

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 (recast) (Text with EEA relevance)

Article 1

Objectives

- 1 The objectives of this Regulation are to:
 - a implement the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (the ‘Convention’);
 - b promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals in order to protect human health and the environment from potential harm;
 - c contribute to the environmentally sound use of hazardous chemicals.

The objectives set out in the first subparagraph shall be achieved by facilitating the exchange of information concerning the characteristics of hazardous chemicals, by providing for a decision-making process within the Union on their import and export and by disseminating decisions to Parties and other countries as appropriate.

- 2 In addition to the objectives set out in paragraph 1, this Regulation shall ensure that the provisions of Regulation (EC) No 1272/2008 relating to classification, labelling and packaging apply to all chemicals when they are exported from the Member States to other Parties or other countries, unless those provisions would conflict with any specific requirements of those Parties or other countries.

Article 2

Scope

- 1 This Regulation shall apply to:
 - a certain hazardous chemicals that are subject to the prior informed consent procedure under the Convention (the ‘PIC procedure’);
 - b certain hazardous chemicals that are banned or severely restricted within the Union or a Member State;
 - c chemicals when exported in so far as their classification, labelling and packaging are concerned.
- 2 This Regulation shall not apply to any of the following:
 - a narcotic drugs and psychotropic substances covered by Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors⁽¹⁾;
 - b radioactive materials and substances covered by Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation⁽²⁾;
 - c wastes covered by Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste⁽³⁾;

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- d chemical weapons covered by Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items⁽⁴⁾;
- e food and food additives covered by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁽⁵⁾;
- f feedingstuffs covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽⁶⁾, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
- g genetically modified organisms covered by Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms⁽⁷⁾;
- h save to the extent covered by Article 3(5)(b) of this Regulation, proprietary medicinal products and veterinary medicinal products covered by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁽⁸⁾ and 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⁽⁹⁾ respectively.

3 This Regulation shall not apply to chemicals exported for the purpose of research or analysis in quantities that are unlikely to affect human health or the environment and that in any event do not exceed 10 kg from each exporter to each importing country per calendar year.

Notwithstanding the first subparagraph, exporters of the chemicals referred to therein shall obtain a special reference identification number using the Database referred to in Article 6(1)(a) and provide that reference identification number in their export declaration.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (1) ‘chemical’ means a substance, whether by itself or in a mixture, or a mixture, whether manufactured or obtained from nature, but does not include living organisms, which belongs to either of the following categories:
 - (a) pesticides, including severely hazardous pesticide formulations;
 - (b) industrial chemicals;
- (2) ‘substance’ means any chemical element and its compounds as defined in point 1 of Article 3 of Regulation (EC) No 1907/2006;
- (3) ‘mixture’ means a mixture or a solution as defined in point 8 of Article 2 of Regulation (EC) No 1272/2008;
- (4) ‘article’ means a finished product containing or including a chemical, the use of which has been banned or severely restricted by Union legislation in that particular product where that product does not fall under point 2 or 3;

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- (5) ‘pesticides’ means chemicals in either of the following subcategories:
- (a) pesticides used as plant protection products covered by 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⁽¹⁰⁾;
 - (b) other pesticides, such as:
 - (i) biocidal products under Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market⁽¹¹⁾; and
 - (ii) disinfectants, insecticides and parasiticides covered by Directives 2001/82/EC and 2001/83/EC;
- (6) ‘industrial chemicals’ means chemicals in either of the following subcategories:
- (a) chemicals for use by professionals;
 - (b) chemicals for use by the public;
- (7) ‘chemical subject to export notification’ means any chemical that is banned or severely restricted within the Union within one or more categories or subcategories, and any chemical listed in Part 1 of Annex I that is subject to the PIC procedure;
- (8) ‘chemical qualifying for PIC notification’ means any chemical that is banned or severely restricted within the Union or a Member State within one or more categories. Chemicals banned or severely restricted in the Union within one or more categories are listed in Part 2 of Annex I;
- (9) ‘chemical subject to the PIC procedure’ means any chemical listed in Annex III to the Convention and in Part 3 of Annex I to this Regulation;
- (10) ‘banned chemical’ means either of the following:
- (a) a chemical all uses of which within one or more categories or subcategories have been prohibited by final regulatory action by the Union in order to protect human health or the environment;
 - (b) a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the Union market or from further consideration in a notification, registration or approval process and where there is evidence that the chemical raises concern for human health or the environment;
- (11) ‘severely restricted chemical’ means either of the following:
- (a) a chemical, virtually all use of which within one or more categories or subcategories has been prohibited by final regulatory action by the Union in order to protect human health or the environment, but for which certain specific uses remain allowed;
 - (b) a chemical that has, for virtually all uses, been refused for approval or been withdrawn by industry either from the Union market or from further consideration in a notification, registration or approval process, and where there is evidence that the chemical raises concern for human health or the environment;

