible	categories 9, 11, 13, 18
	PS, XPS, EPS	categories 15, 16
	Other rigid plastics	category 17
	Biodegradable (rigid and flexible)	category 19

Materials	Categories	Link to Table 1, Annex II
Paper/cardboard	Paper/cardboard (except liquid packaging board)	categories 2, 3
	Liquid packaging board	category 3
Metal	Aluminium	categories 5, 6
	Steel	category 4
Glass	Glass	category 1
Wood	Wood, cork	category 20
Others	Textile, ceramics/porcelain and others	categories 21, 22

Table 3

Recyclability performance grades

Packaging recyclability shall be expressed in the performance grades A, B or C.

From 2030, recyclability performance is based on design for recycling criteria. The design for recycling criteria shall ensure the circularity of the use of the resulting secondary raw materials of sufficient quality to substitute the primary raw materials.

The assessment based on design for recycling criteria shall be carried out for each packaging category listed in Table 1, taking into account the methodology established under Article 6(4) and the related delegated acts, as well as the parameters established in Table 4. After weighing the criteria per packaging unit, it will be classified into categories A, B or C. When a packaging unit's recyclability performance grade is below 70 %, it is considered to be non-compliant with the recyclability performance grades and therefore the packaging will be considered technically non-recyclable and its placing on the market shall be restricted.

From 2035, a new factor shall be added to the assessment of the packaging recyclability, which is the recycled-at-scale assessment. Consequently, a new assessment shall be carried out based on the quantity (weight) of the material effectively recycled from each of the packaging categories in accordance with the methodology established in the implementing acts adopted under Article 6(5). The thresholds related to the annual recycled packaging materials for compliance with the recycled-at-scale assessment shall be defined taking into account the targets set in Article 3(1), point (39).

2030		2035			2038		
Recyclability performance grade	Design for recycling (DfR) Assessment of recyclability per unit, in terms of weighting	Recyclability performance grade (for DfR)	Design for recycling (DfR) Assessment of recyclability per unit, in terms of weighting	Recyclability performance grade (for recycled-at-scale assessment)	Recyclability performance grade	Design for recycling (DfR) Assessment of recyclability per unit, in terms of weighting	Recyclability performance grade (for recycled-at-scale assessment)
Grade A	higher or equal to 95 %	Grade A	higher or equal to 95 %	Grade A RaS	Grade A	higher or equal to 95 %	Grade A RaS
Grade B	higher or equal to 80 %	Grade B	higher or equal to 80 %	Grade B RaS	Grade B	higher or equal to 80 %	Grade B RaS
Grade C	higher or equal to 70 %	Grade C	higher or equal to 70 %	Grade C RaS	Grade C CANNOT BE PLACED ON THE MARKET	higher or equal to 70 %	Grade C RaS
TECHNICALLY NON-RECYCLABLE	lower than 70 %	TECHNICALLY NON-RECYCLABLE	lower than 70 %	NOT RECYCLED AT SCALE (below thresholds of Article 3(1), point (39).	TECHNICALLY NON-RECYCLABLE	lower than 70 %	NOT RECYCLED AT SCALE (below thresholds of Article 3(1), point (39).

Table 4

Non-exhaustive list of parameters for setting design for recycling criteria under Article 6

The list in this Table shall be used as a basis when defining design for recycling criteria, as set out in Article 6(4). The design for recycling criteria shall then be used in order to set the calculations leading to the performance grades listed in Table 3. In addition, the assessment of the parameters set out in that list shall consider:

- separability of any component of packaging, either manually by end users or in processing plants,
- efficiency of sorting and recycling processes, for example yield,
- evolution of sorting and recycling technologies (to address the aspect if the packaging cannot be sorted today, but it might be sortable in 2 years), and
- preservation of functionality of secondary raw materials enabling the substitution of primary raw materials.

The packaging functionality that the following parameters provide to the packaging shall be factored-in in the setting of design for recycling criteria.

