



EUROPEAN  
COMMISSION

Brussels, **XXX**  
[...](2021) **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, industrial chemicals, persistent organic pollutants  
and mercury and an update of customs codes**

(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 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, Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), Regulation (EU) 2019/1021 on persistent organic pollutants and Regulation (EU) No 2017/852 on mercury have been taken into account. At the ninth meeting of the Conference of the Parties to the Stockholm Convention, held in Geneva from 29 April to 10 May 2019, decisions were taken to include further chemicals in Annex A to the Convention.

In addition, Article 14(2) of Regulation (EU) No 649/2012 requires the Commission to revise the classification in the European Union's Combined Nomenclature of chemicals listed in Annex I in the light of any changes made in the World Customs Organisation's Harmonised System Nomenclature or in the European Union's Combined Nomenclature for the chemicals concerned.

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

The draft amendment was consulted with an expert group (the 'PIC DNA meeting') on 5 November 2020, 23 April 2021 and 14 October 2021 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 Annexes I and V 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) (a), (b), (c) 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, industrial chemicals, persistent organic pollutants and mercury and an update of customs codes**

(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), (b), (c) 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 trade<sup>2</sup> ('the Rotterdam Convention').
- (2) By Implementing Regulations (EU) 2020/1280<sup>3</sup>, (EU) 2020/892<sup>4</sup>, (EU) 2020/1276<sup>5</sup>, (EU) 2020/18<sup>6</sup>, (EU) 2020/17<sup>7</sup>, (EU) 2020/1246<sup>8</sup>, (EU) 2020/2087<sup>9</sup>,

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<sup>1</sup> OJ L 201, 27.7.2012, p. 60.

<sup>2</sup> OJ L 63, 6.3.2003, p. 29.

<sup>3</sup> Commission Implementing Regulation (EU) 2020/1280 of 14 September 2020 concerning the non-renewal of the approval of the active substance benalaxyl, 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 301, 15.9.2020, p. 4).

<sup>4</sup> Commission Implementing Regulation (EU) 2020/892 of 29 June 2020 concerning the non-renewal of the approval of the active substance beta-cyfluthrin, 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 206, 30.6.2020, p. 5).

<sup>5</sup> Commission Implementing Regulation (EU) 2020/1276 of 11 September 2020 concerning the non-renewal of the approval of the active substance bromoxynil, 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 300, 14.9.2020, p. 32).

<sup>6</sup> Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, 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 7, 13.1.2020, p. 14).

<sup>7</sup> Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, 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 7, 13.1.2020, p. 11).

(EU) 2019/1606<sup>10</sup>, (EU) 2020/23<sup>11</sup>, and (EU) 2020/1498<sup>12</sup>, the Commission decided not to renew the approval of the substances benalaxyl, beta-cyfluthrin, bromoxynil, chlorpyrifos, chlorpyrifos-methyl, fenamiphos, mancozeb, methiocarb, thiacloprid and thiophanate-methyl, respectively, as active substances under Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>13</sup>. The effect of those final regulatory actions 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. Therefore, those substances should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

- (3) The active substances epoxiconazole and mecoprop 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 epoxiconazole and mecoprop under Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>14</sup> is sufficient evidence that the substances raise concerns for human health and the environment. Therefore, epoxiconazole and mecoprop should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (4) The active substance bifenthrin has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that bifenthrin is banned from use in the subcategory ‘pesticide in the group of plant

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<sup>8</sup> Commission Implementing Regulation (EU) 2020/1246 of 2 September 2020 concerning the non-renewal of the approval of the active substance fenamiphos, 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 288, 3.9.2020, p. 18).

<sup>9</sup> Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of the approval of the active substance mancozeb, 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 423, 15.12.2020, p. 50).

<sup>10</sup> Commission Implementing Regulation (EU) 2019/1606 of 27 September 2019 concerning the non-renewal of the approval of the active substance methiocarb, 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 250, 30.9.2019, p. 53).

<sup>11</sup> Commission Implementing Regulation (EU) 2020/23 of 13 January 2020 concerning the non-renewal of the approval of the active substance thiacloprid, 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 8, 14.1.2020, p. 8).

<sup>12</sup> Commission Implementing Regulation (EU) 2020/1498 of 15 October 2020 concerning the non-renewal of approval of the active substance thiophanate-methyl, 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 342, 16.10.2020, p. 5).

<sup>13</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).