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- (12) ‘chemical banned or severely restricted by a Member State’ means any chemical that is banned or severely restricted by national final regulatory action of a Member State;
- (13) ‘final regulatory action’ means a legally binding act the purpose of which is to ban or severely restrict a chemical;
- (14) ‘severely hazardous pesticide formulation’ means a chemical formulated for use as a pesticide that produces severe health or environmental effects observable within a short period of time after single or multiple exposure, under conditions of use;
- (15) ‘customs territory of the Union’ means the territory as determined in Article 3 of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code⁽¹²⁾;
- (16) ‘export’ means the following:
- (a) the permanent or temporary export of a chemical meeting the conditions of Article 28(2) TFEU;
 - (b) the re-export of a chemical not meeting the conditions of Article 28(2) TFEU which is placed under a customs procedure other than the external Union transit procedure for movement of goods through the customs territory of the Union;
- (17) ‘import’ means the physical introduction into the customs territory of the Union of a chemical that is placed under a customs procedure other than the external Union transit procedure for movement of goods through the customs territory of the Union;
- (18) ‘exporter’ means any of the following persons, whether natural or legal:
- (a) the person on whose behalf an export declaration is made, that is to say the person who, at the time the declaration is accepted, holds the contract with the consignee in a Party or other country and has the power to determine that the chemical be sent out of the customs territory of the Union;
 - (b) where no export contract has been concluded or where the holder of the contract does not act on its own behalf, the person who has the power to determine that the chemical be sent out of the customs territory of the Union;
 - (c) where the benefit of a right to dispose of the chemical belongs to a person established outside the Union pursuant to the contract on which the export is based, the contracting party established in the Union;
- (19) ‘importer’ means any natural or legal person who at the time of import into the customs territory of the Union is the consignee for the chemical;
- (20) ‘Party to the Convention’ or ‘Party’ means a State or a regional economic integration organisation that has consented to be bound by the Convention and for which the Convention is in force;
- (21) ‘other country’ means any country that is not a Party;
- (22) ‘Agency’ means the European Chemicals Agency established under Regulation (EC) No 1907/2006;
- (23) ‘Secretariat’ means the Secretariat of the Convention, unless otherwise specified in this Regulation.

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Article 4

Designated national authorities of the Member States

Each Member State shall designate the authority or authorities (the ‘designated national authority’ or the ‘designated national authorities’) to carry out the administrative functions required by this Regulation, unless it has already done so before the entry into force of this Regulation.

It shall inform the Commission of such designation by 17 November 2012, unless that information has been already provided before entry into force of this Regulation, and shall also inform the Commission of any change of designated national authority.

Article 5

Participation of the Union in the Convention

1 Participation in the Convention shall be a joint responsibility of the Commission and the Member States, in particular as regards technical assistance, the exchange of information and matters relating to dispute settlement, participation in subsidiary bodies and voting.

2 The Commission shall act as a common designated authority for the administrative functions of the Convention with reference to the PIC procedure on behalf of and in close cooperation and consultation with all the designated national authorities of the Member States.

The Commission shall, in particular, be responsible for the following:

- a the transmission of Union export notifications to Parties and other countries pursuant to Article 8;
- b the submission to the Secretariat of notifications of relevant final regulatory actions concerning chemicals qualifying for PIC notification pursuant to Article 11;
- c the transmission of information concerning other final regulatory actions involving chemicals not qualifying for PIC notification in accordance with Article 12;
- d the receiving of information from the Secretariat more generally.

The Commission shall also provide the Secretariat with Union import responses for chemicals subject to the PIC procedure pursuant to Article 13.

In addition, the Commission shall coordinate the Union input on all technical issues relating to the following:

- a the Convention;
- b the preparation of the Conference of the Parties established by Article 18(1) of the Convention;
- c the Chemical Review Committee established in accordance with Article 18(6) of the Convention (the ‘Chemical Review Committee’);
- d other subsidiary bodies of the Conference of the Parties.

3 The Commission and the Member States shall take the necessary initiatives to ensure appropriate representation of the Union in the various bodies implementing the Convention.

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Article 6

Tasks of the Agency

- 1 The Agency shall, in addition to the tasks allocated to it under Articles 7, 8, 9, 10, 11, 13, 14, 15, 18, 19, 20, 21, 22 and 25, carry out the following tasks:
- a maintain, further develop and regularly update a database on export and import of hazardous chemicals (the 'Database');
 - b make the Database publicly available on its website;
 - c where appropriate, provide, with the agreement of the Commission and after consultations with Member States, assistance and technical and scientific guidance and tools for the industry in order to ensure the effective application of this Regulation;
 - d provide, with the agreement of the Commission, the designated national authorities of the Member States with assistance and technical and scientific guidance in order to ensure the effective application of this Regulation;
 - e at the request of Member State or Commission experts of the Chemical Review Committee, and within the available resources, provide input in drafting of decision guidance documents referred to in Article 7 of the Convention and other technical documents related to the implementation of the Convention;
 - f upon request, provide the Commission with technical and scientific input and assist it in order to ensure the effective implementation of this Regulation;
 - g upon request, provide the Commission with technical and scientific input and assist it in exercising its role as the common designated authority of the Union.
- 2 The Secretariat of the Agency shall carry out the tasks allocated to the Agency under this Regulation.