Parameters for design for recycling criteria	Parameter's relevance
Additives	Additives refer often to substances added to materials to confer specific properties. The presence of additives in the packaging containers can result in incorrect sorting of the packaging materials during the sorting process and can contaminate the obtained secondary raw materials.
Labels	Coverage rate of labels can affect the efficiency of the sorting process. Material from which the label is made and type of glue or adhesive also affect the quality of the secondary raw material.
Sleeves	Coverage rate of the sleeve on the main packaging body affects the possibilities for sorting. In addition, the use of sleeves can affect the ability to separate them from the main packaging body. The material from which the sleeve is made can affect both the sortability and the recyclability of the packaging.
Closures and other small packaging components	Closures refer to components used to close or seal the packaging. There may be different types of closures, rigid or flexible, such as tamper-evident shrink wrap, linings, caps, lids, seals, valves, etc. The material from which the closures is made can affect both the sortability and the recyclability of the packaging. Closures that are not firmly attached to the packaging can increase litter. Small packaging components attached to the main packaging body can affect the separability and the recyclability of the packaging. In addition, the components can be lost in the sorting and recycling process.
Adhesives	Adhesives can be used in such a way that they can be easily separated in the recycling process or by the end user or in a way that they do not affect the efficiency of the sorting and recycling processes. The presence of adhesive residues on the packaging can downgrade the quality (purity) of the secondary raw materials. Washable adhesives can ensure the separation from the main packaging body and that no adhesive residue remains in the secondary raw material.

Parameters for design for recycling criteria	Parameter's relevance
Colours	Colours are substances that impart colour to the packaging material. Heavily dyed materials in paper or plastics can cause problems with regard to sorting and can downgrade the quality of secondary raw materials.
Material composition	Use of mono-materials or material combinations that permit easy separation and ensure high yield of secondary raw materials is preferable.
Barriers / coatings	The material or substance added to confer barrier properties (barrier), or a variety of materials applied on the surface to impart other properties (coating). The presence of barriers or coatings within the packaging can make recycling more difficult. Combinations that ensure high yield of secondary raw materials are preferable.
Inks and lacquers / printing / coding	Inks and lacquers are mixtures of colorants with other substances applied onto the material by a printing or coating process (ink) or a protective coating made of resin or cellulose ester, or both, dissolved in a volatile solvent (lacquer). Coding refers to printing applied directly to sales packaging for the purpose of batch coding and other information and branding. The use of inks with substances of concern hinders recycling, as those packaging units cannot be recycled. Printing inks when released can contaminate the recycling stream through the washing water. Likewise, printing inks which are not released can impair the transparency of the recycling stream.
Product residues / ease of emptying	Residues of the content of the packaging can affect the sortability and the recyclability of the packaging. The design of the packaging should enable the easy emptying of its content and when disposed of should be in a fully drained condition.
Ease of dismantling	Components that are firmly attached to each other can affect the sortability and the recyclability of the packaging. Packaging design can facilitate the possibility of separating different components into different material streams.

ANNEX III

Compostable packaging

Conditions to be considered when mandating or introducing the use of compostable packaging format:

- (a) it could not have been designed as reusable packaging or the products could not be placed on the market without packaging;
- (b) it is designed to enter the organic waste stream at the end of its life;
- (c) it is of such biodegradable nature that it allows the packaging to undergo physical or biological decomposition, including anaerobic digestion, resulting ultimately in conversion into carbon dioxide and water, new microbial biomass, mineral salts, and, in the absence of oxygen, methane;
- (d) its use significantly increases the collection of organic waste compared to the use of non-compostable packaging materials;
- (e) its use significantly reduces the contamination of compost with non-compostable packaging and does not cause any problems in bio-waste processing;
- (f) its use does not increase the contamination of non-compostable packaging waste streams.

