



EUROPEAN  
COMMISSION

Brussels, XXX  
[...] (2024) XXX draft

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of XXX**

**amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards dechlorane plus**

(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**

The objective of Regulation (EU) 2019/1021 is 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 ('the Convention'). At the eleventh meeting of the Conference of the Parties to the Stockholm Convention, which took place in Geneva, Switzerland in May 2023, it was decided to include dechlorane plus in Annex A to the Convention with certain specific exemptions. This decision should be reflected in Annex I to Regulation (EU) 2019/1021.

This delegated act implements decision SC-11/10 to list dechlorane plus in Annex A, in accordance with Article 15(1) of Regulation (EU) 2019/1021.

Norway prepared a restriction dossier for dechlorane plus in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council and ECHA's opinion was finalised in September 2022<sup>1</sup>. The opinion supports a broad restriction of manufacture and placing on the market of dechlorane plus, with some exemptions.

Decision SC-11/10 includes a list of specific exemptions granted under the Convention, which covers all the exemptions recommended in the ECHA's opinion. To limit the specific exemptions as far as possible, it is proposed to only allow in the Union the specific exemptions recommended in the ECHA's opinion. The Stockholm Convention establishes that specific exemptions can be allowed for five years, with a possibility to extend them for additional five years. The ECHA's opinion recommends some specific exemptions for a duration longer than five years. The Commission proposes to grant five years as the longest duration of an exemption and to indicate the possibility to extend it for a maximum of five additional years.

Add text on UTC after the public consultation.

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

Experts designated by each Member State were consulted in the relevant expert group (the 'POPs CA meeting') on the draft delegated act on 14 June 2023, on 29 November 2023 and on 7 June 2024 and comments were taken into account.

All relevant stakeholders have also been consulted, including the chemicals industry and the civil society in the 'POPs CA meeting' on 14 June 2023 and on 29 November 2023 and comments were taken into account.

A public consultation on the draft act was carried out through the public feedback mechanism portal **from to** and the comments have been taken into account.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The delegated act amends the list of chemicals in Annex I on the basis of developments under the Convention, as required by Article 15(1) of Regulation (EU) 2019/1021. The legal basis for the delegated act is Article 15(1) of Regulation (EU) 2019/1021.

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<sup>1</sup> [d4e88790-cfe2-c934-7ea4-489e1602d6c2 \(europa.eu\)](https://d4e88790-cfe2-c934-7ea4-489e1602d6c2.europa.eu)

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**amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards dechlorane plus**

(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<sup>1</sup>, 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<sup>2</sup> ('the Convention') and under the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants<sup>3</sup> ('the Protocol').
- (2) Annex A to the Convention contains a list of chemicals. Each Party to the Convention is required to prohibit the chemicals on the list or take the legal and administrative measures necessary to eliminate their production, use, import and export.
- (3) The Conference of the Parties to the Convention has, pursuant to Article 8(9) of the Convention, decided in its eleventh meeting held from 1 to 12 May 2023 to amend Annex A to the Convention to include dechlorane plus in that Annex with specific exemptions. The Union supported the inclusion of dechlorane plus in Annex A with specific exemptions as stipulated in Council Decision (EU) 2023/1006<sup>4</sup>. Part A of Annex I to Regulation (EU) 2019/1021, which contains a list of the substances listed in the Convention and in the Protocol as well as substances listed only in the Convention, should therefore also be amended to include dechlorane plus.
- (4) In 2022, the European Chemicals Agency's Committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) adopted their opinions<sup>5</sup> on a restriction dossier from Norway for dechlorane plus under Regulation (EC) No 1907/2006 of the

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

<sup>2</sup> Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants (OJ L 209, 31.7.2006, p. 1, ELI: <http://data.europa.eu/eli/dec/2006/507/oj>).

<sup>3</sup> Council Decision 2004/259/EC of 19 February 2004 concerning the conclusion, on behalf of the European Community, of the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants (OJ L 81, 19.3.2004, p. 35, ELI: <http://data.europa.eu/eli/dec/2004/259/oj>).

<sup>4</sup> Council Decision (EU) 2023/1006 of 25 April 2023 on the position to be taken on behalf of the European Union at the eleventh meeting of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants as regards the proposals for amendments of Annex A to that Convention.

<sup>5</sup> [d4e88790-cfe2-c934-7ea4-489e1602d6c2 \(europa.eu\)](https://d4e88790-cfe2-c934-7ea4-489e1602d6c2.europa.eu)

European Parliament and of the Council<sup>6</sup>. The opinions support a restriction of manufacture and use of dechlorane plus, with certain derogations for specific uses. Those derogations are included in the list of specific exemptions granted under the Convention by Decision SC-11/10 of the Conference of the Parties and should be granted as exemptions also under Regulation (EU) 2019/1021 since they are still needed in the Union.

- (5) The maximum duration of the exemptions should be 5 years, with the possibility to extend for additional 5 years, in accordance with Article 4(4) of the Convention. This is especially relevant for the exemptions for medical imaging applications and radiotherapy devices and installations, for which the European Chemicals Agency's Committees opinions supported a duration of 7 and 10 years, respectively. The Commission should review the need for a prolongation of the specific exemptions at the latest by 1 April 2028 in order to prepare for the Conference of the Parties that is expected to be held in May 2029, since a potential extension of the specific exemptions for this substance under the Convention will have to be decided at that Conference of the Parties
- (6) Dechlorane plus is used in articles with complex supply chains, such as in articles in electronics, medical devices and motorised machineries. A deferral of the date of application of this Regulation to dechlorane plus until the entry into force in the Union of the amendment of Annex A to the Stockholm Convention on 26 February 2025, will provide stakeholders with further time to substitute dechlorane plus in such applications.
- (7) Articles containing Dechlorane Plus produced or placed on the market within a specific exemption laid down in Annex I to Regulation (EU) 2019/1021 are not allowed to be placed on the market after the relevant exemption expires. However, articles containing Dechlorane Plus produced or placed on the market within a specific exemption laid down in that Annex that were already in use by the expiry date of the relevant exemption should be allowed to continue to be used after that date. This is to avoid the need to recall articles containing Dechlorane Plus that were already in use by their final user at the expiry of the relevant exemption.
- (8) Furthermore, in line with Decision SC-11/10, an exemption covering the production and use of spare parts for products in certain applications is granted until the end of the service life of the relevant product or until 31 December 2043, whichever comes earlier. The service life of products in defence, aerospace and space applications may go beyond 2043. The placing on the market and use of the spare parts already produced in the Union or imported before or on the date of the expiry of the relevant exemption should therefore be allowed after that date.
- (9) To reinforce the application and enforcement of Article 3(1)(b) of Regulation (EU) 2019/1021 in the Union, a limit value should be set for dechlorane plus occurring as an unintentional trace contaminant in substances, mixtures and articles. That limit value should be set at 1 mg/kg.

<sup>6</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

(10) 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.

It shall apply from 26 February 2025.

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*