Article 7

Chemicals subject to export notification, chemicals qualifying for PIC notification, and chemicals subject to the PIC procedure

- 1 The chemicals subject to export notification, the chemicals qualifying for PIC notification and the chemicals subject to the PIC procedure shall be as listed in Annex I.
- 2 Chemicals listed in Annex I shall be assigned to one or more of three groups of chemicals, set out as Parts 1, 2 and 3 of that Annex.

The chemicals listed in Part 1 of Annex I shall be subject to the export notification procedure laid down in Article 8, with detailed information being given on the identity of the substance, on the use category and/or subcategory subject to restriction, the type of restriction and, where appropriate, additional information, in particular on exemptions to requirements for export notification.

The chemicals listed in Part 2 of Annex I shall, in addition to being subject to the export notification procedure laid down in Article 8, qualify for the PIC notification procedure set out in Article 11, with detailed information being given on the identity of the substance and on the use category.

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The chemicals listed in Part 3 of Annex I shall be subject to the PIC procedure with the use category being given and, where appropriate, additional information, in particular on any requirements for export notification.

3 The lists set out in Annex I shall be made publicly available by means of the Database.

Article 8

Export notifications forwarded to Parties and other countries

1 In the case of substances listed in Part 1 of Annex I or mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances, paragraphs 2 to 8 of this Article shall apply regardless of the intended use of the chemical in the importing Party or other country.

2 When an exporter is due to export a chemical referred to in paragraph 1 from the Union to a Party or other country for the first time on or after the date on which it becomes subject to this Regulation, the exporter shall notify the designated national authority of the Member State in which he is established (the 'exporter's Member State'), no later than 35 days before the expected date of export. Thereafter the exporter shall notify that designated national authority of the first export of the chemical each calendar year no later than 35 days before the export takes place. The notifications shall comply with the information requirements laid down in Annex II and shall be made available to the Commission and to the Member States by means of the Database.

The designated national authority of the exporter's Member State shall check compliance of the information with Annex II and if the notification is complete forward it to the Agency no later than 25 days before the expected date of export.

The Agency shall, on behalf of the Commission, transmit the notification to the designated national authority of the importing Party or the appropriate authority of the importing other country and take the measures necessary to ensure that they receive that notification no later than 15 days before the first intended export of the chemical and thereafter no later than 15 days before the first export in any subsequent calendar year.

The Agency shall register each export notification and assign it a reference identification number in the Database. The Agency shall also make available to the public and the designated national authorities of the Member States, as appropriate, an updated list of the chemicals concerned and the importing Parties and other countries for each calendar year by means of the Database.

3 If the Agency does not receive from the importing Party or other country an acknowledgement of receipt of the first export notification made after the chemical is included in Part 1 of Annex I within 30 days of the dispatch of such notification, it shall, on behalf of the Commission, submit a second notification. The Agency shall, on behalf of the Commission, make reasonable efforts to ensure that the designated national authority of the importing Party or the appropriate authority of the importing other country receives the second notification.

4 A new export notification shall be made in accordance with paragraph 2 for exports which take place subsequent to the entry into force of amendments to Union legislation concerning the marketing, use or labelling of the substances in question or whenever the composition of the mixture in question changes so that the labelling of such mixture is altered. The new notification shall comply with the information requirements laid down in Annex II and shall indicate that it is a revision of a previous notification.

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5 Where the export of a chemical relates to an emergency situation in which any delay may endanger public health or the environment in the importing Party or other country, an exemption from the obligations set out in paragraphs 2, 3 and 4 in whole or in part may be granted at the reasoned request of the exporter or the importing Party or other country and at the discretion of the designated national authority of the exporter's Member State, in consultation with the Commission assisted by the Agency. A decision on the request shall be considered to have been made in consultation with the Commission if there is no dissenting response from the Commission within 10 days of the designated national authority of the Member State sending it details of the request.

6 Without prejudice to the obligations set out in Article 19(2), the obligations set out in paragraphs 2, 3 and 4 of this Article shall cease when all of the following conditions are fulfilled:

- a the chemical has become a chemical subject to the PIC procedure;
- b the importing country is a Party to the Convention and has provided the Secretariat with a response in accordance with Article 10(2) of the Convention indicating whether or not it consents to import of the chemical; and
- c the Commission has been informed of that response by the Secretariat and has forwarded that information to the Member States and the Agency.

