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COVER NOTE

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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 16.6.2023 amending Regulation (EU) No 649/2012 of the European Parliament and of the Council as regards the listing of pesticides and industrial chemicals

Delegations will find attached document C(2023) 3822 final.

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EUROPEAN
COMMISSION

Brussels, 16.6.2023
C(2023) 3822 final

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

of 16.6.2023

**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)

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 tenth meeting of the Conference of the Parties to the Rotterdam Convention, held in Geneva from 6 to 17 June 2022, decisions were taken to include further chemicals in Annex III 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 20 October 2022 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 was carried out for the draft act from 20 March 2023 to 17 April 2023 during which 6 comments were received. The comments underline the importance of import controls to protect in particular consumers from chemicals that are not allowed to be used in the Union, but that may enter the Union through imported products. In addition, there was a request to give industry enough time for implementation of such an amendment, which is already established practice for some years.

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 delegated act is Article 23(4), point (a), of Regulation (EU) No 649/2012.

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

of 16.6.2023

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), 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) 2021/1379³ and (EU) 2022/94⁴, the Commission decided not to renew the approval of the substances famoxadone and phosmet, respectively, as active substances under Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁵. 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, famoxadone and phosmet should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

¹ OJ L 201, 27.7.2012, p. 60.

² OJ L 63, 6.3.2003, p. 29.

³ Commission Implementing Regulation (EU) 2021/1379 of 19 August 2021 concerning the non-renewal of approval of the active substance famoxadone, 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 297, 20.8.2021, p. 32).

⁴ Commission Implementing Regulation (EU) 2022/94 of 24 January 2022 concerning the non-renewal of the approval of the active substance phosmet, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 16, 25.1.2022, p. 33).

⁵ 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).

- (3) By Implementing Regulation (EU) 2021/2081⁶, the Commission decided not to renew the approval of the substance indoxacarb as an active substance under Regulation (EC) No 1107/2009. That decision amounts to a severe restriction of the use of that substance at the level of the category ‘pesticides’, considering that indoxacarb is only approved for use in biocidal products under Regulation (EU) No 528/2012 of the European Parliament and of the Council⁷ for product-type 18 in the subcategory ‘other pesticide including biocides’. Therefore, indoxacarb 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) 2021/795⁸ the Commission decided to withdraw the approval of the substance alpha-cypermethrin as an active substance under Regulation (EC) No 1107/2009. The effect of that decision is that alpha-cypermethrin is banned from use in the subcategory ‘pesticide in the group of plant protection products’. In addition, the harmonised classification of alpha-cypermethrin under Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁹ is sufficient evidence that the substance raises concerns for human health or the environment. Therefore, alpha-cypermethrin should be added to the list of chemicals set out in Part 1 of Annex I to Regulation (EU) No 649/2012.
- (5) The active substance bromadiolone has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that bromadiolone is banned from use in the subcategory ‘pesticide in the group of plant protection products’. In addition, the harmonised classification of bromadiolone under Regulation (EC) No 1272/2008 is sufficient evidence that the substance raises concerns for human health or the environment. Therefore, bromadiolone should be added to the list of chemicals set out in Part 1 of Annex I to Regulation (EU) No 649/2012.
- (6) The active substance metam-sodium has been withdrawn by industry from the approval process under Regulation (EU) No 528/2012. The effect of that withdrawal is that metam-sodium is banned from all use in the subcategory ‘other pesticide including biocides’. In addition, the harmonised classification of that substance under Regulation (EC) No 1272/2008 is sufficient evidence that the substance raises concerns for human health or the environment. Therefore, metam-sodium should be added to the list of chemicals set out in Part 1 of Annex I to Regulation (EU) No 649/2012.

⁶ Commission Implementing Regulation (EU) 2021/2081 of 26 November 2021 concerning the non-renewal of approval of the active substance indoxacarb, 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 426, 29.11.2021, p. 28).

⁷ 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).

⁸ Commission Implementing Regulation (EU) 2021/795 of 17 May 2021 withdrawing the approval of the active substance alpha-cypermethrin 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 174, 18.5.2021, p. 2).

⁹ 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).

- (7) By Implementing Regulation (EU) 2022/782¹⁰ the Commission decided to withdraw the approval of the substance isopyrazam as an active substance under Regulation (EC) No 1107/2009. The effect of that decision is that isopyrazam 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, isopyrazam 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) The active substance diuron 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 diuron is severely restricted at the level of the category ‘pesticides’, considering that diuron is only allowed to be used in biocidal products under Regulation (EU) No 528/2012 for product-types 7 and 10 in the subcategory ‘other pesticide including biocides’. In addition, the harmonised classification of diuron under Regulation (EC) No 1272/2008 is sufficient evidence that the substance raises concerns for human health or the environment. Therefore, diuron 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) The active substances azimsulfuron, carbetamide, carboxin, cyproconazole, ethamsulfuron-methyl, etridiazole, fenbuconazole, fluquinconazole, lufenuron, metosulam, myclobutanil, penycuron, prochloraz, profoxydim, spirodiclofen and triflumizole have been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that 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.
- (10) By Implementing Decisions (EU) 2018/622¹¹, (EU) 2020/1765¹² and (EU) 2021/98¹³, the Commission decided not to approve the substances chlorophene and esbiothrin as active substances under Regulation (EU) No 528/2012. The effect of that decision is that chlorophene and esbiothrin 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, chlorophene and esbiothrin should be added to the lists of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (11) The active substance fenoxycarb has been withdrawn by industry from the approval processes under Regulation (EC) No 1107/2009 and under Regulation (EU) No

