



EUROPEAN
COMMISSION

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

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

of XXX

**amending 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

Pursuant to Article 23(1) of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals, at least once a year the Commission is required to review, on the basis of developments in Union law and under the Convention, the list of chemicals in Annex I to that Regulation. Since the last review of Annex I 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. In addition, the legal requirements under 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) have been taken into account. At the eleventh meeting of the Conference of the Parties to the Rotterdam Convention, held in Geneva from 1 to 12 May 2023, decisions were taken to include further chemicals in Annex III to the Convention. At the tenth meeting of the Conference of the Parties to the Stockholm Convention, held in Geneva from 6 to 17 June 2022, decisions were taken to include further chemicals in Annex A to the Convention.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft amendment was consulted with an expert group (the 'PIC DNA meeting') on 27 October 2023 and 16 May 2024 and comments were taken into account. The group is composed of all the relevant stakeholders - representatives of Member States, of the European Chemicals Agency, the chemicals industry and the civil society.

A public consultation will be carried out for the draft act from XXX to XXX and comments will be taken into account.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends the lists of chemicals in Annex I on the basis of developments in Union law and under the Convention, as required by Article 23(1) of Regulation (EU) No 649/2012. The legal basis for the proposed delegated act is Article 23(4), point (a), (b) and (d) of Regulation (EU) No 649/2012.

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

of **XXX**

amending 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 chemicals¹, and in particular Article 23(4), point (a), (b) and (d) 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 Trade² ('the Rotterdam Convention').
- (2) By Implementing Regulations (EU) 2023/149³, (EU) 2023/2657⁴, (EU) 2023/2456⁵, (EU) 2023/1436⁶, (EU) 2023/2455⁷, (EU) 2023/741⁸, (EU) 2024/20⁹ and (EU)

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¹ OJ L 201, 27.7.2012, p. 60.

² OJ L 63, 6.3.2003, p. 29.

³ Commission Implementing Regulation (EU) 2023/149 of 20 January 2023 concerning the non-renewal of approval of the active substance benfluralin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 20, 23.1.2023, p. 30).

⁴ Commission Implementing Regulation (EU) 2023/2657 of 6 November 2023 concerning the non-renewal of the approval of the active substance benthiavalicarb, 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 (OJ L, 23.11.2023).

⁵ Commission Implementing Regulation (EU) 2023/2456 of 7 November 2023 concerning the non-renewal of the approval of the active substance clofentezine, 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 (OJ L, 8.11.2023).

⁶ Commission Implementing Regulation (EU) 2023/1436 of 10 July 2023 concerning the non-renewal of the approval of the active substance dimoxystrobin, 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 176, 11.7.2023, p. 10).

⁷ Commission Implementing Regulation (EU) 2023/2455 of 7 November 2023 concerning the non-renewal of the approval of the active substance metiram, 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 (OJ L, 8.11.2023).

⁸ Commission Implementing Regulation (EU) 2023/741 of 5 April 2023 concerning the non-renewal of the approval of the active substance oxamyl, 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 (OJ L 98, 11.4.2023, p. 1).

2023/2513¹⁰, the Commission decided not to renew the approval of the substances benfluralin, benthialdicarb, clofentezine, dimoxystrobin, metiram, oxamyl, S-metolachlor and triflurosulfuron-methyl, respectively, as active substances under Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹¹. The effect of that decision is that famoxadone and phosmet are banned from all use in the category 'pesticides', due to the fact that they have not been approved for any other use in that category. Therefore, benfluralin, benthialdicarb, clofentezine, dimoxystrobin, metiram, oxamyl, s-metolachlor and triflurosulfuron-methyl should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