Notwithstanding the first subparagraph of this paragraph, the obligations set out in paragraphs 2, 3 and 4 of this Article shall not cease where an importing country is a Party to the Convention and explicitly requires continued export notification by exporting Parties, for example through its import decision or otherwise.

Without prejudice to the obligations set out in Article 19(2), the obligations set out in paragraphs 2, 3 and 4 of this Article shall also cease when both of the following conditions are fulfilled:

- a the designated national authority of the importing Party or the appropriate authority of the importing other country has waived the requirement to be notified before the export of the chemical; and
- b the Commission has received the information from the Secretariat or from the designated national authority of the importing Party or the appropriate authority of the importing other country and has forwarded it to the Member States and the Agency, which has made it available by means of the Database.

7 The Commission, the relevant designated national authorities of the Member States, the Agency and the exporters shall, on request, provide importing Parties and other countries with available additional information concerning the exported chemicals.

8 Member States may establish, in a transparent manner, systems obliging exporters to pay an administrative fee for each export notification made and for each request for explicit consent made, corresponding to the costs they incur in carrying out the procedures set out in paragraphs 2 and 4 of this Article and in Article 14(6) and (7).

Article 9

Export notifications received from Parties and other countries

1 Export notifications received by the Agency from the designated national authorities of Parties or the appropriate authorities of other countries concerning the export to the Union of a chemical the manufacture, use, handling, consumption, transport or sale of which is subject to prohibition or severe restriction under that Party's or other country's legislation shall be made available by means of the Database within 15 days of the Agency's receipt of such notification.

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The Agency shall, on behalf of the Commission, acknowledge receipt of the first export notification received for each chemical from each Party or other country.

The designated national authority of the Member State receiving that import shall receive a copy of any notification received by the Agency, within 10 days of its receipt, together with all available information. Other Member States shall be entitled to receive copies on request.

2 Where the Commission or the designated national authorities of the Member States receive any export notifications either directly or indirectly from the designated national authorities of Parties or the appropriate authorities of other countries, they shall immediately forward those notifications to the Agency together with all available information.

Article 10

Information on export and import of chemicals

- 1 Each exporter of one or more of the following:
 - a substances listed in Annex I;
 - b mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances; or
 - c articles containing substances listed in Part 2 or 3 of Annex I in unreacted form or mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances;

shall, during the first quarter of each year, inform the designated national authority of the exporter's Member State regarding the quantity of the chemical, as a substance and as contained in mixtures or in articles, shipped to each Party or other country during the preceding year. That information shall be given together with a list of the names and addresses of each natural or legal person importing the chemical into a Party or other country to which shipment took place during the same period. That information shall list separately exports pursuant to Article 14(7).

Each importer within the Union shall provide the equivalent information for the quantities imported into the Union.

2 At the request of the Commission, assisted by the Agency, or the designated national authority of its Member State, the exporter or importer shall provide any additional information relating to chemicals that is necessary to implement this Regulation.

3 Each Member State shall provide the Agency each year with aggregated information in accordance with Annex III. The Agency shall summarise that information at Union level and shall make the non-confidential information publicly available by means of the Database.

Article 11

Notification of banned or severely restricted chemicals under the Convention

1 The Commission shall notify the Secretariat in writing of the chemicals listed in Part 2 of Annex I, which qualify for PIC notification.

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2 Whenever further chemicals are added to Part 2 of Annex I pursuant to the second subparagraph of Article 23(2), the Commission shall notify those chemicals to the Secretariat. That PIC notification shall be submitted as soon as possible after adoption of the relevant final regulatory action at Union level banning or severely restricting the chemical, and no later than 90 days after the date on which the final regulatory action is to be applied.

3 The PIC notification shall provide all relevant information required in Annex IV.

4 In determining priorities for notifications, the Commission shall take into account whether the chemical is already listed in Part 3 of Annex I, the extent to which the information requirements laid down in Annex IV can be met, and the severity of the risks presented by the chemical, in particular for developing countries.

Where a chemical qualifies for PIC notification, but the information is insufficient to meet the requirements of Annex IV, identified exporters or importers shall, upon request by the Commission, provide all relevant information available to them, including that from other national or international chemical control programmes, within 60 days of the request.

5 The Commission shall notify the Secretariat in writing when a final regulatory action notified under paragraphs 1 or 2 is amended as soon as possible after adoption of the new final regulatory action, and no later than 60 days after the date on which the new final regulatory action is to be applied.

The Commission shall provide all relevant information that was not available at the time the initial notification was made under paragraphs 1 or 2 respectively.

6 At the request of any Party or the Secretariat, the Commission shall provide additional information concerning the chemical or the final regulatory action, as far as practicable.

The Member States and the Agency shall, upon request, assist the Commission as necessary in compiling that information.

7 The Commission shall forward immediately to the Member States and the Agency information that it receives from the Secretariat regarding chemicals notified as banned or severely restricted by other Parties.

