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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 15.5.2025 amending Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards dechlorane plus

Delegations will find attached document C(2025) 2887 final.

Encl.: C(2025) 2887 final



EUROPEAN
COMMISSION

Brussels, 15.5.2025
C(2025) 2887 final

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

of 15.5.2025

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

(Text with EEA relevance)

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 2022¹. 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 ECHA's opinion. The Convention includes exemptions not recommended in ECHA's opinion for spare parts for outdoor power equipment, medical devices and in-vitro diagnostic devices and instruments for analysis, measurements, control, monitoring, testing production and inspection. Following comments submitted through the public feedback mechanism portal on the need for such exemptions and considering that the use is for spare parts needed to repair and maintain already existing products, the Commission is of the view that such exemptions should be granted.

The Stockholm Convention establishes that specific exemptions can be allowed for five years, with a possibility to extend them for additional five years. ECHA's opinion recommends some specific exemptions for a duration longer than five years. The Commission is of the view that it is appropriate 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.

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 and comments were taken into account.

Relevant stakeholders, including the chemicals industry and the civil society, also took part in the discussions on the listing of dechlorane plus in Annex I to the POPs Regulation in the 'POPs CA meeting' and comments were taken into account.

A public consultation on the draft act was carried out through the public feedback mechanism portal from 26 June to 24 July 2024 and the comments have been taken into account as follows.

Several comments requested the addition of exemptions for spare parts that are included in the Stockholm Convention decision but not recommended in ECHA's Committees opinion on the REACH restriction. The Commission accepts these requests, considering that it would be in

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

line with the Stockholm Convention and that the volume of dechlorane plus used in such spare parts is likely small.

Other comments concerned the proposed UTC limit of 1 mg/kg and suggest using the limit of the recommended REACH restriction of 1000 mg/kg. The Commission considers that the limit should not be changed, as the limit recommended in the REACH restriction on dechlorane plus did not respond to the concept of UTC but intended to prevent intentional use and it was also linked to the limit triggering certain obligations in REACH. UTC limits are meant to remove as far as possible POPs from products, including from recycled materials and should represent a “minimal” amount. The information available seems to indicate that levels of 1 mg/kg can be measured in products. However, considering the need for laboratories to improve analysis accuracy and to ensure uniform and adequate application of analytical methods, for example by means of proficiency testing, the Commission considers that the UTC limit should be set at 1000 mg/kg upon entry into force of this Regulation and at 1 mg/kg 30 months after the entry into force of this Regulation.

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.

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

of 15.5.2025

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 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 ('the Convention') and under the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants³ ('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) 2023/1006⁴. 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) (the 'committees') adopted their opinions⁵ on a restriction dossier from Norway for dechlorane plus under Regulation (EC) No

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

² 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>).

³ 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>).

4 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.

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1907/2006 of the European Parliament and of the Council⁶. 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. This concerns, among others, spare parts for land-based motor vehicles, such as cars, motorcycles, agricultural and construction motor vehicles and industrial trucks, including motor vehicles covered by Regulations (EU) 2018/858⁷, (EU) 167/2013⁸ and (EU) 168/2013⁹.

- (5) The Convention includes exemptions for the use of dechlorane plus that are not recommended in the committees' opinions. This includes use of that substance for the purpose of spare parts for outdoor power equipment, medical devices, in-vitro diagnostic devices and instruments for analysis, measurements, control, monitoring, testing, production and inspection as well as for the repair of certain articles. Considering that the volume of dechlorane plus used in spare parts and for the repair of articles is small and taking into account the importance of maintaining articles already in use, such exemptions should be included in Regulation (EU) 2019/1021.
- (6) The maximum duration of the exemptions should be five years, with the possibility to extend for an additional period of five 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 committees' opinions supported a duration of seven and ten 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.
- (7) Article 3 of Regulation (EU) 2019/1021 prohibits the manufacturing, placing on the market and use of substances listed in Annex I to that Regulation whether on their own, in mixtures or in articles. In this regard, it should be clarified that articles that contain dechlorane plus and that are produced or placed on the market under an exemption laid down in Annex I to that Regulation and that were already in use on the

⁶ 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>).

⁷ Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1, ELI: <http://data.europa.eu/eli/reg/2018/858/oj>).

⁸ Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1, ELI: <http://data.europa.eu/eli/reg/2013/167/oj>).

⁹ Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52, ELI: <http://data.europa.eu/eli/reg/2013/168/oj>).

expiry date of the relevant exemption, are allowed to continue to be used after that date.

- (8) Furthermore, in line with Decision SC-11/10, the exemption covering the placing on the market and use of dechlorane plus for the purposes of spare parts for certain vehicles, certain machines, for the purposes of marine, garden, forestry and outdoor power equipment, for the purposes of aerospace, space and defence applications and for the purposes of certain instruments is granted until the end of the service life of the relevant product or until 31 December 2043, whichever comes earlier, or, with regard to spare parts for the purposes of medical devices and in-vitro diagnostic devices, until the end of the service life of the relevant product. The service life of products in defence, aerospace and space applications may go beyond 2043. The placing on the market and use of spare parts for such applications, present in the territory of the Union before or on the date of the expiry of the relevant exemption, should therefore be allowed even after that date.
- (9) To reinforce the application and enforcement of Article 3(1) 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.
- (10) Considering that laboratories need to improve analysis accuracy and to ensure uniform and adequate application of analytical methods, the unintentional trace contaminant limit should be set at 1000 mg/kg. 30 months after the entry into force of this Regulation, that limit should be 1 mg/kg.
- (11) 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, 15.5.2025

For the Commission
The President
Ursula VON DER LEYEN