ANNEX IV

Methodology for packaging minimisation assessment

Part A

Performance criteria

1. Product protection: packaging design shall ensure protection of the product, from the point of packaging or filling until its end use, with a view to preventing significant product damage, loss, deterioration or waste. Requirements may consist of protection against mechanical or chemical damage, vibration, compression, humidity, moisture loss, oxidation, light, oxygen, microbiological infection, pest, deterioration of organoleptic properties, etc. and include references to specific Union law setting out requirements on product quality.
2. Packaging manufacturing processes: the packaging design shall be compatible with the packaging manufacturing and filling processes. The packaging manufacturing processes may determine packaging design elements, such as the shape of a container, thickness tolerances, size, feasibility of tooling, or specifications minimising waste in manufacturing. The processes operated by manufacturer of products may also require certain design elements of packaging, such as impact and stress resistance, mechanical strength, packing line speed and efficiency, stability in conveying, heat resistance, effective closing, minimum headspace, or hygiene.
3. Logistics: the packaging design shall ensure adequate and safe distribution, transport, handling and warehousing of the packaged product. Requirements may consist of dimensional coordination for optimum space utilisation, compatibility with palletising and de-palletising systems, handling and warehousing system, and packaging system integrity during transport and handling.
4. Packaging functionality: the packaging design shall ensure its functionality, taking into account the purpose of the product and particularities giving rise to its sale, such as sales for gift purposes, or on the occasion of seasonal events.
5. Information requirements: the packaging design shall ensure that any necessary information regarding the packaged product itself, its use, storage and care, including safety instructions, can be provided to end users. Requirements may include providing product information, instructions for storage, application and use, bar codes and the best before date.
6. Hygiene and safety: the packaging design shall ensure user and consumer safety as well as product safety and hygiene throughout the distribution, end use and disposal of the packaged product. Requirements may include those on safe handling design, child resistance, anti-tamper, anti-theft, anti-counterfeit, hazard warnings, clear identification of content, safe opening device or pressure-release closure.
7. Legal requirements: the packaging design shall ensure that the packaging and packaged product can comply with applicable law.
8. Recycled content, recyclability and re-use: the packaging design shall ensure reusability, recyclability and inclusion of recycled content as required under this Regulation. If the packaging is intended for re-use, it shall fulfil the requirements laid down in Article 11(1). This means that the packaging weight or volume may have to be increased beyond what would otherwise be possible under the other performance factors in order to enable for example a higher number of trips or rotations, to facilitate inclusion of recycled content or to enhance recyclability (for example when moving to a mono-material or post-consumer recycled content).

Part B

Assessment methodology and determination of the minimum packaging volume and weight

The assessment of the minimum packaging volume and weight necessary to ensure the packaging functionality as described in Article 3(1), point (1), shall be explained in the technical documentation and shall include at least:

- (a) the description of the outcome of the assessment, including the details of the calculation of the minimum necessary weight and volume for the packaging; possible variations between production batches for a same packaging shall be taken into account and documented;
- (b) for each performance criterion as listed in Part A, a description which explains the design requirement that prevents further reduction of the packaging weight or volume without endangering the packaging functionality, including safety and hygiene, for the packaged product, packaging and user; the method used for the identification of these design requirements shall be described, and the reasons preventing further reduction of the packaging weight or volume shall be explained; all reduction opportunities with a given packaging material shall be investigated, such as the reduction of any superfluous layer which does not perform a packaging function; substitution of one packaging material with another shall not be considered sufficient;
- (c) any test results, market research or studies that have been used for the assessment conducted under points (a) and (b).

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ANNEX V

Restrictions on use of packaging formats

	Packaging format	Restricted use	Illustrative example
1.	Single-use plastic grouped packaging	Single-use plastic packaging used at the point of sale to group goods sold in bottles, cans, tins, pots, tubs, and packets designed as convenience packaging to enable or encourage consumers to purchase more than one product. This excludes grouped packaging necessary to facilitate handling.	Collation films, shrink wrap
2.	Single-use plastic packaging for unprocessed fresh fruit and vegetables	Single-use plastic packaging for less than 1,5 kg pre-packed fresh fruit and vegetables. Member States may set up exemptions in respect of this restriction if there is a demonstrated need to avoid water loss, or turgidity loss, microbiological hazards or physical shocks, oxidation, or if there is no other possibility to avoid commingling of organic fruits and vegetables with non-organic fruits and vegetables in compliance with requirements in Regulation (EU) 2018/848 of the European Parliament and of the Council ⁽¹⁾ on certification or labelling, without entailing disproportionate economic and administrative costs.	Nets, bags, trays, containers
3.	Single-use plastic packaging	Single-use plastic packaging for foods and beverages filled and consumed within the premises in the HORECA sector, which include all eating areas inside and outside a place of business, covered with tables and stools, standing areas, and eating areas offered to the end users jointly by several economic operators or a third party for the purpose of food and drinks consumption. Establishments in the HORECA sector that do not have access to drinking water are exempted.	Trays, disposable plates and cups, bags, boxes
4.	Single-use plastic packaging for condiments, preserves, sauces, coffee creamer, sugar, and seasoning in HORECA sector	Single-use plastic packaging in the HORECA sector, containing individual portions or servings, used for condiments, preserves, sauces, coffee creamer, sugar and seasoning, except in the following cases: (a) such packaging is provided together with take-away ready-prepared food intended for immediate consumption without the need of any further preparation; (b) such packaging is required to ensure safety and hygiene in establishments where there is a medical requirement for individualised care, such as hospitals, clinics or nursing homes.	Sachets, tubs, trays, boxes