Where appropriate, the Commission shall evaluate, in close cooperation with the Member States and the Agency, the need to propose measures at Union level in order to prevent any unacceptable risks to human health or the environment within the Union.

8 Where a Member State takes national final regulatory action in accordance with the relevant Union legislation to ban or severely restrict a chemical, it shall provide the Commission with relevant information. The Commission shall make that information available to the Member States. Within four weeks of that information having been made available, Member States may send comments on a possible PIC notification, including, in particular, relevant information about their national regulatory position in respect of the chemical to the Commission and to the Member State which submitted the national final regulatory action. After consideration of the comments, the submitting Member State shall inform the Commission whether the latter has to:

- a make a PIC notification to the Secretariat, pursuant to this Article; or
- b provide the information to the Secretariat, pursuant to Article 12.

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Article 12

Information to be transmitted to the Secretariat concerning banned or severely restricted chemicals not qualifying for PIC notification

In the case of chemicals listed only in Part 1 of Annex I or following receipt of information from a Member State pursuant to point (b) of Article 11(8), the Commission shall provide the Secretariat with information concerning the relevant final regulatory actions, so that the information can be disseminated to other Parties to the Convention as appropriate.

Article 13

Obligations in relation to import of chemicals

1 The Commission shall immediately forward to the Member States and the Agency any decision guidance documents which it receives from the Secretariat.

The Commission shall, by means of an implementing act, adopt an import decision in the form of a final or interim import response on behalf of the Union concerning the future import of the chemical concerned. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2). The Commission shall communicate the decision to the Secretariat as soon as possible, and no later than nine months after the date of dispatch of the decision guidance document by the Secretariat.

Where a chemical becomes subject to additional or amended restrictions under Union legislation, the Commission shall, by means of an implementing act, adopt a revised import decision. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2). The Commission shall communicate the revised import decision to the Secretariat.

2 In the case of a chemical banned or severely restricted by one or more Member States, the Commission shall, at the written request of the Member States concerned, take the information into account in its import decision.

3 An import decision under paragraph 1 shall relate to the category or categories specified for the chemical in the decision guidance document.

4 When communicating the import decision to the Secretariat, the Commission shall provide a description of the legislative or administrative measure upon which it is based.

5 Each designated national authority of the Member States shall make the import decisions under paragraph 1 available to those concerned within its competence, in accordance with its legislative or administrative measures. The Agency shall make the import decisions under paragraph 1 publicly available by means of the Database.

6 Where appropriate, the Commission shall evaluate, in close cooperation with the Member States and the Agency, the need to propose measures at Union level in order to prevent any unacceptable risks to human health or the environment within the Union, taking into account the information given in the decision guidance document.

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Article 14

Obligations in relation to export of chemicals other than export notification

1 The Commission shall immediately forward to the Member States, the Agency and European industry associations the information which it receives, whether in the form of circulars or otherwise, from the Secretariat regarding chemicals subject to the PIC procedure and the decisions of importing Parties regarding import conditions applicable to those chemicals. It shall also immediately forward to the Member States and the Agency information concerning any cases of failure to transmit a response in accordance with Article 10(2) of the Convention. The Agency shall assign each import decision a reference identification number and keep all information regarding such decisions publicly available by means of the Database, and provide anyone with that information upon request.

2 The Commission shall assign each chemical listed in Annex I a classification in the European Union's Combined Nomenclature. Those classifications shall be revised as necessary 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.

3 Each Member State shall communicate the information and decisions forwarded by the Commission under paragraph 1 to those concerned within its jurisdiction.

4 Exporters shall comply with decisions in each import response no later than six months after the Secretariat first informs the Commission of such decisions under paragraph 1.

5 The Commission, assisted by the Agency, and the Member States shall advise and assist importing Parties, upon request and as appropriate, in obtaining further information needed to prepare a response to the Secretariat concerning the import of a given chemical.

6 Substances listed in Part 2 or 3 of Annex I or mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances shall, regardless of their intended use in the importing Party or other country, not be exported unless either of the following conditions is fulfilled:

- a explicit consent to import has been sought and received by the exporter through the designated national authority of the exporter's Member State in consultation with the Commission, assisted by the Agency, and the designated national authority of the importing Party or an appropriate authority in an importing other country;
- b in the case of chemicals listed in Part 3 of Annex I, the latest circular issued by the Secretariat pursuant to paragraph 1 indicates that the importing Party has given consent to import.

In the case of chemicals listed in Part 2 of Annex I that are to be exported to OECD countries, the designated national authority of the exporter's Member State may, at the request of the exporter, in consultation with the Commission and on a case-by-case basis, decide that no explicit consent is required if the chemical, at the time of importation into the OECD country concerned, is licensed, registered or authorised in that OECD country.