- (3) By Implementing Regulation (EU) 2021/1379¹², the Commission decided to withdraw the approval of the substance ipconazole, as active substances under Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹³. The effect of that decision is that ipconazole is banned 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, ipconazole should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (4) By Implementing Regulation (EU) 2024/425¹⁴, the Commission decided not to approve the active substance asulam-sodium since it has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that asulam-sodium is banned from all use in the category 'pesticides', due to the fact that it has not been approved for any other use in that category. In addition, the harmonised classification of the substance under Regulation (EC) No 1272/2008 is sufficient evidence that it raises concerns for human health or the environment. Therefore, asulam-sodium 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 calcium phosphide, chloridazon, chlorsulfuron, flusilazole, fuberidazole, ioxynil, molinate, oxadiazon, profenofos, quinoclamine, spirotetramat, tralkoxydim and triadimenol have been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that

⁹ Commission Implementing Regulation (EU) 2024/20 of 12 December 2023 concerning the non-renewal of the approval of the active substance S-metolachlor, 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 (OJ L, 3.1.2024).

¹⁰ Commission Implementing Regulation (EU) 2023/2513 of 16 November 2023 concerning the non-renewal of the approval of the active substance triflurosulfuron-methyl, 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 (OJ L, 17.11.2023).

¹¹ 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).

¹² Commission Implementing Regulation (EU) 2023/939 of 10 May 2023 withdrawing the approval of the active substance ipconazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Commission Implementing Regulation (EU) No 571/2014 (OJ L 125, 11.5.2023, p. 19).

¹³ 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).

¹⁴ Commission Implementing Regulation (EU) 2024/425 of 2 February 2024 concerning the non-approval of the active substance asulam-sodium, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L, 5.2.2024).

those substances are banned from all use in the category ‘pesticides’, due to the fact that they have not been approved for any other use in that category. In addition, the harmonised classification of those substances under Regulation (EC) No 1272/2008 is sufficient evidence that the substances raise concerns for human health or the environment. 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.

- (6) The active substance difenacoum has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that difenacoum is banned from use in the subcategory ‘pesticide in the group of plant protection products’. In addition, the harmonised classification of difenacoum under Regulation (EC) No 1272/2008 is sufficient evidence that the substance raises concerns for human health or the environment. Therefore, difenacoum should be added to the list of chemicals set out in Part 1 of Annex I to Regulation (EU) No 649/2012.
- (7) The active substance penflufen has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that the use of that substance at the level of the category ‘pesticides’ is severely restricted, considering that penflufen is only approved for use in biocidal products under Regulation (EU) No 528/2012 of the European Parliament and of the Council¹⁵ for product-type 18 in the subcategory ‘other pesticide including biocides’. In addition, the harmonised classification of penflufen under Regulation (EC) No 1272/2008 is sufficient evidence that the substance raises concerns for human health or the environment. Therefore, penflufen should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (8) By Implementing Decisions (EU) 2023/470¹⁶ and (EU) 2022/2005¹⁷, the Commission decided not to approve the substances d-Allethrin and methylene dithiocyanate as active substances under Regulation (EU) No 528/2012. The effect of that decision is that d-allethrin and methylene dithiocyanate are banned from all use in the category ‘pesticides’, due to the fact that the substances have not been approved for any other use in that category. Therefore, d-allethrin and methylene dithiocyanate 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) By Implementing Decisions (EU) 2023/2377¹⁸, (EU) 2023/2052¹⁹ and (EU) 2023/2648²⁰, the Commission decided not to approve the substances silver copper

¹⁵ Regulation (EC) 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).

¹⁶ Commission Implementing Decision (EU) 2023/470 of 2 March 2023 not approving d-Allethrin as an existing active substance for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 68, 6.3.2023, p. 177).

¹⁷ Commission Implementing Decision (EU) 2022/2005 of 21 October 2022 not approving methylene dithiocyanate as an existing active substance for use in biocidal products of product-type 12 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 274, 24.10.2022, p. 76).

¹⁸ Commission Implementing Decision (EU) 2023/2377 of 28 September 2023 not approving silver copper zeolite as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 3.10.2023).

