



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 polychlorinated biphenyls

(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 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.

Polychlorinated biphenyls (PCB) are listed in Annex I to Regulation (EU) 2019/1021 without an unintentional trace contaminant (UTC) limit value. PCB were produced on a large scale across the world between the 1930s and 1980s. They were used in particular in lubricants and in electrical and hydraulic equipment, but also in oil-based paint, plastics, insulation material and adhesives and tapes. The use of PCB as a raw material or chemical intermediate has been banned in the EU since 1985. However, PCB may still be present in old equipment. In addition, trace levels of PCB may unintentionally be generated in certain chemical processes. The European Chemicals Agency (ECHA) received several inquiries concerning a limit value for the presence of PCB as impurities in substances, mixtures and articles.

The lack of a specified UTC limit value results in legal uncertainty since stakeholders do not know whether a limit value applies nor which value. The absence of a harmonised UTC limit value would be interpreted as if the limit of detection applies, which may lead to uncertainties for operators and difficulties for enforcement and would also prevent the placing on the market of any substance, mixture or article containing PCB unintentionally. Article 4(1)(b) of the POPs Regulation sets out that the prohibition of the manufacturing, placing on the market and use of substances listed in Annex I, whether on their own, in mixtures or in articles, does not apply in the case of a substance present as an unintentional trace contaminant, as specified in the relevant entries of Annex I, in substances, mixtures or articles.

It is therefore considered appropriate to specify a limit value for the presence of PCB as UTC in substances, mixtures or articles in Annex I. Such UTC would clarify the legal situation and would facilitate harmonised enforcement throughout the Union.

Based on information on concentrations of unintentional PCB in substances, mixtures and articles, on the performance of available analytical methods and on the objectives of the POPs Regulation, that limit value should be set at 0,2 mg/kg (0,00002 % by weight) for the presence of PCB as UTC in substances, mixtures and articles. Given that PCB are unintentionally produced in the manufacturing of organic pigments and dyes and are present in them at concentrations which are on average higher than 0,2 mg/kg and taking into account the technical limitations to remove PCB from organic pigments and dyes, a specific UTC limit value should be set for PCB in organic pigments and dyes and in mixtures and articles containing them of 25 mg/kg (0,0025 % by weight) upon entry into force of this Regulation, and 10 mg/kg (0,001 % by weight) three years after entry into force of this Regulation. Such gradual decrease should allow the sector sufficient time to ensure that the unintentional presence of PCB in organic pigments and dyes does not exceed that limit or to find suitable alternatives for them.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Experts designated by Member States were involved in discussions on the foreseen measure in meetings of the POPs expert group (the ‘POP CA meeting’) on 23 November 2021, 2 June 2022, 24 November 2022, 14 June 2023, 29 November 2023 and 7 June 2024, and consulted on the draft delegated act on 13 September 2024 and 29 November 2024 and their comments were taken into account. Relevant stakeholders also took part in the discussions on the foreseen measure 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 entry for polychlorinated biphenyls in Annex I to Regulation (EU) 2019/1021 in order to adapt it to scientific and technical progress. The legal basis for the delegated act is Article 15(1) of Regulation (EU) 2019/1021.

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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 pollutants¹, 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 Pollutants² and under the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants³.
- (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) Polychlorinated biphenyls (PCB) are listed in Annex I to Regulation (EU) 2019/2021 without an Unintentional Trace Contaminant (UTC) limit value.
- (4) The Commission has assessed the presence of PCB as unintentional trace contaminants in some substances, mixtures and articles, including silicone-based adhesives, chlorinated paraffins and their applications and organic pigments and their applications.
- (5) In order to facilitate enforcement as regards the use of substances, mixtures or articles containing PCB as unintentional trace contaminants, a UTC limit should be set for PCB.
- (6) Taking into account the objective of Regulation (EU) 2019/2021 to protect human health and the environment from persistent organic pollutants (POPs) by prohibiting, phasing out as soon as possible, or restricting their manufacturing, placing on the market and use, the concentrations at which PCB are unintentionally present in substances, mixtures and articles and the limit of detection of relevant determination methods, a UTC limit value of 0,2 mg/kg (0,00002 % by weight) should be set for the sum of PCB in substances, mixtures and articles.
- (7) Considering that PCB are unintentionally produced in the manufacturing of organic pigments and dyes and are present in those pigments and dyes at concentrations which

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 OJ L 81, 19.3.2004, p. 37, ELI: <http://data.europa.eu/eli/prot/2004/259/oj>.

are on average higher than 0,2 mg/kg and taking into account the technical limitations to remove PCB from organic pigments and dyes, a specific UTC limit value should be set for the presence of PCB in organic pigments and dyes and for the presence of PCB in mixtures and articles containing organic pigments or dyes of 25 mg/kg (0,0025 % by weight) upon entry into force of this Regulation and 10 mg/kg (0,001 % by weight) three years after entry into force of this Regulation. Such gradual decrease should allow the sector sufficient time to ensure that the unintentional presence of PCB in organic pigments and dyes does not exceed that limit or to find suitable alternatives for them.

- (8) In order to ensure a harmonised approach with regard to the determination of the PCB content in organic pigments and dyes so that the same congeners are taken into account when measuring the concentration, a concentration determination method should be specified.
- (9) 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