<sup>14</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).

protection products'. That ban amounts to a severe restriction of the use of that substance at the level of the category 'pesticides', considering that bifenthrin is only approved for use in biocidal products under Regulation (EU) No 528/2012 of the European Parliament and of the Council<sup>15</sup> for product-type 8 in the subcategory 'other pesticide including biocides', and that there are no national authorisations for use of biocidal products containing bifenthrin under that Regulation. In addition, the harmonised classification of bifenthrin under Regulation (EC) No 1272/2008 is sufficient evidence that the substance raises concerns for human health and the environment. Therefore, bifenthrin should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

- (5) By Implementing Decision (EU) 2018/1251<sup>16</sup>, the Commission decided not to approve empenethrin as an active substance under Regulation (EU) No 528/2012. The effect of that final regulatory action was that empenethrin 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, empenethrin should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (6) The active substances azinphos-ethyl, ferbam and hexazinone 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. Therefore, azinphos-ethyl, ferbam and hexazinone should be added to the list of chemicals in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (7) The active substance methomyl has been withdrawn by industry from the approval process under Regulation (EC) No 1107/2009. The effect of that withdrawal is that methomyl is banned from use in the subcategory 'pesticide in the group of plant protection products'. That ban amounts to a ban of the use of the substance at the level of the category 'pesticides', considering that methomyl has not been approved for any other use in that category. Therefore, methomyl should be added to the list of chemicals in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (8) The substances 2,4-dinitrotoluene (2,4-DNT) and 4,4'-diaminodiphenylmethane (MDA) are listed in Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>17</sup> 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, 2,4-dinitrotoluene (2,4-DNT) and 4,4'-diaminodiphenylmethane (MDA) are severely restricted for industrial use. Therefore, those substances should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

<sup>15</sup> 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).

<sup>16</sup> Commission Implementing Decision (EU) 2018/1251 of 18 September 2018 not approving empenethrin as an existing active substance for use in biocidal products of product-type 18 (OJ L 235, 19.9.2018, p. 24).

<sup>17</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).

- (9) The use of the substance mercury is restricted by Regulation (EU) 2017/852 of the European Parliament and of the Council<sup>18</sup>, Regulation (EC) No 1907/2006, Directive 2011/65/EU of the European Parliament and of the Council<sup>19</sup> and Directive 2006/66/EC of the European Parliament and of the Council<sup>20</sup>, with the effect that the use of mercury is severely restricted for all industrial use. Therefore, mercury should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (10) The use of the substance cadmium and of its compounds is severely restricted by Regulation (EC) No 1907/2006 in the subcategory 'industrial chemical for public use'. That restriction amounts to a severe restriction of the use of the substance at the level of the category 'industrial chemicals', considering that cadmium and its compounds are also severely restricted in the subcategory 'industrial chemical for professional use'. Therefore, cadmium and its compounds should be added to the list of chemicals in Part 2 of Annex I to Regulation (EU) No 649/2012.
- (11) The use of the substance lead is severely restricted by Regulation (EC) No 1907/2006 in the subcategory 'industrial chemical for public use'. Therefore, lead should be added to the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012 for that subcategory.
- (12) The use of benzene as a constituent of other substances is severely restricted by Regulation (EC) No 1907/2006 in the subcategory 'industrial chemical for public use'. Therefore, benzene as a constituent of other substances should be added to the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012 for that subcategory.
- (13) The use of the substances bis(pentabromophenyl) ether (decaBDE) and perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds is severely restricted by Regulation (EU) 2019/1021 of the European Parliament and of the Council<sup>21</sup> for all industrial use. Therefore, those substances should be added to the list of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (14) By Implementing Regulation (EU) 2017/1506<sup>22</sup>, the Commission decided to renew the approval of the active substance maleic hydrazide under Regulation (EC) No 1107/2009, with the effect that maleic hydrazide and its choline, potassium and sodium salts are no longer banned for use in the subcategory 'pesticide in the group of plant protection products'. Therefore, those substances should be removed from the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012.

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<sup>18</sup> Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1).

<sup>19</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

<sup>20</sup> Directive 2006/66/EU of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (OJ L 266, 26.9.2006, p. 1).

<sup>21</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).

<sup>22</sup> Commission Implementing Regulation (EU) 2017/1506 of 28 August 2017 renewing the approval of the active substance maleic hydrazide 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 222, 29.8.2017, p. 21).