¹⁰ Commission Implementing Regulation (EU) 2022/782 of 18 May 2022 withdrawing the approval of the active substance isopyrazam 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, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Implementing Regulation (EU) No 1037/2012 (OJ L 140, 19.5.2022, p. 3).

¹¹ Commission Implementing Decision (EU) 2018/622 of 20 April 2018 not approving chlorophene as an existing active substance for use in biocidal products of product-type 3 (OJ L 102, 23.4.2018, p. 80).

¹² Commission Implementing Decision (EU) 2020/1765 of 25 November 2020 not approving chlorophene as an existing active substance for use in biocidal products of product-type 2 (OJ L 397, 26.11.2020, p. 24).

¹³ Commission Implementing Decision (EU) 2021/98 of 28 January 2021 not approving esbiothrin as an existing active substance for use in biocidal products of product-type 18 (OJ L 31, 29.1.2021, p. 214).

528/2012. The effect of those withdrawals is that fenoxycarb 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, fenoxycarb 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 Commission Delegated Regulation (EU) 2018/172¹⁴, the substance triflumuron has been added to the list of chemicals set out in Part 1 of Annex I to Regulation (EU) No 649/2012, based on a ban in the subcategory ‘other pesticide including biocides’. In addition, the active substance triflumuron has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009 and the conclusions of the risk assessment under Regulation (EU) No 528/2012 constitute sufficient evidence that the substance raises concerns for human health or the environment, which amounts to a ban in the subcategory ‘pesticide in the group of plant protection products’. Consequently, triflumuron 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.
- (13) By Commission Delegated Regulation (EU) No 1078/2014¹⁵, the substance cyfluthrin has been added to the list of chemicals set out 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’. That ban amounts to a severe restriction of the use of that substance at the level of the category ‘pesticides’, considering that cyfluthrin is only approved for use in biocidal products under Regulation (EU) No 528/2012 for product-type 18 in the subcategory ‘other pesticide including biocides’. Therefore, cyfluthrin should be added to the list of chemicals set out in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (14) The substances chlorfenvinphos and terbufos are not approved as active substances under Regulation (EC) No 1107/2009 and those substances are not approved as active substances under Regulation (EU) No 528/2012. Consequently, chlorfenvinphos and terbufos are 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 chlorfenvinphos and terbufos are already listed in Part 1 they should be added to the list of chemicals set out in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (15) The substances 1-bromopropane, diisopentyl phthalate, 1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich, 1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters, 1,2-benzenedicarboxylic acid, dipentylester, branched and linear, bis(2-methoxyethyl) phthalate, dipentyl phthalate and n-pentyl-isopentyl phthalate are listed in Annex XIV to Regulation (EC) No 1907/2006 of the European

¹⁴ Commission Delegated Regulation (EU) 2018/172 of 28 November 2017 amending Annexes I and V to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (OJ L 32, 6.2.2018, p. 6).

¹⁵ Commission Delegated Regulation (EU) No 1078/2014 of 7 August 2014 amending Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (OJ L 297, 15.10.2014, p. 1).

Parliament and of the Council¹⁶ 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.

- (16) At its tenth meeting held from 6 to 17 June 2022, the Conference of the Parties to the Rotterdam Convention decided to include decabromodiphenyl ether and perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex III to that Convention, with the effect that those chemicals became subject to the prior informed consent procedure under that Convention. Consequently, those chemicals should be added to the list of chemicals set out in Part 3 of Annex I to Regulation (EU) No 649/2012. Since decabromodiphenyl ether and perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds are already listed in Part 2 of Annex I to that Regulation, those chemicals should be removed from the list of chemicals set out in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (17) The entries for bromoxynil, epoxiconazole and nonylphenol ethoxylates included in the lists of chemicals set out in Parts 1 and 2 of Annex I should be amended by clarifying the scope or adding additional numerical identifiers in order to facilitate implementation of Regulation (EU) No 649/2012.
- (18) Regulation (EU) No 649/2012 should therefore be amended accordingly.
- (19) 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

Annex I to Regulation (EU) No 649/2012 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 ... *[OJ, please insert the date: the first day of the first month following the 44th day after publication of this Regulation]*.

¹⁶ 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).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16.6.2023

For the Commission
The President
Ursula VON DER LEYEN