EUROPEAN
COMMISSION

Brussels, XXX
[…](2025) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the persistent organic pollutants tetrabromodiphenyl ether, pentabromodiphenyl ether, hexabromodiphenyl ether, heptabromodiphenyl ether and decabromodiphenyl ether

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 1 of Regulation (EU) 2019/1021 on persistent organic pollutants ('POPs Regulation') establishes as the objective of that Regulation to protect human health and the environment from Persistent Organic Pollutants ('POPs') by, among others, prohibiting, phasing out as soon as possible, or restricting the manufacturing, placing on the market and use of substances subject to the Stockholm Convention on POPs.

Tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE), hexabromodiphenyl ether (hexaBDE), heptabromodiphenyl ether (heptaBDE) and decabromodiphenyl ether (decaBDE) are polybrominated diphenyl ethers (PBDE) and are listed in Annex I to Regulation (EU) 2019/1021. Following Article 4(1)(b) of the POPs Regulation, each entry on a polybrominated diphenyl ether in Annex I includes an Unintentional Trace Contaminant (UTC) limit of 10 mg/kg (0,001% by weight) for the presence of the respective PBDE in substances. In addition, Annex I contains a UTC limit value of up to 500 mg/kg for the sum of the concentrations of all listed PBDEs where they are present in mixtures or articles. Following point 2 of the fourth column of each entry on a PBDE, the UTC limit for the presence of the listed PBDEs in mixtures and articles is subject to review.

Following the adoption of Regulation (EU) 2022/2400 amending Annexes IV and V of the POPs Regulation for PBDEs *inter alia*, the concentration limit of 1000 mg/kg for the sum of the concentrations of the relevant PBDEs in waste is lowered to 500 mg/kg. The limit value is further reduced to 350 mg/kg from 30 December 2025 and to ~~200 mg~~/kg from 30 December 2027.

PBDEs display persistent and bioaccumulative properties and have the potential to cause adverse effects on humans and aquatic organisms. They have been used as flame retardants in a wide range of products including electrical and electronic equipment, textiles and foams.

The manufacturing, placing on the market and use of PBDEs in the Union has been largely phased out. Commercial pentaBDE and octaBDE were originally restricted in the Union in 2003[1] whilst the production, placing on the market and use of decaBDE had been restricted under Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals ('REACH'), from March 2019 until January 2021 with certain exemptions. The congeners of commercial pentaBDE (tetra- and pentaBDE) and commercial octaBDE (hexa- and heptaBDE) were listed in Annex A to the Stockholm Convention in 2009 whilst decaBDE was listed in 2017.

Due to past and current recycling activities PBDEs occur in recovered materials and products made from recovered materials, including toys, hair accessories, kitchen utensils and other products for the general public. A number of studies have examined the presence of PBDEs in articles for the general public made from recovered plastics and have primarily detected decaBDE.

[1] OJ L177, 6.7.2002, p. 21; Directive 2003/11/EC of the European Parliament and of the Council of 6 February 2003 amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenyl ether).

Analytical techniques used to determine bromine content are X-ray fluorescence spectroscopy (XRF) (for quick and regular screening of every batch) and gas chromatography – mass spectrometry (GC-MS) (typically on programmed basis only). According to a study[2] to support the assessment of impacts associated with the review of limit values that apply to waste for POPs listed in Annexes IV and V of Regulation (EU) 2019/1021, the analytical potential of the XRF method lies at 30 mg/kg bromine, which corresponds to approximately 5 mg/kg PBDE listed as POPs, while that of GC-MS is at 0.1 mg/kg.

Considering that the objective of the Stockholm Convention and the POPs Regulation is to protect human health and the environment from persistent organic pollutants, that aspects related to the recycling of waste containing PBDE listed as POPs need to be considered in the context of a circular economy, that the Annex IV concentration limit for the sum of the listed PBDE was lowered to 500 mg/kg and will be further reduced to 350 mg/kg and 200 mg/kg as of 30 December 2025 and 30 December 2027, respectively, and that there are no immediate analytical constraints to a significant lowering of the UTC limit value in Annex I, the Commission proposes setting different UTC limit values for mixtures and articles made from or containing listed PBDE-containing recovered material and other mixtures and articles.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Experts designated by Member States were involved in preliminary discussions and consulted on the draft delegated act in several meetings of the POPs expert group (the 'POP CA meeting') on 8 June and 23 November 2021, 2 June and 24 November 2022, 29 November 2023, 7 June 2024, 13 September 2024 and 29 November 2024 and comments were taken into account. Relevant stakeholders also took part in the discussions in those meetings and their comments were taken into account.

