



EUROPEAN  
COMMISSION

Brussels, XXX  
[...] (2025) XXX draft

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

**of XXX**

**amending and correcting Regulation (EU) No 649/2012 of the European Parliament and  
of the Council as regards the listing of pesticides and industrial chemicals**

(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 delegated act amends the lists of chemicals in Annexes I and V to Regulation (EU) No 649/2012 on the basis of developments in Union law and under the Rotterdam Convention. Article 23(1) of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals requires the Commission to review, at least every year and on the basis of developments in Union law and under the Rotterdam Convention, the list of chemicals in Annex I to that Regulation.

Since the last review of Annex I in October 2024, a number of final regulatory actions in respect of certain chemicals have been taken under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. Account has also been taken of the legal requirements under both Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products and Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH).

At the twelfth meeting of the Conference of the Parties to the Rotterdam Convention, held in Geneva from 28 April to 9 May 2025, it was decided to include further chemicals in Annex III to the Rotterdam Convention.

At the eleventh meeting of the Conference of the Parties to the Stockholm Convention, held in Geneva from 1 to 12 May 2023, it was decided to include further chemicals in Annex A to the Stockholm Convention. These chemicals have been included in Annex I to Regulation (EU) 2019/1021 on persistent organic pollutants.

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

Experts designated by Member States were consulted on the draft delegated act within the relevant expert group (the 'PIC DNA expert group') on 2 April 2025 and their comments were taken into account. Relevant stakeholders (including the chemicals industry and the civil society) also took part in the discussions on the amendments to the Regulation during the meeting of the PIC DNA expert group and their comments were also taken into account.

A public consultation was carried out on the draft delegated act from XXX to XXX. XXX stakeholders representing YYY submitted comments, which were considered and YYY.

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

The delegated act amends the lists of chemicals in Annexes I and V to Regulation (EU) No 649/2012 on the basis of developments in Union law and under the Rotterdam Convention. Article 23(1) of Regulation (EU) No 649/2012 requires this. The legal basis for the proposed delegated act is Article 23(4), points (a) and (b) of Regulation (EU) No 649/2012.

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

of **XXX**

**amending and correcting Regulation (EU) No 649/2012 of the European Parliament and of the Council as regards the listing of pesticides and industrial chemicals**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals<sup>1</sup>, and in particular Article 23(4), points (a) and (b) thereof,

Whereas:

- (1) Regulation (EU) No 649/2012 implements the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade<sup>2</sup> ('the Rotterdam Convention').
- (2) By Commission Implementing Decision (EU) 2024/2402<sup>3</sup>, the Commission decided not to renew the approval of the substance sulfuryl fluoride for use in biocidal products of product-types 8 and 18 pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council<sup>4</sup>. That Decision had the effect of banning sulfuryl fluoride for use in the subcategory 'other pesticide including biocides'. Therefore, sulfuryl fluoride should be added to the list of chemicals set out in Part 1 of Annex I to Regulation (EU) No 649/2012.
- (3) The substance carbendazim is listed in Part 1 of Annex I to Regulation (EU) No 649/2012, based on a ban in the subcategory 'pesticide in the group of plant protection products'. In addition, the active substance carbendazim has been withdrawn by industry from the approval process pursuant to Regulation (EU) No 528/2012, which amounts to a ban in the subcategory 'other pesticide including biocides'. Consequently, carbendazim is banned from all use in the category 'pesticides' and should be added to the list of chemicals set out in Part 2 of Annex I to Regulation (EU) No 649/2012. Due to the listing of the substance carbendazim in Part 2 it is necessary to update the entry on carbendazim in Part 1 to reflect that the substance is also listed in Part 2.

<sup>1</sup> OJ L 201, 27.7.2012, p. 60, ELI: <http://data.europa.eu/eli/reg/2012/649/oj>.

<sup>2</sup> OJ L 63, 6.3.2003, p. 27, ELI: [http://data.europa.eu/eli/dec/2003/106\(1\)/oj](http://data.europa.eu/eli/dec/2003/106(1)/oj).

<sup>3</sup> Commission Implementing Decision (EU) 2024/2402 of 12 September 2024 not renewing the approval of sulfuryl fluoride for use in biocidal products of product-types 8 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L series, 13.9.2024, ELI: [http://data.europa.eu/eli/dec\\_impl/2024/2402/oj](http://data.europa.eu/eli/dec_impl/2024/2402/oj)).

<sup>4</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>).

