

PET Thermoforms regulatory update

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Key regulatory developments in 2024 and 2025

Food Contact Materials

Ongoing revision of the Food Contact Materials legislation

Regulation (EU) 2024/3190: restrictions on BPA uses Regulation (EU) 2025/351: "Quality Amendment"

Recycled plastics (EU) 2022/1616: 1st batch mechanical recycling authorisations

New EFSA guidelines for the evaluation of mechanical recycling*

• **SUP Directive (EU) 2019/904** – Pending implementing act on recycled content:

Leaked draft in Feb 2025, final draft not yet published for public consultation

- PPWregulation (EU) 2025/40
- Waste shipments regulation (EU) 2024/1157
 entered into force on 20th May 2024
- CLP regulation (EU) 2024/2865 entered into force on 10th December 2024
- Waste Framework Directive 20/10/2024: interinstitutional agreement voted in EP ENVI on 18th March 2025.
- Ecodesign Requirements for Sustainable Products regulation (EU) 2024/1781 entered into force on 18 July 2024
- **Green claims**: At the Trilogue stage (Next trilogue 10th June 2025)

^{*}Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food

Regulatory developments still to come in 2025

Food Contact Materials:

- Continuation of the revision of the Food Contact Materials legislation: publication of scoping paper and sustainability study
- Recycled plastics (EU) 2022/1616: 2nd batch mechanical recycling authorisations voted on 10 April 2025.
- Recycled plastics (EU) 2022/1616 draft amendment?
- Amendment to BPA (EU) 2024/3190 + Guidance
- SUP Directive (EU) 2019/904: Implementing act on recycled content « phase II »
- PPWR (EU) 2025/40: Preparation of Secondary legislation

- Regulation on Preventing the Loss of Plastic
 Pellets to Reduce Microplastic Pollution:
 Provisional interinstitutional agreement
- Waste Framework Directive (2008/98/EC): amendment to be voted in EP plenary in July 2025
- REACH
- End-of-waste criteria for plastics
- End-of-waste criteria for textiles?
- Textiles strategy
- Ecodesign Requirements for Sustainable Products regulation (EU) 2024/1781: secondary legislation
- Green claims: Next trilogue in June 2025

SUP directive (EU) 2019/904

Scope: Single-use plastics are made wholly or partly of plastic and are typically intended to be used just once or for a short period of time before they are thrown away.

- Market restrictions (bans): does not apply to PET beverage bottles, does not apply to PET trays
- Consumption reductions of following products by 2026*
 Beverage cups including covers and lids,

Containers of prepared food for immediate consumption (irrespective of the type of plastic)

- Design requirements for beverage containers up to 3 liter
 - Caps and lids to remain attached
 - 25% recycled content by 2025 for beverage PET bottles**
 - 30% recycled content by 2030 for beverage bottles
- Compulsory marking: applies to beverage cups
- EPR: applies to food and beverage containers, bottles, cups,...
- Separate collection for recycling:
 - Beverage bottles up to 3 liter (including their caps and lids) 77% (by 2025); 90% (by 2029)
- Awareness raising (responsible consumer behaviour, reusable alternative products and impact of inappropriate disposal)

^{*}compared to a 2022 baseline

^{**}rules established in implementing decision (EU) 2023/2683

PPWR – Overall content

- Definitions
- Sustainability requirements:
 - Substances of concern (SoC) in packaging
 - Recyclability
 - Recycled content
 - Restrictions on packaging formats
 - Packaging minimisation
 - Reusability
- Labelling, marking, info requirements
- Claims
- Obligations of economic operators
- Plastic carrier bags

- Conformity of packaging Declaration of conformity
- Management of packaging and packaging waste
 - Waste prevention(5%/10%/15% by 2030/2035/2040; per capita in 2018)
 - Register of producers, EPR, PRO, DRS, ...
- Safeguard procedures
- Green public procurement
- Delegated powers and committee procedure, amendments, final provisions

PPWR - Recyclable



EC to establish:

- design for recycling criteria
- recyclability performance grades

BY 1 JAN2030 (IAct)

EC to establish:

- methodology for recycled at scale
- •Chain of custody mechanism ensuring packaging is recycled at scale

FROM 1 JAN2030

All packaging shall be recyclable:

- design for recycling
- recyclable within grades:
 - o A≥95%,
 - o B≥80%,
 - o C≥70%

FROM 1 JAN2035

All packaging shall be recyclable:

- design for recycling + recyclable within grades A,B or C
- separately collected + sorted + recycled at scale

2038

All packaging shall be recyclable:

- within grades
 A or B
- design for recycling + separately collected + sorted + recycled at scale

DAct = Delegated Act IAct = Implementing Act

PPWR – Restrictions on packaging formats

BY 12 FEB2027

Publication of guidelines in consultation with MS and EFSA to explain Annex V with examples, the exemptions to the restrictions and list of fruit and vegetables excluded from annex V point 2.