⁽¹⁾ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

	Packaging format	Restricted use	Illustrative example
5.	Single-use accommodation sector packaging intended for an individual booking	Single-use packaging for cosmetics, hygiene and toiletry products for the use in the accommodation sector, as described in NACE Rev. 2 – Statistical classification of economic activities, intended for an individual booking only and intended to be discarded before the next guest arrives.	Shampoo bottles, hand and body lotion bottles, sachets around bar soap
6.	Very lightweight plastic carrier bags	Very lightweight plastic carrier bags, except for very lightweight plastic carrier bags required for hygiene reasons or provided as sales packaging for loose food when this helps to prevent food wastage.	Very thin bags provided for bulk groceries

ANNEX VI

Requirements specific to re-use systems and refill stations

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

- (a) 'governance guidelines' means the governance structure of a re-use system that defines the role of system participants, ownership and any envisaged transfer of ownership of packaging, as well as other relevant governance elements of the re-use system as defined in this Annex;
- (b) 'closed loop system' means a re-use system in which reusable packaging is circulated by a system operator or a co-operating group of system participants without the change of the ownership of packaging;
- (c) 'open loop system' means a re-use system in which reusable packaging circulates amongst an unspecified number of system participants, and the ownership of the packaging changes at one or more points in the re-use process;
- (d) 'system operator' means any natural or legal person who is a system participant and manages a re-use system;
- (e) 'system participant' shall mean any natural or legal person who participates in a re-use system and performs at least one of the following actions: collects the packaging either from end users or from other system participants, reconditions it, distributes it among system participants, transports it, fills it with products, packs it or offers it to end users; a re-use system can comprise one or more system participants.

Part A

Requirements for re-use systems

1. General requirements for re-use systems

All re-use systems shall:

- (a) have a clearly defined governance structure as described in the governance guidelines;
- (b) have a governance structure that:
 - (i) ensures that the objectives of the system in the governance guidelines and, if applicable, the re-use targets and any other objectives of the system can be met;
 - (ii) allows for equal access and fair conditions of all economic operators wishing to become a part of the system;
 - (iii) allows for equal access and fair conditions for all end users;
- (c) be designed to ensure that reusable packaging rotating within them completes at least the minimum intended number of rotations as set out in the delegated act adopted pursuant to Article 11(2);
- (d) have rules defining their functioning, including requirements for packaging use, that are accepted by all system participants and which:
 - (i) specify types and design of packaging allowed to circulate in the system;
 - (ii) describe the products intended to be used, filled or transported through the system;
 - (iii) specify the terms and conditions for proper handling and packaging use;
 - (iv) specify detailed requirements for packaging reconditioning;
 - (v) specify the requirements for packaging collection;
 - (vi) specify the requirements for packaging storage;

- (vii) specify the requirements for packaging filling or uploading;
- (viii) specify rules to ensure the effective and efficient collection of reusable packaging, including by providing for incentives for end users to return the packaging to the collection points or grouped collection system;
- (ix) specify rules to ensure equal and fair access to the re-use system, including for vulnerable consumers;
- (e) have a system operator that controls the proper functioning of the system and verifies whether re-use is properly enabled;
- (f) have reporting rules allowing to access data on the number of fillings or re-uses (i.e. rotations per category) and rejects, collection rate (i.e. return rates), sales units or equivalent units, including the material and per category, or an average estimation if the calculation is not feasible, number of units of reusable or refillable packaging added to the system, and number of units of packaging that have been handled by the end-of-life plan;
- (g) ensure that the design of the packaging is laid down in accordance with mutually agreed specifications or standards;
- (h) ensure a fair distribution of costs and benefits for all system participants;
- (i) ensure the implementation of the extended producer responsibility obligations for reusable packaging used in the system and that has become waste.