Where explicit consent has been sought pursuant to point (a) of the first subparagraph, if the Agency has not received a response to the request within 30 days, the Agency shall, on behalf of the Commission, send a reminder unless the Commission or the designated

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national authority of the exporter's Member State received a response and forwarded it to the Agency. Where appropriate, if there is still no response within a further 30 days, the Agency may send further reminders as necessary.

7 In the case of chemicals listed in Part 2 or 3 of Annex I, the designated national authority of the exporter's Member State may, in consultation with the Commission assisted by the Agency, on a case-by-case basis and subject to the second subparagraph, decide that the export may proceed, if no evidence from official sources of final regulatory action to ban or severely restrict the use of the chemical taken by the importing Party or other country exists and if, after all reasonable efforts, no response to a request for explicit consent pursuant to point (a) of paragraph 6 has been received within 60 days and where one of the following conditions is met:

- a there is evidence from official sources in the importing Party or other country that the chemical is licensed, registered or authorised; or
- b the intended use declared in the export notification and confirmed in writing by the natural or legal person importing the chemical into a Party or other country, is not in a category for which the chemical is listed in Part 2 or 3 of Annex I, and there is evidence from official sources that the chemical has in the last five years been used in or imported into the importing Party or other country concerned.

In the case of chemicals listed in Part 3 of Annex I, an export based on the fulfilment of the condition under point (b) may not proceed if the chemical has been classified in accordance with Regulation (EC) No 1272/2008 as carcinogenic category 1A or 1B, or mutagenic category 1A or 1B, or toxic for reproduction category 1A or 1B or the chemical fulfils the criteria of Annex XIII to Regulation (EC) No 1907/2006 for being persistent, bioaccumulative and toxic or very persistent and very bioaccumulative.

When deciding on the export of chemicals listed in Part 3 of Annex I, the designated national authority of the exporter's Member State shall, in consultation with the Commission assisted by the Agency, consider the possible impact on human health or the environment of the use of the chemical in the importing Party or other country, and submit relevant documentation to the Agency, to be made available by means of the Database.

8 The validity of each explicit consent obtained pursuant to point (a) of paragraph 6 or decision to proceed with export in the absence of explicit consent pursuant to paragraph 7 shall be subject to periodic review by the Commission in consultation with the Member States concerned as follows:

- a for each explicit consent obtained pursuant to point (a) of paragraph 6 a new explicit consent shall be required by the end of the third calendar year after the consent was given, unless the terms of that consent require otherwise;
- b unless a response to a request has been received in the meantime, each decision to proceed without explicit consent pursuant to paragraph 7 shall be valid for a maximum period of 12 months, upon expiry of which explicit consent shall be required.

In the cases referred to in point (a) of the first subparagraph, exports may, however, continue after the end of the relevant period, pending a response to a new request for explicit consent, for an additional period of 12 months.

9 The Agency shall register all requests for explicit consent, responses obtained and decisions to proceed without explicit consent, including the documentation referred to in the third subparagraph of paragraph 7, in the Database. Each explicit consent obtained or decision to proceed without explicit consent shall be assigned a reference identification number and shall be

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listed with all relevant information concerning any conditions attached, such as validity dates. The non-confidential information shall be made publicly available by means of the Database.

10 No chemical shall be exported later than six months before its expiry date, where such a date exists or can be inferred from the production date, unless the intrinsic properties of the chemical render that impracticable. In particular, in the case of pesticides, exporters shall ensure that the size and packaging of containers is optimised so as to minimise the risk of creating obsolete stocks.

11 When exporting pesticides, exporters shall ensure that the label contains specific information about storage conditions and storage stability under the climatic conditions of the importing Party or other country. In addition, they shall ensure that the pesticides exported comply with the purity specification laid down in Union legislation.

Article 15

Export of certain chemicals and articles

1 Articles shall be subject to the export notification procedure laid down in Article 8 if they contain any of the following:

- a substances listed in Part 2 or 3 of Annex I in unreacted form;
- b mixtures containing such substances in a concentration that triggers labelling obligations under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances.

2 Chemicals and articles the use of which is prohibited in the Union for the protection of human health or the environment, as listed in Annex V, shall not be exported.

Article 16

Information on transit movements

1 Parties to the Convention requiring information concerning transit movements of chemicals subject to the PIC procedure, together with the information requested by each Party to the Convention through the Secretariat, shall be as listed in Annex VI.

2 Where a chemical listed in Part 3 of Annex I is transported through the territory of a Party to the Convention listed in Annex VI, the exporter shall, as far as practicable, provide the designated national authority of the exporter's Member State with the information required by the Party to the Convention in accordance with Annex VI no later than 30 days before the first transit movement takes place and no later than eight days before each subsequent transit movement.

3 The designated national authority of the exporter's Member State shall forward to the Commission with a copy to the Agency, the information received from the exporter under paragraph 2 together with any additional information available.

4 The Commission shall forward the information received under paragraph 3 to the designated national authorities of Parties to the Convention which requested that information, together with any additional information available, no later than 15 days before the first transit movement and prior to any subsequent transit movement.