- (4) By Implementing Regulation (EU) 2024/2806<sup>5</sup>, the Commission decided not to renew the approval of the substance metribuzin as an active substance pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>6</sup>. That decision had the effect of banning metribuzin from all use in the category ‘pesticides’, due to the fact that it has not been approved for any other use in that category. Therefore, metribuzin should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (5) The active substances dodemorph, fenpyrazamine, flumetralin, metaflumizone, pyridalyl and tritosulfuron have been withdrawn by the relevant industry from the approval process pursuant to Regulation (EC) No 1107/2009. That withdrawal had the effect of banning those substances from use in the subcategory ‘pesticide in the group of plant protection products’, which amounts to a ban from all use in the category ‘pesticides’, due to the fact that those substances are not approved for any other use in that category. In addition, the harmonised classification of dodemorph, fenpyrazamine, flumetraline, metaflumizone, pyridalyl and tritosulfuron pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>7</sup> is sufficient evidence that the substances raise concerns for human health or the environment. Therefore, dodemorph, fenpyrazamine, flumetraline, metaflumizone, pyridalyl and tritosulfuron should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (6) The active substance polyhexamethylene biguanide hydrochloride PHMB (1600; 1.8) has been withdrawn by the relevant industry from the approval process pursuant to Regulation (EU) No 528/2012 as regards the use in biocidal products of product-types 2, 3 and 11. In addition, the substance is not approved for use in product-types 1, 5, 6 and 9 and is only approved for use in biocidal products of product-type 4. This amounts to a severe restriction of the use of the substance in the subcategory ‘other pesticide including biocides’. Furthermore, the substance is not approved for use in the subcategory ‘pesticide in the group of plant protection products’. Consequently, polyhexamethylene biguanide hydrochloride PHMB (1600; 1.8) is severely restricted for use in the category ‘pesticides’ and should thus be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (7) The substances DEHP, DBP, diarsenic trioxide, trichloroethylene, chromium trioxide, “acids generated from chromium trioxide and their oligomers: oligomers of chromic acid and dichromic acid, chromic acid, dichromic acid”, sodium dichromate, potassium dichromate, ammonium dichromate, potassium chromate, sodium chromate, “formaldehyde, oligomeric reaction products with aniline”, arsenic acid, bis(2-methoxyethyl) ether, “2,2'-dichloro-4,4'-methylenedianiline (MOCA)”, dichromium

<sup>5</sup> Commission Implementing Regulation (EU) 2024/2806 of 31 October 2024 concerning the non-renewal of approval of the active substance metribuzin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 and Commission Implementing Regulation (EU) 2015/408 (OJ L series, 4.11.2024, ELI: [http://data.europa.eu/eli/reg\\_impl/2024/2806/oj](http://data.europa.eu/eli/reg_impl/2024/2806/oj)).

<sup>6</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>).

<sup>7</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

tris(chromate), strontium chromate, potassium hydroxyoctaoxodizincatedichromate, pentazinc chromate octahydroxide, and “pitch, coal tar, high-temp” are classified as carcinogenic category 1A or 1B, or mutagenic category 1A or 1B, or toxic for reproduction category 1A or 1B in accordance with Regulation (EC) No 1272/2008. Furthermore, they are included in Appendices 1 to 6 to Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>8</sup> and covered by entries 28, 29 or 30 of Annex XVII to that Regulation, which means that they are banned from placing on the market and use for supply to the general public. Consequently, the use of those substances is severely restricted in the subcategory “industrial chemical for use by the public” and they should thus be added to the list of chemicals set out in Part 1 of Annex I to Regulation (EU) No 649/2012.

- (8) The substances 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2]”, UV-328, UV-327, UV-350, UV-320, “4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol”, “reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP)”, and “reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)” are identified as substances of very high concern in accordance with Regulation (EC) No 1907/2006 and are listed in Annex XIV to that Regulation. Consequently, the use of those substances is subject to authorisation in accordance with Title VII of Regulation (EC) No 1907/2006. Since no authorisations have been granted, those substances are severely restricted for industrial use. Therefore, those substances should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (9) Dechlorane Plus is listed in Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council<sup>9</sup>. The inclusion in that Annex has the effect of severely restricting the use of Dechlorane Plus in the category ‘industrial chemical’. It should thus be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (10) The substance abamectin is listed in Part 1 of Annex I to Regulation (EU) No 649/2012. In order to clarify the scope of the entry an additional numerical identifier should be added in that entry.
- (11) The substance terbufos is listed in Part 3 of Annex I to Regulation (EU) No 649/2012. In that entry the HS code for mixtures containing terbufos should be corrected.
- (12) At its twelfth meeting held from 28 April to 9 May 2025, the Conference of the Parties to the Rotterdam Convention decided to include the substances carbosulfan and fenthion (ultra-low-volume formulations at or above 640 g active ingredient/L) in Annex III to that Convention, with the effect that those chemicals became subject to

<sup>8</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>).

<sup>9</sup> Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45, ELI: <http://data.europa.eu/eli/reg/2019/1021/oj>).

the prior informed consent procedure under the Convention. Consequently, those substances should be added to the list of chemicals set out in Part 3 of Annex I to Regulation (EU) No 649/2012. Since carbosulfan is already listed in Part 2 of Annex I to that Regulation, that substance should be removed from the list of chemicals set out in Part 2 of Annex I to Regulation (EU) No 649/2012. Due to the removal of carbosulfan from Part 2 and its listing in Part 3 it is necessary to update the entry on carbendazim in Part 1 to reflect these changes.

- (13) At its eleventh meeting held from 1 to 12 May 2023, the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants decided to include the substances Dechlorane Plus, methoxychlor and UV-328 in Annex A to that Convention. Consequently, those substances were listed in Part A of Annex I to Regulation (EU) 2019/1021 and should therefore be added to the list of chemicals set out in Part 1 of Annex V to Regulation (EU) No 649/2012.
- (14) Regulation (EU) No 649/2012 should therefore be amended and corrected accordingly.
- (15) It is appropriate to provide for a reasonable period of time for interested parties to take the measures necessary to comply with this Regulation and for Member States to take the measures necessary for its implementation, therefore the date of application should be deferred,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

#### **Amendments**

Regulation (EU) No 649/2012 is amended as follows:

- (1) Annex I is amended in accordance with Annex I to this Regulation;
- (2) Annex V is amended in accordance with Annex II to this Regulation.

#### *Article 2*

#### **Correction**

In Annex I to Regulation (EU) No 649/2012, Part 3, the table, the entry for ‘terbufos’, the fourth column, ‘ex 3808.59’ is replaced by ‘ex 3808.91’.

#### *Article 3*

#### **Entry into force and application**

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 1 January 2026.

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*

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