



Brussels, 15.5.2020
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COMMISSION DELEGATED REGULATION (EU) .../...

of 15.5.2020

**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**

(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 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 (EU) No 2017/852 on mercury have been taken into account. At the ninth meeting of the Conference of the Parties to the Rotterdam Convention, held in Geneva from 29 April to 10 May 2019, 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 15 October 2019 and on 5 February 2020 (by a written procedure) 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 14 February to 13 March 2020 during which 4 comments were received. The comments informed about the importance of clothianidin for malaria vector control in third countries and about the approved use of that chemical for product type 18 under Regulation (EU) No 528/2012, which is currently the only approved use and had been the main use under that Regulation in the past. Since the status under Regulation (EU) No 528/2012 had already been considered in the context of this measure and it had been concluded that the chemical is severely restricted for use as a pesticide since virtually all use is prohibited, the proposal is based on the current legal status of the chemical. However, a change was made that addresses that information.

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) and (c) of Regulation (EU) No 649/2012.

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(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 points (a) and (c) of Article 23(4) 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) 2019/677³, (EU) 2019/989⁴, (EU) 2019/1100⁵, (EU) 2019/1090⁶, (EU) 2018/1532⁷, (EU) 2019/344⁸, (EU) 2018/1043⁹, (EU)

¹ OJ L 201, 27.7.2012, p. 60.

² OJ L 63, 6.3.2003, p. 29.

³ Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 concerning the non-renewal of the approval of the active substance chlorothalonil, 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 114, 30.4.2019, p. 15).

⁴ Commission Implementing Regulation (EU) 2019/989 of 17 June 2019 concerning the non-renewal of approval of the active substance chlorpropham, 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 160, 18.6.2019, p. 11).

⁵ Commission Implementing Regulation (EU) 2019/1100 of 27 June 2019 concerning the non-renewal of approval of the active substance desmedipham, 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 175, 28.6.2019, p. 17).

⁶ Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, 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 173, 27.6.2019, p. 39).

⁷ Commission Implementing Regulation (EU) 2018/1532 of 12 October 2018 concerning the non-renewal of approval of the active substance diquat, 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 257, 15.10.2018, p. 10).

⁸ Commission Implementing Regulation (EU) 2019/344 of 28 February 2019 concerning the non-renewal of approval of the active substance ethoprophos, in accordance with Regulation (EC) No 1107/2009 of

2018/1917¹⁰, (EU) 2018/1019¹¹, (EU) 2018/309¹², (EU) 2018/1501¹³ and (EU) 2018/1914¹⁴, the Commission decided not to renew the approval of the substances chlorothalonil, chlorpropham, desmedipham, dimethoate, diquat, ethoprophos, fenamidone, flurtamone, oxasulfuron, propineb, pymetrozine and quinoxyfen, respectively, as active substances under Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹⁵, with the effect that those substances are banned from all uses in the category “pesticide” due to the absence of 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) By Implementing Regulation (EU) 2018/1500¹⁶, the Commission decided not to renew the approval of the substance thiram as active substance under Regulation (EC) No 1107/2009, with the effect that that substance is banned from use in the subcategory “pesticide in the group of plant protection products” as referred to in Regulation (EU) No 649/2012. Since thiram is only approved under Regulation (EU) No 528/2012 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 62, 1.3.2019, p. 7).

⁹ Commission Implementing Regulation (EU) 2018/1043 of 24 July 2018 concerning the non-renewal of approval of the active substance fenamidone, 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 188, 25.7.2018, p. 9).

¹⁰ Commission Implementing Regulation (EU) 2018/1917 of 6 December 2018 concerning the non-renewal of approval of the active substance flurtamone, 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 311, 7.12.2018, p. 27).

¹¹ Commission Implementing Regulation (EU) 2018/1019 of 18 July 2018 concerning the non-renewal of approval of the active substance oxasulfuron, 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 183, 19.7.2018, p. 14).

¹² Commission Implementing Regulation (EU) 2018/309 of 1 March 2018 concerning the non-renewal of approval of the active substance propineb, 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 60, 2.3.2018, p. 16).

¹³ Commission Implementing Regulation (EU) 2018/1501 of 9 October 2018 concerning the non-renewal of approval of the active substance pymetrozine, 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 254, 10.10.2018, p. 4).

¹⁴ Commission Implementing Regulation (EU) 2018/1914 of 6 December 2018 concerning the non-renewal of approval of the active substance quinoxyfen, 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 311, 7.12.2018, p. 17).

¹⁵ 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).

¹⁶ Commission Implementing Regulation (EU) 2018/1500 of 9 October 2018 concerning the non-renewal of approval of the active substance thiram, and prohibiting the use and sale of seeds treated with plant protection products containing thiram, 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 254, 10.10.2018, p. 1).

the European Parliament and of the Council¹⁷ for use in biocidal products for product-type 9, which fall in the subcategory "other pesticide including biocides" as referred to in Regulation (EU) No 649/2012, virtually all use of that substance is prohibited at the level of the category "pesticide". Therefore, thiram is considered severely restricted at the level of the category "pesticide" and thus should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.