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Article 17

Information to accompany exported chemicals

1 Chemicals that are intended for export shall be subject to the provisions on packaging and labelling established in, or pursuant to, Regulation (EC) No 1107/2009, Directive 98/8/EC and Regulation (EC) No 1272/2008, or any other relevant Union legislation.

The first subparagraph shall apply unless those provisions would conflict with any specific requirements of the importing Parties or other countries.

2 Where appropriate, the expiry date and the production date of chemicals referred to in paragraph 1 or listed in Annex I shall be indicated on the label, and if necessary such expiry dates shall be given for different climate zones.

3 A safety data sheet in accordance with Regulation (EC) No 1907/2006 shall accompany chemicals referred to in paragraph 1 when exported. The exporter shall send such a safety data sheet to each natural or legal person importing the chemical into a Party or other country.

4 The information on the label and on the safety data sheet shall as far as practicable be given in the official languages, or in one or more of the principal languages, of the country of destination or of the area of intended use.

Article 18

Obligations of the authorities of the Member States for controlling import and export

1 Each Member State shall designate authorities such as customs authorities that shall have the responsibility of controlling the import and export of chemicals listed in Annex I, unless it has already done so before the entry into force of this Regulation.

The Commission, supported by the Agency, and the Member States shall act in a targeted and coordinated way in monitoring exporters' compliance with this Regulation.

2 The Forum for Exchange of Information on Enforcement established by Regulation (EC) No 1907/2006 shall be used to coordinate a network of the Member States' authorities responsible for enforcement of this Regulation.

3 Each Member State shall, in its regular reports on the operation of procedures pursuant to Article 22(1), include details of the activities of its authorities in that regard.

Article 19

Further obligations of exporters

1 Exporters of chemicals subject to the obligations set out in Article 8(2) and (4) shall provide the applicable reference identification numbers in their export declaration (box 44 of the Single Administrative Documents or corresponding data element in an electronic export declaration) as referred to in Article 161(5) of Regulation (EEC) No 2913/92.

2 Exporters of chemicals exempted by Article 8(5) from the obligations set out in paragraphs 2 and 4 of that Article or of chemicals for which those obligations have ceased in

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accordance with Article 8(6) shall obtain a special reference identification number using the Database and provide that reference identification number in their export declaration.

3 Where requested by the Agency, exporters shall use the Database for the submission of information required for the fulfilment of their obligations under this Regulation.

Article 20

Exchange of information

1 The Commission, assisted by the Agency, and the Member States shall, as appropriate, facilitate the provision of scientific, technical, economic and legal information concerning chemicals subject to this Regulation, including toxicological, ecotoxicological and safety information.

The Commission, with the support of the Member States and the Agency as necessary, shall, as appropriate, ensure the following:

- a the provision of publicly available information concerning regulatory actions relevant to the objectives of the Convention;
- b the provision of information for Parties and other countries directly or through the Secretariat concerning those actions which substantially restrict one or more uses of a chemical.

2 The Commission, the Member States and the Agency shall protect any confidential information received from a Party or other country as mutually agreed.

3 As regards the transmission of information under this Regulation, and without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information⁽¹³⁾, the following information at least shall not be regarded as confidential:

- a the information specified in Annex II and Annex IV;
- b the information contained in safety data sheets referred to in Article 17(3);
- c the expiry date of a chemical;
- d the production date of a chemical;
- e information concerning precautionary measures, including hazard classification, the nature of the risk and the relevant safety advice;
- f the summary results of toxicological and ecotoxicological tests;
- g information concerning handling packaging after chemicals have been removed.

4 A compilation of the information transmitted shall be prepared every two years by the Agency.

Article 21

Technical assistance

The Commission, the designated national authorities of the Member States and the Agency shall, taking into account in particular the needs of developing countries and countries with economies in transition, cooperate in promoting technical assistance, including training, for the development of the infrastructure, the capacity and the expertise necessary to manage chemicals properly throughout their lifecycles.

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In particular, and with a view to enabling those countries to implement the Convention, technical assistance shall be promoted by means of the provision of technical information concerning chemicals, the promotion of the exchange of experts, support for the establishment or maintenance of designated national authorities and the provision of technical expertise for the identification of hazardous pesticide formulations and for the preparation of notifications to the Secretariat.

The Commission and the Member States shall actively participate in international activities in capacity-building in chemicals management, by providing information concerning the projects they are supporting or financing to improve the management of chemicals in developing countries and countries with economies in transition. The Commission and the Member States shall also consider giving support to non-governmental organisations.

Article 22

Monitoring and reporting

1 Member States and the Agency shall forward information to the Commission every three years concerning the operation of the procedures provided for in this Regulation, including customs controls, infringements, penalties and remedial action, as appropriate. The Commission shall adopt an implementing act laying down in advance a common format for reporting. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2).