A public consultation was carried out on the draft delegated act from xx to xx. [summary of consultation]

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act modifies the existing entries for tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE), hexabromodiphenyl ether (hexaBDE), heptabromodiphenyl ether (heptaBDE) and decabromodiphenyl ether (decaBDE) in Annex I to Regulation (EU) 2019/1021 in order to adapt them to scientific and technical progress. The legal basis for the proposed delegated act is Article 15(1) of Regulation (EU) 2019/1021.

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[2] Study to support the assessment of impacts associated with the review of limit values in waste for POPs listed in Annexes IV and V of Regulation (EU) 2019/1021 - Publications Office of the EU (europa.eu)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants[1], and in particular Article 15(1) thereof,

Whereas:

(1) Regulation (EU) 2019/1021 implements the commitments of the Union under the Stockholm Convention on Persistent Organic Pollutants[2] ('the Convention') and under the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants[3].

(2) Pursuant to Article 3(1) of Regulation (EU) 2019/1021, the manufacturing, placing on the market and use, whether on their own, in mixtures or in articles, of substances listed in Annex I to that Regulation are prohibited, subject to Article 4 of that Regulation.

(3) Tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE), hexabromodiphenyl ether (hexaBDE), heptabromodiphenyl ether (heptaBDE) and decabromodiphenyl ether (decaBDE) (together 'listed polybrominated diphenyl ethers', 'listed PBDE') are listed in Annex I to Regulation (EU) 2019/1021 with an unintentional trace contaminant (UTC) limit value of 500 mg/kg for the sum of the concentrations of the five substances where they are present in mixtures or articles. That UTC limit value is subject to review by the Commission.

(4) Regulation (EU) 2022/2400 of the European Parliament and of the Council amending Annexes IV and V to Regulation (EU) 2019/1021 on persistent organic pollutants[4] reduces the concentration limit in waste for the sum of tetraBDE, pentaBDE, hexaBDE, heptaBDE and decaBDE to 500 mg/kg as of 10 June 2023, to 350 mg/kg from 30 December 2025 and to 200 mg/kg from 30 December 2027.

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1 OJ L 169, 25.6.2019, p. 45, ELI: http://data.europa.eu/eli/reg/2019/1021/oj.

2 OJ L 209, 31.7.2006, p. 3.

3 Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants (OJ L 81, 19.3.2004, p. 37, ELI: http://data.europa.eu/eli/prot/2004/259/oj).

4 Regulation (EU) 2022/2400 of the European Parliament and of the Council of 23 November 2022 amending Annexes IV and V to Regulation (EU) 2019/1021 on persistent organic pollutants (OJ L 317, 9.12.2022, p. 24, ELI: http://data.europa.eu/eli/reg/2022/2400/oj).

(5) The manufacturing, placing on the market and use of PBDE in the Union have been largely phased out. However, due to past and current recycling activities the substances occur in products made from recovered materials, including products for the general public.

(6) Particular attention should be given to childcare products and toys in view of potential exposure to listed PBDE contained in them. To address the situation where listed PBDE may be present unintentionally in childcare products and toys manufactured from recovered material, it is justified to set an unintentional trace contaminant limit value for them.

(7) Taking into account the objective of Regulation (EU) 2019/1021 to protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting their manufacturing, placing on the market and use, the fact that listed PBDE occur mainly in products from recovered materials, and the limit of detection of relevant determination methods, different UTC limit values should be set for mixtures and articles made from or containing listed PBDE-containing recovered material and other mixtures and articles. Food contact materials subject to Regulation (EC) No 1935/2004 of the European Parliament and of the Council[5] should be excluded from this Regulation as listed PBDE should in principle not be present in food contact materials in accordance with Regulation (EU) 10/2011[6] and Regulation (EU) 2022/1616[7].

(8) Regulation (EU) 2019/1021 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) 2019/1021 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

[5] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13/11/2004, p. 4, ELI: http://data.europa.eu/eli/reg/2004/1935/oj).

[6] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1, ELI: http://data.europa.eu/eli/reg/2011/10/oj).

[7] Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243, 20.9.2022, p. 3, ELI: http://data.europa.eu/eli/reg/2022/1616/oj).