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EUROPEAN
COMMISSION

Brussels, XXX
[…](2026) 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)

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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.

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 that are not included in Annex I. 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).

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') 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.

The draft delegated act was subject to public feedback from XX to XX. XX stakeholders submitted comments, which were considered.

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

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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 chemicals[1], and in particular Article 23(4), points (a) and (b), thereof,

Whereas:

(1) Regulation (EU) No 649/2012 implements the 1998 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade[2] ('the Rotterdam Convention').

(2) By Commission Implementing Regulation (EU) 2025/910[3], the Commission decided not to renew the approval of flufenacet as an active substance under Regulation (EC) No 1107/2009 of the European Parliament and of the Council[4]. The effect of that Decision is that flufenacet is banned from all use in the category 'pesticides', since it has not been approved for any other use in that category. Therefore, flufenacet 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 Commission Implementing Regulation (EU) 2024/1696[5], the Commission decided to withdraw the approval of acibenzolar-S-methyl as an active substance under Regulation (EC) No 1107/2009. The effect of that decision is that acibenzolar-S-methyl is banned from all use in the category 'pesticides', since it has not been approved for any other use in that category. In addition, the harmonised classification

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

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

3 Commission Implementing Regulation (EU) 2025/910 of 20 May 2025 concerning the non-renewal of the approval of the active substance flufenacet, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulations (EU) No 540/2011 and (EU) 2015/408. OJ L, 2025/910, 21.5.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/910/oj).

4 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).

5 Commission Implementing Regulation (EU) 2024/1696 of 19 June 2024 withdrawing the approval of the active substance acibenzolar-S-methyl 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) 2016/389 (OJ L, 2024/1696, 20.6.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1696/oj).

of acibenzolar-S-methyl under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[6] confirms that acibenzolar-S-methyl raises concerns for human health or the environment. Therefore, acibenzolar-S-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.

(4) 2-methyl-1,2-benzisothiazol-3(2H)-one (MBIT) is approved under Regulation (EU) No 528/2012 of the European Parliament and of the Council[7] as an active substance for use in biocidal products for product-type 6 pursuant to Commission Implementing Regulation (EU) 2017/2327[8]. By Commission Implementing Decision (EU) 2017/1282[9], the Commission decided not to approve MBIT as an active substance for use in biocidal products of product-type 13 under Regulation (EU) No 528/2012. The effect of that decision is that MBIT is severely restricted from use in the category 'pesticides', since it is only approved for use in biocidal products for product-type 6 under Regulation (EU) No 528/2012 and since there are no national authorisations for use of biocidal products containing MBIT under that Regulation. In addition, the harmonised classification of MBIT under Regulation (EC) No 1272/2008 shows that the substance raises concerns for human health or the environment. Therefore, MBIT 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 approval of disodium octaborate tetrahydrate[10] as an active substance for use in biocidal products under Regulation (EU) No 528/2012 has expired. Its approval as an active substance for use in plant protection products under Regulation (EC) No 1107/2009 has also expired[11]. The effect of that expiration is that disodium octaborate tetrahydrate is banned from all use in the category 'pesticides', since it has not been approved for any use in that category. In addition, the harmonised classification of disodium octaborate tetrahydrate under Regulation (EC) No 1272/2008 shows that the substance raises concerns for human health or the environment. Therefore, disodium octaborate tetrahydrate should be added to the list of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) 649/2012. In addition disodium octaborate tetrahydrate is included in Appendix 6 to Annex XVII to Regulation (EC) No 1907/2006 of the

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6 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).

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. ELI: http://data.europa.eu/eli/reg/2012/528/oj).

8 Commission Implementing Regulation (EU) 2017/2327 of 14 December 2017 approving 2-methyl-1,2-benzisothiazol-3(2H)-one as an active substance for use in biocidal products of product-type 6 (OJ L 333, 15.12.2017, p. 25, ELI: http://data.europa.eu/eli/reg_impl/2017/2327/oj).

9 Commission Implementing Decision (EU) 2017/1282 of 14 July 2017 not approving 2-methyl-1,2-benzisothiazol-3(2H)-one as an active substance for use in biocidal products of product-type 13 (OJ L 184, 15.7.2017, p. 69, ELI: http://data.europa.eu/eli/dec_impl/2017/1282/oj).

10 Commission Directive 2009/96/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium octaborate tetrahydrate as an active substance in Annex I thereto. (OJ L 201, 1.8.2009, pp. 58–61,. ELI: http://data.europa.eu/eli/dir/2009/96/oj).

11 Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances (OJ L 319, 23.11.2002, p. 3, ELI: http://data.europa.eu/eli/reg/2002/2076/oj).

European Parliament and of the Council[12] and covered by entry 30 of Annex XVII to that Regulation. Therefore, it is banned from placing on the market and use for supply to the general public. Consequently, the use of that substance is also severely restricted in the subcategory 'industrial chemical for use by the public', which should also be indicated in Part 1 of Annex I to Regulation (EU) No 649/2012.

(6) The approval of diboron trioxide[13] as active substance for use in biocidal products under Regulation (EU) No 528/2012 has expired. The effect of this expiration is that diboron trioxide is banned from all use in the category 'pesticides', since it has not been approved for any other use in that category. In addition, the harmonised classification of diboron trioxide under Regulation (EC) No 1272/2008 shows that the substance raises concerns for human health or the environment. Therefore, diboron trioxide should be added to the list of chemicals set out in Parts 1 and 2 of Annex I to Regulation (EU) 649/2012. In addition diboron trioxide is included in Appendix 6 to Annex XVII to Regulation (EC) No 1907/2006 and covered by entry 30 of Annex XVII to that Regulation. Therefore, it is banned from placing on the market and use, for supply to the general public. Consequently, the use of that substance is also severely restricted in the subcategory 'industrial chemical for use by the public', which should also be indicated in Part 1 of Annex I to Regulation (EU) No 649/2012.

