



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 medium chain chlorinated paraffins

(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 twelfth meeting of the Conference of the Parties to the Convention, which took place in Geneva, Switzerland from 28 April to 9 May 2025, it was decided to include medium chain chlorinated paraffins (MCCP) 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-12/10 to list MCCP in Annex A, in accordance with Article 15(1) of Regulation (EU) 2019/1021.

The European Chemical Agency (ECHA) prepared a restriction dossier for MCCP in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council and the opinions of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) were finalised in September 2023¹. These opinions were used as a basis for the EU contribution to the Convention scientific process and for the EU position at the Conference of the Parties.

Decision SC-12/10 includes a list of specific exemptions granted under the Convention, which covers all the exemptions recommended in RAC and SEAC opinions. The Convention includes exemptions not recommended in those opinion, for example for various uses of MCCP in PVC (including in wires and cables for medical devices and in-vitro diagnostic devices), in aerospace and defence sectors and in certain spare parts. The Commission is of the view that the exemptions for aerospace and defence sectors, for medical devices and in-vitro diagnostic devices and for spare parts should be granted.

The Convention establishes that specific exemptions can be allowed for five years, with a possibility to extend them for additional 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 when needed.

Concerning the Unintentional Trace Contaminant (UTC) limits, it is proposed using the concentration limit recommended in ECHA's opinion (0,1 % by weight). Such limit is considered to prevent intentional use and to be enforceable.

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 MCCP in Annex I to the POPs Regulation in the 'POPs CA meeting' and comments were taken into account.

Additionally, the REACH restriction process for MCCP, leading to the RAC and SEAC opinions, included two public consultations. The SEAC opinion includes a socio-economic assessment of the costs and the benefits of the REACH restriction in the dossier prepared by

¹ [3de158a7-8ab9-ba32-be7f-0125bb0174d3](https://echa.europa.eu/en/chemicals-restriction/consultations/3de158a7-8ab9-ba32-be7f-0125bb0174d3)

ECHA. SEAC estimated the costs of the restriction of approximately 4 billion over 20 years (mostly costs of substitution of MCCP with alternatives). SEAC considered such costs to be affordable to industry and that no major impacts on employment were expected. Taking into account the socio-economic costs and the socio-economic benefits, including the benefits of reduction of emissions from MCCP, SEAC concludes that the restriction is, as modified by SEAC, the most appropriate Union wide measure to address the risk.

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 as follows.

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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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 twelfth meeting held from 28 April to 9 May 2025 to amend Annex A to the Convention to include medium chain chlorinated paraffins in that Annex with specific exemptions. The Union supported the inclusion of medium chain chlorinated paraffins in Annex A with specific exemptions as decided in Council Decision (EU) 2025/868⁴.
- (4) 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 medium chain chlorinated paraffins.
- (5) In 2023, 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 the European Chemicals Agency for medium chain chlorinated paraffins under Regulation (EC) No 1907/2006 of the European

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, ELI: <http://data.europa.eu/eli/convention/2006/507/oj>.

³ OJ L 81, 19.3.2004, p. 37, ELI: <http://data.europa.eu/eli/dec/2004/259/oj>.

⁴ Council Decision (EU) 2025/868 of 23 April 2025 on the position to be taken on behalf of the European Union at the twelfth meeting of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants as regards the requests for extension of specific exemptions and the proposals for amendments of Annex A to that Convention (OJ L, 2025/868, 12.5.2025, ELI: <http://data.europa.eu/eli/dec/2025/868/oj>).

⁵ [3de158a7-8ab9-ba32-be7f-0125bb0174d3](http://data.europa.eu/eli/dec/2025/868/oj)

Parliament and of the Council⁶. Both RAC and SEAC supported a restriction on placing on the market of medium chain chlorinated paraffins. SEAC supported a derogation on placing on the market for the use in metal working fluids. That derogation is included in the list of specific exemptions granted under the Convention by Decision SC-12/10 of the Conference of the Parties ('Decision SC-12/10') and should be granted as exemption also under Regulation (EU) 2019/1021 since it is still needed in the Union. This concerns the use of medium chain chlorinated paraffins as extreme pressure additives in metalworking fluids used in 'heavy-duty' metal working operations which are limited to professional or industrial settings.