FROM 1 JAN2030

- SU plastic* grouped packaging at point of sale for bottles, cans, tins, pots, tubs excl. grouped packaging to facilitate handling
- SU plastic* packaging** for <1.5 kg unprocessed fresh fruit and vegetables
- SU plastic* packaging for foods and beverages filled and consumed in HORECA***. Flexible non-plastic* packets and wrappers exempted.
- SU plastic* packaging for individual portions for servings used in HORECA (some exemptions)
- SU accommodation sector packaging for individual booking

BY 12 FEB2032

- •EC to assess the positive environmental impact of the restrictions and the derogations
- Revision of the provisions and Annex V
- Appropriatness of establishing new restrictions, relevance of maintaining exemptions/derogations
- Where appropriate make a legislative proposal

^{*}MS may maintain restrictions on these packaging formats but made from other materials, if adopted before 1 January 2025

^{**} With potential derogations at MS level

^{***} Derogation if no access to drinking water 27-05-25

Recycled content under PPWR





Important implementing/delegated acts are still to be developed and adopted.

PPWR is open to different interpretations:

For trays where the major component is PET, the 30% applies in principle to the PET parts.

It remains unclear whether the non-PET parts also have to comply with this 30% target or with the 10% for contact sensitive packaging made of plastic materials other than PET.

The question is whether the lid of the tray should be considered as part of the "tray packaging" or as a separate packaging.

The text is leaning towards a per-packaging recycling target.

Regulation (EU) 2025/35 – Quality Amendment - Overall content

- Amends Regulation (EU) 10/2011 but also Regulations (EU) 2022/1616 and (EC) 2023/2006
- Contains new definitions of additive, reprocessing and UVCB* substance.
- Defines "High degree of purity" criteria for substances (new article 3a). Includes a derogation for certain substances of natural origin
- Sets the conditions for the reprocessing of plastics, i.e. off-cuts and scraps, under Regulation (EU) 10/2011. Exclusion of FB!
- Requires substance composition knowledge by the manufacturer of the substance.
- Amends compliance requirements for multimaterial multilayers.
- Amends compliance testing (Annex V)
- Amends Article 16 (supporting documents)
- Introduces new requirements on repeated use articles.
- SML for containers below 500ml to be assessed on real S/V ratio.
- Others: DoC, labelling, simulants for cheese, biocides, transitional provisions,....

^{*&}quot;UVCB substance" means a substance of unknown or variable composition, complex reaction products or a material of a biological or other natural origin.

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27-05-25

Regulation (EU) 2025/35 – Quality Amendment

Art 10(2):

Plastic materials and articles may contain reprocessed plastic if such reprocessed plastic meets the following conditions:

- it is a **by-product** in accordance with Article 5 of Directive 2008/98/EC of the European Parliament and of the Council;
- it is collected and used in accordance with section C of the Annex to Regulation (EC) No 2023/2006;
- it originates from one of the following off-cuts and scraps from plastic materials and plastics:
 - (i) off-cuts and scraps from plastic materials and articles referred to in point (a) of Article 2(1) that meet the compositional requirements set out in chapter II of this Regulation, or
 - (ii) off-cuts and scraps from plastic materials and articles referred to points (b) and (c) of Article 2(1), provided that such reprocessed plastic does not contain a layer which functions as a functional barrier and all of its individual constituents either meet the compositional requirements set out in Chapter II of this Regulation, or have been subject to risk assessment on the basis of Article 19 taking into account the conditions of reprocessing and their presence in the reprocessed material;
- it does not contain substances in an amount which could:
 - (i) exceed migration limits applicable for the substance as specified in Regulation (EU) No 10/2011; or,
 - (ii) cause any other non-compliance of those plastic materials and articles with Article 3 of Regulation (EC) No 1935/2004;



For the purposes of FCM, the use of off-cuts and scraps from functional barrier should then « fall under regulation (EU) 1616/2022 »

Regulation (EU) 2025/35 - Quality Amendment

Impact of off-cuts and scraps from functional barrier « falling under regulation (EU) 2022/1616 »