(7) Boric acid is approved under Regulation (EU) No 528/2012 for use in biocidal products for product-type 8. The approval of boric acid as an active substance for use in plant protection products under Regulation (EC) No 1107/2009 has expired[14]. The effect of that expiration is that boric acid is banned from use in the subcategory 'pesticides in the group of plant protection products'. In addition, the harmonised classification of boric acid under Regulation (EC) No 1272/2008shows that the substance raises concerns for human health or the environment. Therefore, boric acid should be added to the lists of chemicals set out in Part 1 of Annex I to Regulation (EU) No 649/2012. In addition Boric acid is included in Appendix 6 to Annex XVII to Regulation (EC) No 1907/2006 and covered by entry 30 of Annex XVII to that Regulation. Therefore, it is banned from placing on the market and use, for supply to the general public. Consequently, the use of that substance is also severely restricted in the subcategory 'industrial chemical for use by the public', which should also be indicated in Part 1 of Annex I to Regulation (EU) No 649/2012.

(8) The substance lead chromate is listed, within the entry for 'Lead and its compounds', in Part 1 of Annex I to Regulation (EU) No 649/2012 as severely restricted as industrial chemical in the subcategory 'industrial chemical for use by the public'. Lead chromate is identified as a substance of very high concern in accordance with Regulation (EC) No 1907/2006 and is listed in Annex XIV to that Regulation.

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[12] 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, EL,I: http://data.europa.eu/eli/reg/2006/1907/oj).

[13] Commission Directive 2009/98/EC of 4 August 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include boric oxide as an active substance in Annex I thereto (OJ L 203, 5.8.2009, p. 58, ELI: http://data.europa.eu/eli/dir/2009/98/oj).

[14] Commission Decision 2004/129/EC of 30 January 2004 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances (OJ L , ELI: http://data.europa.eu/eli/dec/2004/129(1)/oj).

Consequently, the use of that substance is subject to authorisation in accordance with Title VII of Regulation (EC) No 1907/2006. Since no authorisation is in force, that substance is severely restricted for industrial use, which includes the subcategory 'for use by professionals'. Therefore, lead chromate should be added to the lists of chemicals set out in Part 2 of Annex I to Regulation (EU) No 649/2012. The severe restriction in the subcategory 'industrial chemical for use by professionals' should be indicated in Part 1 of Annex I for lead chromate. A specific entry should be included in Part 1 of Annex I for that substance and the entry for lead and its compounds in Part 1 of that Annex should be modified by removing the EC number 231-846-0, CAS number 7758-97-6 and CN code 2841 50 00 corresponding to the substance lead chromate.

(9) The substances 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one, 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone, 2-(4-tert-butylbenzyl) propionaldehyde, 'orthoboric acid, sodium salt', diisohexyl phthalate, disodium octaborate, dicyclohexyl phthalate, bisphenol A, 2-methoxyethanol, 2-ethoxyethanol, 1-methyl-2-pyrrolidone, 'tetraboron disodium heptaoxide, hydrate', 'Refractory Ceramic Fibres, Special Purpose Fibres, except those specified elsewhere in Annex VI to Regulation (EC) No 1272/2008 other than in Index No 650-017-00-8', 'N,N-dimethylformamide', 'N,N-dimethylacetamide', cobalt sulphate, cobalt dinitrate, cobalt di(acetate), cobalt dichloride, cobalt carbonate, disodium tetraborate, disodium tetraborate pentahydrate and disodium tetraborate decahydrate, 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 and covered by entries 28, 29 or 30 of Annex XVII to that Regulation. Therefore, 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.

(10) At its twelfth meeting held from 28 April to 9 May 2025, the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants decided to include the substances chlorpyrifos, medium-chain chlorinated paraffins (MCCPs) and long-chain perfluorocarboxylic acids, their salts and related compounds in Annex A to that Convention. Consequently, those substances were listed in Part A of Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council[15] and should therefore be added to the list of chemicals set out in Part 1 of Annex V to Regulation (EU) No 649/2012. Since the listing of chlorpyrifos in Part 1 of Annex V to Regulation (EU) No 649/2012 prohibits the export of that substance, the listing of chlorpyrifos in Parts 1 and 2 of Annex I to that Regulation is no longer required and should be removed. *[Regulation (EU) 2019/1021 is in the process of being amended to include* chlorpyrifos, MCCPs and long-chain perfluorocarboxylic acids, their salts and related compounds, *in its Annex I. The inclusion of these substances in the draft Annex V to Regulation (EU) No 649/2012 is conditional on the finalisation of that process under Regulation (EU) 2019/1021]*

[15] 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).

(11) The specific exemption for Perfluoro-octane sulfonic acid (PFOS), its salts and PFOS-related compounds in Annex I to Regulation (EU) 2019/1021 has expired and unintentional trace contaminant limits have been laid down under Regulation (EU) 2019/1021 for some of the entries listed in Annex I to that Regulation. Therefore, Part 1 of Annex V to Regulation (EU) No 649/2012 needs to be updated in line with the current status of Annex I to Regulation (EU) 2019/1021. In addition, the description of some substances listed in Part 1 of Annex V of Regulation (EU) No 649/2012 should be aligned to the description of the same substances in Annex I to Regulation (EU) 2019/1021.

(12) Regulation (EU) No 649/2012 should therefore be amended accordingly.

(13) 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

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

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 [same day as date of entry into force plus 2 months or 1 April 2027, whichever is latest].

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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