The open loop systems which do not have a system operator shall be exempt from points (b)(i), (e), (f) and (h).

Open loop systems established prior to the entry into force of this Regulation shall be exempt from the requirements under points (a), (b)(i) and (ii), (e), (f) and (h).

2. Requirements for closed loop systems

In addition to the general requirements for re-use systems listed under point 1, closed loop systems shall satisfy the following requirements:

- (a) the system has reverse logistics facilitating transfer of the packaging from the end users back to the system participants;
- (b) the system ensure the collection, reconditioning and redistribution of packaging;
- (c) system participants are obliged to take the packaging back from the collection point if it has been used, collected and stored in accordance with the system rules.

3. Requirements for open loop systems

In addition to the general requirements for re-use systems listed under point 1, open loop systems shall satisfy the following requirements:

- (a) after packaging is used, the system participant decides whether to re-use the packaging or to pass it to another system participant for re-use;
- (b) the system ensures that the collection, reconditioning and redistribution of packaging are in place and are generally available;
- (c) reconditioning meeting the requirements under Part B is part of the system.

Part B Reconditioning

1. The reconditioning process shall not create risks for the health and safety of those responsible for carrying out the reconditioning of the packaging and shall minimise the impact of that process on the environment. It shall be operated in accordance with applicable laws on contact-sensitive materials, waste and industrial emissions.

2. Reconditioning shall cover the following operations adapted to the reusable packaging format and its intended use:

- (a) assessment of the condition of the packaging;
 - (b) removal of damaged or non-reusable components of the packaging;
 - (c) conveyance of removed components of the packaging to an appropriate recovery process;
 - (d) cleaning and washing the packaging according to required hygiene conditions;
 - (e) repair of the packaging;
 - (f) inspection and assessment of fitness-for-purpose of the packaging.
3. Where necessary, cleaning and washing processes shall be carried out at different stages of the reconditioning and repeated.
4. The reconditioned product shall meet health and safety requirements applicable to it.

Part C Requirements for refill

Refill stations shall satisfy the following requirements:

- (a) the refill station displays clear and precise information on:
 - (i) the hygiene standards that the end user's container must meet in order for it to be used to purchase products at the refill station;
 - (ii) the types and features of containers that can be used to purchase products through refill;
 - (iii) the contact details of the final distributor to ensure compliance with hygiene standards under applicable law;
- (b) the refill station comprises a measuring device or provides alternative means of ensuring that the end user can choose a specified quantity of product for purchase;
- (c) the price paid by end users does not include the weight of the container.

ANNEX VII

Conformity assessment procedure

Module A

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 and ensures and declares on his sole responsibility that the packaging concerned satisfies the requirements of Articles 5 to 12 of this Regulation that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the packaging's conformity with the applicable requirements, and shall include an adequate analysis and assessment of the risks of non-conformity.

The technical documentation shall specify the applicable requirements and shall cover, as far as relevant for the assessment, the design, manufacture and operation of the packaging. The technical documentation shall contain, wherever applicable, at least the following elements:

- (a) a general description of the packaging and its intended use;
- (b) conceptual design, manufacturing drawings and materials of components;
- (c) descriptions and explanations necessary for the understanding of the drawings provided under point (b) and the schemes and operation of the packaging;
- (d) a list of:
 - (i) the harmonised standards, referred to in Article 36, applied in full or in part;
 - (ii) the common specifications, referred to in Article 37, applied in full or in part;
 - (iii) other relevant technical specifications used for measurement or calculation purposes;
 - (iv) in the event of partly applied harmonised standards or common specifications, an indication of the parts which have been applied;
 - (v) in the event of harmonised standards or common specifications not being applied, a description of the solutions adopted to meet the requirements referred to in point 1;
- (e) a qualitative description of how the assessments provided for in Articles 6, 10 and 11 have been carried out; and
- (f) test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and the monitoring thereof ensure compliance of the manufactured packaging with the technical documentation referred to in point 2 and with the requirements referred to in point 1.