2 The Commission shall compile a report every three years on the performance of the functions provided for in this Regulation for which it is responsible and shall incorporate it in a synthesis report integrating the information provided by the Member States and the Agency under paragraph 1. A summary of that report, which shall be published on the internet, shall be forwarded to the European Parliament and to the Council.

3 As regards the information supplied pursuant to paragraphs 1 and 2, the Commission, the Member States and the Agency shall comply with relevant obligations to protect the confidentiality and ownership of data.

Article 23

Updating annexes

1 The list of chemicals in Annex I shall be reviewed by the Commission at least every year, on the basis of developments in Union law and under the Convention.

2 When determining whether a final regulatory action at Union level constitutes a ban or a severe restriction, the effect of that action shall be assessed at the level of the subcategories within the categories ‘pesticides’ and ‘industrial chemicals’. If the final regulatory action bans or severely restricts a chemical within any one of the subcategories it shall be included in Part 1 of Annex I.

When determining whether a final regulatory action at Union level constitutes a ban or a severe restriction such that the chemical concerned qualifies for PIC notification under Article 11, the effect of that action shall be assessed at the level of the categories ‘pesticides’ and ‘industrial chemicals’. If the final regulatory action bans or severely

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restricts a chemical within either of the categories it shall also be included in Part 2 of Annex I.

3 The decision to include chemicals in Annex I, or to modify their entry where appropriate, shall be taken without undue delay.

4 In order to adapt this Regulation to technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 26 concerning the following measures:

- a inclusion of a chemical in Part 1 or 2 of Annex I pursuant to paragraph 2 of this Article following final regulatory action at Union level, and other amendments of Annex I, including modifications to existing entries;
- b inclusion of a chemical that is subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants⁽¹⁴⁾ in Part 1 of Annex V;
- c inclusion of a chemical already subject to an export ban at Union level in Part 2 of Annex V;
- d modifications to existing entries in Annex V;
- e amendments of Annexes II, III, IV and VI.

Article 24

The budget of the Agency

- 1 For the purposes of this Regulation, the revenues of the Agency shall consist of:
 - a a subsidy from the Union, entered in the general budget of the Union (Commission Section);
 - b any voluntary contribution from the Member States.

2 Revenues and expenditure for activities under this Regulation and those relating to activities under other Regulations shall be dealt with separately, through different sections in the Agency's budget.

The revenues of the Agency referred to in paragraph 1 shall be used for carrying out its tasks under this Regulation.

3 The Commission shall examine whether it is appropriate for the Agency to charge a fee for the services provided to exporters within five years of 1 March 2014 and, if necessary, submit a relevant proposal.

Article 25

Formats and software for submission of information to the Agency

The Agency shall specify formats and software packages and make them available free of charge on its website for any submission of information to the Agency. Member States and other parties subject to this Regulation shall use those formats and packages in their submissions to the Agency pursuant to this Regulation.

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Article 26

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 23(4) shall be conferred on the Commission for a period of five years from 1 March 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than three months before the end of each period.

3 The delegation of power referred to in Article 23(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5 A delegated act adopted pursuant to Article 23(4) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 27

Committee procedure

1 The Commission shall be assisted by the committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Article 28

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure correct implementation of these provisions. The penalties provided for must be effective, proportionate and dissuasive. If they have not already done so before the entry into force of this Regulation, Member States shall notify those provisions to the Commission by 1 March 2014 and shall notify it without delay of any subsequent amendment affecting them.

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Article 29

Transitional period on the classification, labelling and packaging of chemicals

References in this Regulation to Regulation (EC) No 1272/2008 shall be construed, where appropriate, as references to the Union legislation which applies by virtue of Article 61 of that Regulation and in accordance with the timetable set out therein.

Article 30

Repeal

Regulation (EC) No 689/2008 shall be repealed with effect from 1 March 2014.

References to Regulation (EC) No 689/2008 shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VII.

Article 31

Entry into force

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 1 March 2014.

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

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- (1) OJ L 22, 26.1.2005, p. 1.
- (2) OJ L 159, 29.6.1996, p. 1.
- (3) OJ L 312, 22.11.2008, p. 3.
- (4) OJ L 134, 29.5.2009, p. 1.
- (5) OJ L 165, 30.4.2004, p. 1.
- (6) OJ L 31, 1.2.2002, p. 1.
- (7) OJ L 106, 17.4.2001, p. 1.
- (8) OJ L 311, 28.11.2001, p. 67.
- (9) OJ L 311, 28.11.2001, p. 1.
- (10) OJ L 309, 24.11.2009, p. 1.
- (11) OJ L 123, 24.4.1998, p. 1.
- (12) OJ L 302, 19.10.1992, p. 1.
- (13) OJ L 41, 14.2.2003, p. 26.
- (14) OJ L 158, 30.4.2004, p. 7.

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