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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 11 December 2018

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 11.12.2018  
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

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Delegations will find attached document C(2018) 8376 final.

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Encl.: C(2018) 8376 final



Brussels, 11.12.2018  
C(2018) 8376 final

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

**of 11.12.2018**

**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 (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), Regulation (EU) No 528/2012 on the making available of biocidal products on the market and Regulation (EU) No 2017/852 on mercury have to be taken into account. At the eighth Conference of the Parties to the Rotterdam Convention decisions were taken to include further chemicals in Annex III to the Convention. In addition, decisions were taken at the eighth Conference of the Parties to the Stockholm Convention to include further chemicals in Annex A to the Convention. Those regulatory actions and decisions should be reflected in Annexes I and V.

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

The draft amendment was consulted with an expert group (the 'PIC DNA meeting') on 3 October 2017 and 24 April 2018 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 12 September to 10 October 2018 during which one comment was received. The comment informed that applications for approval of one chemical for use in two product types had been submitted in accordance with Regulation (EU) No 528/2012, which may result in the approval of that chemical for those specific uses. 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 and no changes were made.

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

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

of 11.12.2018

## 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)

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) 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 ('the Rotterdam Convention') signed on 11 September 1998 and approved, on behalf of the Union, by Council Decision 2003/106/EC<sup>2</sup>.
- (2) The Commission has adopted Implementing Regulations under Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>3</sup> to not approve, or to not renew the approval of, the substances amitrole, beta-cypermethrin, DPX KE 459 (flupyrsulfuron-methyl), iprodione, linuron, orthosulfamuron, picoxystrobin and triasulfuron. In consequence, those substances are banned within the Union in the use category 'pesticides' and should therefore be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (3) The Commission has adopted an Implementing Regulation under Regulation (EC) No 1107/2009 to not renew the approval of the active substance isoproturon. In consequence, even though isoproturon has been identified and notified for evaluation under Regulation (EU) No 528/2012 of the European Parliament and of the Council<sup>4</sup> for product-types 7 and 10 and may therefore continue to be authorised by Member

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

<sup>2</sup> Council Decision 2003/106/EC of 19 December 2002 concerning the approval, on behalf of the European Community, of the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade (OJ L 63, 6.3.2003, p. 27).

<sup>3</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>4</sup> 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).

States until a decision is taken under that Regulation, the fact remains that virtually all use of it as a pesticide is prohibited. As a result, it is severely restricted within the Union in the use category 'pesticides' and should therefore 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 maneb was previously approved under Regulation (EC) No 1107/2009. An application was then submitted to renew that approval, but the supplementary dossier in support of renewal was not submitted. Consequently, the approval expired. As a result, maneb is banned within the Union in the use category 'pesticides' and should therefore be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (5) The active substance fipronil was previously approved under Regulation (EC) No 1107/2009. An application was then submitted to renew that approval, but the supplementary dossier in support of renewal was not submitted. Consequently, the approval expired. As a result, even though fipronil is approved under Regulation (EU) No 528/2012 for product-type 18, the fact remains that virtually all use of it as a pesticide is prohibited. Therefore, fipronil is severely restricted within the Union in the use category 'pesticides' and should be added to the lists of chemicals in Parts 1 and 2 of Annex I to Regulation (EU) No 649/2012.
- (6) At its eighth meeting held from 24 April to 5 May 2017, the Conference of the Parties to the Rotterdam Convention decided to include carbofuran, trichlorfon and short-chain chlorinated paraffins in Annex III to the Convention, with the effect that those chemicals became subject to the prior informed consent procedure under that Convention. Those changes should therefore be reflected in the lists of chemicals in Parts 1, 2 and 3 of Annex I to Regulation (EU) No 649/2012 by adding carbofuran, trichlorfon and short-chain chlorinated paraffins to the list in Part 3 and removing carbofuran and trichlorfon from the list in Part 2 and by making consequential changes to Part 1.
- (7) Tributyltin compounds were included in Annex III to the Rotterdam Convention in the use category 'pesticide' following a decision taken at the fourth Conference of the Parties in 2008. At its eighth meeting held from 24 April to 5 May 2017, the Conference of the Parties decided to include tributyltin compounds in Annex III in the use category 'industrial', with the effect that tributyltin compounds became subject to the prior informed consent procedure under that Convention in the use category 'industrial' too. That change, together with changes to the regulatory status of tributyltin compounds under Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>5</sup> that were made after tributyltin compounds were listed in Annex I to Regulation (EU) No 649/2012, should be reflected in the lists of chemicals in Parts 1 and 3 of Annex I to Regulation (EU) No 649/2012.
- (8) At its eighth meeting held from 24 April to 5 May 2017, the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants ('the Stockholm

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<sup>5</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).

Convention'), which was approved by Council Decision 2006/507/EC<sup>6</sup>, decided to include short-chain chlorinated paraffins in Annex A to the Stockholm Convention. In order to implement the Stockholm Convention and considering that those substances are already listed in Part B of Annex I to Regulation (EC) No 850/2004 of the European Parliament and of the Council<sup>7</sup>, they should be added to Part 1 of Annex V to Regulation (EU) No 649/2012.

- (9) Regulation (EU) 2017/852 of the European Parliament and of the Council<sup>8</sup> modifies the rules on the export of mixtures of metallic mercury with other substances with a mercury concentration of less than 95 %, and of certain mercury compounds. Those changes should be reflected in the existing entries in Part 2 of Annex V to Regulation (EU) No 649/2012 for mercury compounds and mixtures of metallic mercury with other substances with a mercury concentration of less than 95 %.
- (10) Regulation (EU) No 649/2012 should therefore be amended accordingly.
- (11) It is appropriate to provide 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 to implement it,

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.

#### *Article 2*

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [OJ: please insert the later of the following two dates: (a) 1 February 2019 or (b) the 40th calendar day after publication, if that 40th calendar day happens to fall on the 1st of a month, or if that 40th calendar day falls on any other day of the month, the 1st of the following month].

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

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<sup>6</sup> Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants (OJ L 209, 31.7.2006, p. 1).

<sup>7</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).

<sup>8</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).

Done at Brussels, 11.12.2018

*For the Commission  
The President  
Jean-Claude JUNCKER*