4. Declaration of conformity

The manufacturer shall draw up a written declaration of conformity for each packaging type and keep it together with the technical documentation at the disposal of the national authorities for 5 years after single-use packaging has been placed on the market, and 10 years after reusable packaging has been placed on the market. The declaration of conformity shall identify the packaging for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 as regards keeping the technical documentation may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that those obligations are specified in the mandate.

ANNEX VIII

EU declaration of conformity No (*) ...

1. No ... (unique identification of the packaging):
2. Name and address of the manufacturer and, where applicable, the manufacturer's authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the packaging allowing traceability): description of the packaging:
5. The object of the declaration referred to point 4 is in conformity with the relevant Union harmonisation legislation: ... (reference to the other Union acts applied).
6. References to the relevant harmonised standards or the common specifications used or references to the other technical specifications in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, address, number) ... performed ... (description of intervention) ... and issued the certificate(s): ... (details, including the date of the certificate(s), and, where appropriate, information on the duration and conditions of validity).
8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

(*) (identification number of the declaration)

ANNEX X

Minimum requirements for deposit and return systems

For the purpose of this Annex, the following definition applies:

'system operator' means any natural or legal person who is entrusted with a responsibility to establish or operate a deposit and return system in a Member State.

Minimum general requirements for deposit and return systems

Member States shall ensure that the deposit and return systems established on their territories meet the following minimum requirements:

- (a) a single system operator is established or licenced or, in the case there is more than one system operator, Member State shall adopt measures to ensure coordination between the different system operators;
- (b) the governance and related operational rules of the system allow for equal access and fair conditions of all economic operators wishing to become part of the system, provided they make available on the market packaging that belongs to a packaging type or category included in the system;
- (c) control procedures and reporting systems are set up allowing the system operator to obtain data on the collection of packaging covered by the deposit and return system;
- (d) a minimum deposit level is established, which is sufficient to achieve the required collection rates;
- (e) minimum requirements on the financial capacity of the system operator are established allowing the system operator to perform its functions;
- (f) the system operator is a non-profit and independent legal entity;
- (g) the system operator performs exclusively roles arising from the rules of this Regulation, and any additional roles related to the coordination and operation of the deposit and return system as established by the Member States;
- (h) the system operator coordinates the functioning of the deposit and return system;
- (i) the system operator keeps in writing:
 - (i) a statute establishing the internal organisation of the system;
 - (ii) evidence of the funding system of the system;
 - (iii) a statement proving the compliance of the system with the requirements laid down in this Regulation, as well as any additional requirements established in the Member State in which it operates;
- (j) a sufficient amount of the annual turnover of the system operator is used for public awareness campaigns on the management of packaging waste;
- (k) system operators provide any information requested by the competent authorities of a Member State in which the system operates, for the purposes of monitoring compliance with the requirements in this Annex;
- (l) Member States shall ensure that final distributors are obligated to accept the deposit bearing packaging of the packaging material and format that they distribute and to provide end users with redeemed deposits when the deposit bearing packaging is returned, unless end users have equally accessible means to redeem the deposit after the use of the deposit bearing packaging, through one of the collection channels that, for food packaging, ensure food grade recycling and that are authorised for that purpose by the national authorities.

This obligation does not apply where the sale surface area does not make possible for end users to return deposit bearing packaging. However, final distributors will always have to accept the return of the empty packaging of products they sell;

- (m) the end user is able to return the deposit bearing packaging without the need to purchase any goods; deposit shall be redeemed to the end user;
- (n) all deposit bearing packaging that is to be collected by a deposit and return system is clearly labelled, so that the end users can easily identify the need to return such packaging;
- (o) fees are transparent.

In addition to the minimum requirements, Member States may set additional requirements, as appropriate, in order to ensure the fulfilment of the objectives of this Regulation, in particular to increase the purity of the collected packaging waste, reduce litter or promote other circular economy objectives.

Member States with regions with high transboundary business shall ensure that the deposit and return systems allows for collection of packaging from other Member States' deposit and return systems at designated collection points and shall endeavour to enable the possibility of return of a deposit that was charged to the end user when purchasing the packaging.