REGULATION (EU) 1616/2022:

Art 1:

- 2. This Regulation lays down rules for:
- (a) the placing on the market of plastic materials and articles falling within the scope of Article 1(2) of Regulation (EC) No 1935/2004, containing plastic originating from waste or manufactured therefrom;

Art 2:

- 2. For the purposes of this Regulation, the following definitions also apply:
- (1) 'waste', 'municipal waste', 'waste management', 'collection', 're-use', 'recycling', and 'non-hazardous waste', as laid down in Article 3 of Directive 2008/98/EC of the European Parliament and of the Council (9);



For the purposes of FCM, off-cuts and scraps from functional barrier become waste, not by-products.



REGULATION (EU) 2024/3190

EU measure on BPA and other bisphenols*



- Plastic, varnishes and coatings, inks, adhesives, rubbers, ion-exchange resins, silicones
- Removes authorisation of BPA in FCM plastic from Commission Regulation (EU) No 10/2011
- Two derogations for the use of BPA as monomer or other starting substance
- FCMs manufactured using other bisphenols or derivatives e.g. BADGE must not contain residual BPA from the manufacturing process
- Bans use of other bisphenols and derivatives subject to harmonised classification as CMR category
 1A or 1B in the manufacture of FCM
- Unless for a specific FCM application that does not present a risk
- Possible applications foreseen after EFSA, in consultation with ECHA, has informed on the information necessary for assessing the risk (max 2 years after the Regulation takes effect)
- Transitional periods for packaging and for repeat use

- BPA contamination in recPET is not the result of intentional use of BPA, neither of another bisphenol and/or bisphenol derivative ⇒ outside the scope of the BPA measure.
- However, recPET needs to comply with Framework Regulation(EC) 1935/2004 ⇒
 the safety assessment of BPA as a contaminant needs to be conducted taking
 into consideration the new TDI recently established by EFSA:
 - o Current migration levels could exceed BPA TDI at a frequency not yet fully determined
 - The source of BPA contamination might not completely disappear in the future because the use of another bisphenol and/or bisphenol derivative in adhesives, inks, external can coatings,... is not forbidden
 - BPA limit as contaminant (if any)will take several years to be established
 - o BPA limit in Drinking Water Directive has not yet been adapted.



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BACK-UP

REGULATION (EU) 2024/3190 - scope

Scope

- 2. This Regulation establishes specific requirements concerning 4,4'-isopropylidenediphenol (bisphenol A' or 'BPA') (CAS No 80-05-7) and its salts as well as other hazardous bisphenols and hazardous bisphenol derivatives, as regards their use in the manufacture of the following groups of food contact materials and articles falling within the scope of Article 1(2) of Regulation (EC) No 1935/2004, which are placed on the Union market:
- (a) adhesives;
- (b) rubbers;
- (c) ion-exchange resins;
- (d) plastics;
- (e) printing inks;
- (f) silicones; and
- (g) varnishes and coatings.
- 3. This Regulation also establishes specific requirements on the content of BPA in food contact materials and articles, which have been manufactured using another bisphenol or bisphenol derivative.

Prohibition of "use" and to certain extent on "presence"

Article 3

Prohibition of the use of BPA

- 1. The use of BPA and its salts in the manufacture of food contact materials and articles referred to in Article 1(2) and the placing on the Union market of food contact materials and articles manufactured using BPA, is prohibited.
- 2. By way of derogation from paragraph 1, BPA and its salts may be used in the manufacture of food contact materials and articles for a specific application set out in Annex II, subject to the restrictions laid down therein.

Article 4

Prohibition on the presence of BPA in food contact materials and articles for which other bisphenols or bisphenol derivatives are used in their manufacture

Food contact materials and articles that have been manufactured using another bisphenol or bisphenol derivative shall not contain any residual BPA.

Detection limit of 1 µg/kg

REGULATION (EU) 2024/3190 - DoC



Declaration of compliance

Article 8

Declaration of compliance and supporting documentation

- 1. Business operators shall ensure that food contact materials and articles covered by this Regulation which are not yet in contact with food, as well as bisphenols and bisphenol derivatives intended to be used as monomers or other starting substances in the manufacture of those food contact materials and articles, are accompanied at all marketing stages other than the retail stage by a written declaration as referred to in Article 16(1) of Regulation (EC) No 1935/2004 stating that they comply with the rules applicable to them ('declaration of compliance').
- The declaration of compliance shall contain the information laid down in Annex III.
- 3. Appropriate supporting documentation shall be available to demonstrate such compliance. That documentation shall be made available without delay to the competent authorities on their demand.