- (15) At its sixth meeting held from 28 April to 10 May 2013, the Conference of the Parties to the Rotterdam Convention decided to include commercial pentabromodiphenyl ether, including tetra- and pentabromodiphenyl ether, as well as commercial octabromodiphenyl ether, including hexa- and heptabromodiphenyl ether, 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 were added to the list of chemicals in Part 3 of Annex I to Regulation (EU) No 649/2012 by Commission Delegated Regulation (EU) 2015/2229<sup>23</sup>. In order to facilitate the implementation of that listing and in particular the submission of export notifications for certain articles, those chemicals should also be listed in Part 1 of Annex I to Regulation (EU) No 649/2012.
- (16) The entry on commercial octabromodiphenyl ether in Part 3 of Annex I to Regulation (EU) No 649/2012 also covers the substance octabromodiphenyl ether listed in Parts 1 and 2 of Annex I to that Regulation. Therefore, octabromodiphenyl ether should be removed from the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (17) At its ninth meeting held from 29 April to 10 May 2019, the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants ('the Stockholm Convention') decided to include the substance dicofol in Annex A to that Convention. Consequently, that substance was listed in Part A of Annex I to Regulation (EU) 2019/1021 and should therefore be added to the list of chemicals in Part 1 of Annex V to Regulation (EU) No 649/2012. Since a listing in Part 1 of Annex V to Regulation (EU) No 649/2012 prohibits the export of a substance without any exemption, the listing of dicofol in Parts 1 and 2 of Annex I to that Regulation is no longer required and should be removed.
- (18) At its ninth meeting held from 29 April to 10 May 2019, the Conference of the Parties to the Stockholm Convention decided to include the substance perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex A to that Convention with a number of exemptions and with an obligation for parties to prohibit the export of fire-fighting foams that contain those chemicals. Consequently, perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds were listed in Part A of Annex I to Regulation (EU) 2019/1021 and should therefore be added to the list of chemicals in Part 1 of Annex V to Regulation (EU) No 649/2012 as regards its presence in fire-fighting foams.
- (19) At its seventh meeting held from 4 to 15 May 2015, the Conference of the Parties to the Stockholm Convention decided to include the substances pentachlorophenol and its salts and esters 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 in Part 1 of Annex V to Regulation (EU) No 649/2012.
- (20) At its fourth meeting held from 4 to 8 May 2009, the Conference of the Parties to the Stockholm Convention decided to include the substances perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride in Annex B to that Convention. That entry was subsequently amended by Decision SC-9/4 in 2019. Those substances

<sup>23</sup> Commission Delegated Regulation (EU) 2015/2229 of 29 September 2015 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 317, 3.12.2015, p. 13).

are listed in Part A of Annex I to Regulation (EU) 2019/1021 and should therefore be added to the list of chemicals in Part 1 of Annex V to Regulation (EU) No 649/2012.

- (21) Part 1 of Annex V to Regulation (EU) No 649/2012 contains an entry on articles containing concentrations of tetra-, penta-, hexa- and heptabromodiphenyl ether at or above 0,1 % by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use. That entry is based on a restriction set out in Regulation (EC) No 850/2004 of the European Parliament and of the Council<sup>24</sup>. The provisions concerning those substances have been amended by Regulation (EU) 2019/1021, which reduces the allowed concentrations in articles and adds decabromodiphenyl ether to the list of polybrominated diphenyl ethers. Those changes should be reflected in Part 1 of Annex V to Regulation (EU) No 649/2012.
- (22) Regulation (EU) 2017/852 prohibits the export of mercury, certain mixtures of metallic mercury with other substances, certain mercury compounds and certain mercury-added products. Those export bans should be reflected in Part 2 of Annex V to Regulation (EU) No 649/2012.
- (23) Pursuant to Article 14(2) of Regulation (EU) No 649/2012, the Commission is required to revise the classification of each chemical listed in Annex I to that Regulation in the light of any changes made in the World Customs Organisation's Harmonised System Nomenclature or in the European Union's Combined Nomenclature. A number of classifications of chemicals in the European Union's Combined Nomenclature have been changed since those chemicals were added to Annex I to Regulation (EU) No 649/2012. Those changes should be reflected in that Annex.
- (24) Regulation (EU) No 649/2012 should therefore be amended accordingly.
- (25) 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:

- (a) Annex I is replaced by the text in Annex I to this Regulation;
- (b) Annex V is replaced by the text in Annex II to this Regulation.

#### *Article [...]*

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 45th day after publication of this Regulation].

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

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<sup>24</sup> Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).



Done at Brussels,

*For the Commission  
The President  
Ursula von der Leyen*

DRAFT