- (6) The Convention also includes exemptions for the use of medium chain chlorinated paraffins that are not recommended in the committees' opinions. Those exemptions include some uses in the aerospace and defence sectors, i.e. (adhesives and sealants, tape used for non-structural bonding, intumescent coating and paint for space and defence equipment and its packaging, coating and paint for the repair of, and use in replacement part for, space and defence equipment). They also include other uses in the defence sector, i.e. paints and coatings for ammunition and ammunition marking as well as ammunition pyrotechnic defence devices. Such uses were not known when the committees' opinions were adopted. Considering the long period of time needed to allow for the identification of alternatives to medium chain chlorinated paraffins and for the substitution of such substances for those uses in the highly regulated aerospace and defence sectors, the exemptions should be included in Regulation (EU) 2019/1021.
- (7) The Convention also includes exemptions for the use of medium chain chlorinated paraffins in the medical sector and for spare parts that are not recommended in the committees' opinions. Those exemptions include the use in wires and cables in medical devices and in-vitro diagnostic devices. It also includes uses in spare parts for, and repair of, (i) land-based motor vehicles and machinery used in agriculture, construction, forestry and landscaping, (ii) electric and electronic equipment for medical devices, in-vitro diagnostic devices and instruments for measurement, analysis, manufacturing, control, monitoring, testing and inspection and (iii) aerospace and defence applications. Considering the limited volume of medium chain chlorinated paraffins used in medical devices and in-vitro diagnostic devices, in spare parts and for the repair of articles and considering the importance of preventing the premature obsolescence of such articles, the exemptions should be included in Regulation (EU) 2019/1021.
- (8) The maximum duration of the exemptions should be five years, with the possibility to extend them for an additional period of five years, in accordance with Article 4(4) of the Convention. This is especially relevant for the exemption for paints and coatings for ammunition and ammunition markings, for which it is expected that more than five years will be needed to complete the substitution. The Commission will review the need for a prolongation of the specific exemption in order to prepare for the Conference of the Parties that is expected to be held in May 2031, since a potential

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>).

extension of the specific exemptions for the use of medium chain chlorinated paraffins under the Convention will have to be decided at that Conference of the Parties.

- (9) 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, articles that contain medium chain chlorinated paraffins 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 expiry date of the relevant exemption, are allowed to continue to be used after that date.
- (10) Furthermore, in line with Decision SC-12/10, the exemption covering the placing on the market and use of medium chain chlorinated paraffins in polymers and rubbers for the purposes of spare parts for (i) land based motor vehicles and machinery used in agriculture, construction, forestry and landscaping, (ii) aerospace, space and defence applications, (iii) electric and electronic equipment used for medical devices and in-vitro diagnostic devices and for certain instruments should be granted until the end of the service life of the relevant products or until 31 December 2041, whichever comes earlier. The service life of products in some of those applications may go beyond 2041. 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.
- (11) Decision SC-12/10 establishes that Parties that have registered for a specific exemption for the use of medium chain chlorinated paraffins for metalworking fluids in professional or industrial settings with collection systems and in coating and paint for the repair of, and the use in replacement parts for, space and defence equipment, are to take measures for protecting workers. To ensure a high level of protection of all workers, that requirement should be extended to all exemptions granted in this Regulation. Additionally, as the exemptions granted could lead to emissions of medium chain chlorinated paraffins and in line with the objective of Article 1 of Regulation (EU) 2019/1021 to minimise releases of persistent organic pollutants, a requirement to minimise emissions to the environment from all exempted uses should be introduced.
- (12) Decision SC-12/10 encourages Parties to require that manufacturers of chlorinated paraffins within their jurisdictions disclose information to downstream users on the presence in their products of certain linear C₁₄₋₁₇ chloroalkanes. In the Union, such requirement should be introduced for manufacturers, suppliers and importers of chlorinated paraffins who should be required to provide to downstream users the requested information in the Safety Data Sheet referred to in Article 31 of Regulation (EU) 1907/2006.
- (13) In order for the amendment to Part A of Annex I to Regulation (EU) 2019/1021 to apply at the same time as the entry into force of the amendment of the Convention for the Union, the date of application of this Regulation should be deferred.
- (14) 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 medium chain chlorinated paraffins occurring as an unintentional trace contaminant in substances, mixtures and articles.
- (15) 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*.

It shall apply from (date of the entry into force of the amendment to the Stockholm Convention).

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