- (4) By Implementing Regulation (EU) 2018/1865¹⁸, the Commission decided not to renew the approval of the substance propiconazole as active substance under Regulation (EC) No 1107/2009, with the effect that that substance is banned from use in the subcategory "pesticide in the group of plant protection products". That ban does not amount to a severe restriction of the use of the substance at the level of the category "pesticide", considering that propiconazole is approved for several uses in the subcategory "other pesticide including biocides". Propiconazole has been approved for use in biocidal products of product-types 7, 8 and 9 under Regulation (EU) No 528/2012. Therefore, propiconazole should be added to the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012.
- (5) An application for renewal of the approval of clothianidin and thiamethoxam had been submitted, but the applicants withdrew that application after the adoption of the Implementing Regulations (EU) 2018/784¹⁹ and (EU) 2018/785²⁰, by which the Commission decided to amend the conditions of approval of the active substances clothianidin and thiamethoxam, respectively, under Regulation (EC) No 1107/2009. Since those approvals of clothianidin and thiamethoxam expired, the use of those substances is banned in the subcategory "pesticide in the group of plant protection products". That ban amounts to a severe restriction of the use of the substances at the level of the category "pesticide", since virtually all use of clothianidin and thiamethoxam is prohibited as clothianidin and thiamethoxam are only approved for use in biocidal products of product-type 18 under Regulation (EU) No 528/2012 in the subcategory "other pesticide including biocides". Therefore, clothianidin and thiamethoxam should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (6) By Implementing Regulation (EU) 2018/783²¹, the Commission decided to amend the conditions of approval of the active substance imidacloprid under Regulation (EC) No 1107/2009, with the effect that the use of that substance is severely restricted in the subcategory "pesticide in the group of plant protection products". That severe restriction does not amount to a severe restriction of the use of the substance at the

¹⁷ 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).

¹⁸ Commission Implementing Regulation (EU) 2018/1865 of 28 November 2018 concerning the non-renewal of the approval of the active substance propiconazole, 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 304, 29.11.2018, p. 6).

¹⁹ Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ L 132, 30.5.2018, p. 35).

²⁰ Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (OJ L 132, 30.5.2018, p. 40).

²¹ Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (OJ L 132, 30.5.2018, p. 31).

level of the category "pesticide", considering that imidacloprid is approved for several uses in the subcategory "other pesticide including biocides". Imidacloprid has been approved for use in biocidal products of product-type 18 under Regulation (EU) No 528/2012. In addition, imidacloprid is used in veterinary medicinal products in accordance with Directive 2001/82/EC of the European Parliament and of the Council²². Therefore, imidacloprid should be added to the list of chemicals in Part 1 of Annex I to Regulation (EU) No 649/2012.

- (7) By Implementing Regulation (EU) 2015/404²³, the Commission decided to extend the approval period of the active substance glufosinate under Regulation (EC) No 1107/2009, following an application for renewal of the approval of that active substance. Since that application has been withdrawn, glufosinate is no longer approved as active substance under Regulation (EC) No 1107/2009, with the effect that that substance is banned from all uses in the category "pesticide" due to the absence of any other use in that category. It should therefore be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (8) At its ninth meeting in May 2019, the Conference of the Parties to the Rotterdam Convention decided to include the substances phorate and hexabromocyclododecane in Annex III to that Convention, with the effect that those substances became subject to the Prior Informed Consent procedure under that Convention. Phorate should therefore be added to the lists of chemicals in Parts 1 and 3 of Annex I to Regulation (EU) No 649/2012. Hexabromocyclododecane is already listed in Annex V to Regulation (EU) No 649/2012 and thus banned for export. Therefore, it should be added to the list of chemicals in Part 3 of Annex I to that Regulation.
- (9) Regulation (EU) 2017/852 of the European Parliament and of the Council²⁴ 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.
- (10) Regulation (EU) No 649/2012 should therefore be amended accordingly.
- (11) 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 amended in accordance with Annex I to this Regulation;
- (b) Annex V is amended in accordance with Annex II to this Regulation.

²² Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

²³ Commission Implementing Regulation (EU) 2015/404 of 11 March 2015 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, captan, dimethoate, dimethomorph, ethoprophos, fipronil, folpet, formetanate, glufosinate, methiocarb, metribuzin, phosmet, pirimiphos-methyl and propamocarb (OJ L 67, 12.3.2015, p. 6).

²⁴ 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).

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 39th day after publication of this Regulation*].

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

Done at Brussels, 15.5.2020

For the Commission
The President
Ursula VON DER LEYEN