¹⁹ Commission Implementing Decision (EU) 2023/2052 of 25 September 2023 not approving silver sodium hydrogen zirconium phosphate as an existing active substance for use in biocidal products of

zeolite, silver sodium hydrogen zirconium phosphate and silver zeolite as active substances for use in product type 4 under Regulation (EU) No 528/2012. The effect of that decision is that the use of those substances is severely restricted in the category ‘pesticides’, due to the fact that the substances have not been approved for any other use in that category. Therefore, silver copper zeolite, silver sodium hydrogen zirconium phosphate and silver zeolite should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

- (10) By Implementing Decisions (EU) 2023/1424²¹, the Commission decided not to renew the approval of the substance acrolein since it has been withdrawn by industry from the approval process under Regulation (EU) No 528/2012. The effect of that decision is that acrolein is banned from all use in the category ‘pesticides’, due to the fact that the substance has not been approved for any other use in that category. In addition, the harmonised classification of the substance under Regulation (EC) No 1272/2008 is sufficient evidence that it raises concerns for human health or the environment. Therefore, acrolein should be added to the list of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (11) The active substance fenpropimorph has been withdrawn by industry from the approval processes under Regulation (EC) No 1107/2009 and under Regulation (EU) No 528/2012. The effect of those withdrawals is that fenpropimorph is banned from use in the category ‘pesticides’. In addition, the harmonised classification of fenoxycarb under Regulation (EC) No 1272/2008 is sufficient evidence that the substance raises concerns for human health or the environment. Therefore, fenpropimorph should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (12) By implementing decision (EU) 2023/1097²², the Commission decided not to approve the substance cyanamide as active substance under Regulation (EC) No 528/2012 and cyanamide is not approved as active substances under Regulation (EU) No 1107/2009. Consequently, cyanamide is banned from all use in the category ‘pesticides’ and should be listed in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012. Since cyanamide is already listed in Part 1 it should be added to the list of chemicals set out in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (13) The substances 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear; dihexyl phthalate; 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters; sodium perborate, perboric acid, sodium salt; and sodium peroxometaborate are listed in Annex XIV to Regulation (EC) No 1907/2006 of the

product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 236, 26.9.2023, p. 40).

²⁰ Commission Implementing Decision (EU) 2023/2648 of 27 November 2023 not approving silver zeolite as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 29.11.2023).

²¹ Commission Implementing Decision (EU) 2023/1424 of 5 July 2023 not renewing the approval of acrolein for use in biocidal products of product-type 12 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 174, 7.7.2023, p. 17).

²² Commission Implementing Decision (EU) 2023/1097 of 5 June 2023 not approving cyanamide as an existing active substance for use in biocidal products of product-types 3 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 146, 6.6.2023, p. 27).

European Parliament and of the Council²³ since they have been previously identified as substances of very high concern. Consequently, those substances are 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.

- (14) At its eleventh meeting held from 1 to 12 May 2023, the Conference of the Parties to the Rotterdam Convention decided to include terbufos in Annex III to that Convention, with the effect that terbufos became subject to the prior informed consent procedure under that Convention. Consequently, terbufos should be added to the list of chemicals set out in Part 3 of Annex I to Regulation (EU) No 649/2012. Since terbufos is already listed in Part 2 of Annex I to that Regulation, terbufos should be removed from the list of chemicals set out in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (15) At its tenth meeting held from 6 to 17 June 2022, the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants ('the Stockholm Convention') decided to include the substance perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds in Annex A to that Convention. Consequently, that substance was listed in Part A of Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council²⁴ and should therefore be added to the list of chemicals in Part 1 of Annex V to Regulation (EU) No 649/2012.
- (16) The entry for endosulfan included in the list of chemicals set out in Part A of Annex V should be amended by adding additional numerical identifiers to clarify the scope in order to align it with Regulation (EU) 2019/1021.
- (17) Regulation (EU) No 649/2012 should therefore be amended accordingly.
- (18) 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,

HAS ADOPTED THIS REGULATION:

Article 1

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.

²³ 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).

²⁴ 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).

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 1 January 2025.

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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