ANNEX III

The declaration of compliance referred to in Article 8 shall contain the following information:

- (1) the identity and address as well as contact details including either a current telephone number or email address of the business operator issuing the declaration of compliance;
- (2) the identity and address as well as contact details including either a current telephone number or email address of the business operator which manufactures or imports the food contact material or article;
- (3) the identity of the food contact material or article, including both intermediate food contact materials and final food contact articles;
- (4) the date of the declaration;
- (5) a list of any bisphenols or bisphenol derivatives used in the manufacture of the food contact material or article;
- (6) a statement that the intermediate food contact material or article or final food contact article complies with this Regulation and the requirements set out in Articles 3, 15 and 17 of Regulation (EC) No 1935/2004.



• Q2. Are recycled FCMs within the scope of the Regulation?

Recycled FCMs may contain minute amounts of BPA and other bisphenols adventitiously. This is because they may be present as an incidental contaminant in the input used to produce recycled materials including plastic, such as PET, as well as paper and board. Such contamination can persist in the recycled plastic in minute amounts despite the application of cleaning and decontamination processes and may eventually be present in the final food contact article. As BPA is not used intentionally in such manufacturing processes and such contamination cannot be fully controlled, recycled FCMs are not within the scope of the Regulation.



• Q23. Is the detection limit of 1 μ g/kg (1ppb or 0,001 mg/kg) feasible and practical for compliance and enforcement purposes?

During the discussions preceding the adoption of the Regulation, a limit of detection (LoD) of 0,001 mg/kg (1 µg/kg) was supported and considered feasible to detect BPA. In order to contribute to a uniform application and enforcement of Regulation (EU) 2024/3190, Article 9 of the Regulation gives a role to the European Union-Reference Laboratory (EU-RL) in the development of possible methods, in collaboration with National Reference Laboratories; NRLs.

The development of the parameters for verification of compliance, including a LoD different from 1 μ g/kg, and other approaches will depend on the methods that will be eventually selected in accordance with Article 9(1). The information will be made publicly available in due course.

• Q24. Does this detection limit apply for migration or for residual content?

Article 9 may apply for either testing migration of BPA from the food contact articles laid down in Annex II, for which migration should not be detected; or the requirement stemming from Article 4, that FCM manufactured using other bisphenols or bisphenol derivatives are not to contain any residual BPA. The detection limit of 1 µg/kg set in Regulation (EU) 2024/3190 applies for verification of compliance in both cases unless the work of the EU-RL leads to a different conclusion.



• Q25. Does the limit of detection apply to BPA as a "non-intentionally added substance" ("NIAS") or as a contaminant?

The emphasis of the Regulation is on the *use* of BPA in the manufacture of certain FCMs, rather than its presence. This is because the main source of BPA from FCMs is due to its intentional use in the manufacture FCMs, as a monomer in materials such as plastics and coatings. In order to comply with Article 4 of the Regulation, if other bisphenols or bisphenol derivatives such as BADGE are used in the manufacture of FCMs, the absence of BPA as a NIAS should be ensured. This can be achieved by ensuring purity of the starting substance and through good manufacturing practices throughout production to avoid undesirable reaction and degradation products). If such control cannot be achieved and the use of other bisphenols or derivatives would lead to the presence of BPA, alternative starting substances would need to be used.

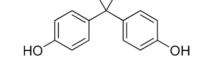
Regulation (EU) 2024/3190 does not simply ban the presence of BPA in FCMs, as this presence can arise from adventitious sources, most notably as contamination from recycling streams where levels of BPA or other hazardous bisphenols cannot be reduced to zero.

REGULATION (EU) 2024/3190

EU measure on BPA and other bisphenols
- impact on recPET



BPA



- Commission Regulation (EU) 2024/3190 entered into force 20 January 2025
- Bans the <u>use</u> of BPA in manufacture of FCMs (only in FCMs!)
 - transition periods spanning about 4 years
 - the presence of BPA is in principle not banned → important for recycling
 - no BPA to be present in FCM made using other bisphenols (including BADGE)
- For recyclers it is important to:
 - ensure proper input → plastic from food packaging should not contain BPA
 - at least the level should go down over the next few years
 - take Article 4 and 6 of Regulation (EU) 2022/1616 seriously
 - special considerations for novel technologies
 - we suggest to monitor for BPA content, and let us know what to expect

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