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from: General Secretariat

to: Delegations

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Subject: Proposal for a Regulation of the European Parliament and of the Council concerning the export and import of dangerous chemicals (recast)

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With a view to the WPE meeting on 27 July 2011, delegations will find attached a revised Presidency text (articles only). Modifications/deletions are underlined.

**REGULATION (EU) No [...] OF THE EUROPEAN PARLIAMENT AND OF THE  
COUNCIL  
of [...]  
concerning the export and import of dangerous chemicals  
(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, hereinafter 'the Treaty', and in particular Article 192(1) and Article 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the Opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

Preamble

*Article 1*  
*Objectives*

1. The objectives of this Regulation are the following:
  - (a) to implement the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, hereinafter ‘the Convention’;
  - (b) to 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) to contribute to the environmentally sound use of hazardous chemicals.

The objectives referred to in the first subparagraph shall be achieved by facilitating the exchange of information concerning the characteristics of such 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 referred to in paragraph 1, this Regulation shall ensure that the classification, labelling and packaging provisions of [...] Regulation (EC) No 1272/2008 of the European Parliament and of the Council apply to all such 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 the following:
  - (a) certain hazardous chemicals that are subject to the prior informed consent procedure under the Convention, hereinafter ‘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, packaging and labelling 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 <sup>1</sup>
  - (b) radioactive materials and substances covered by Council Directive 96/29/Euratom <sup>2</sup>;
  - (c) wastes covered by Directive 2008/98/EC of the European Parliament and of the Council <sup>3</sup> and Council Directive 91/689/EEC <sup>4</sup>;
  - (d) chemical weapons covered by Council Regulation (EC) No 428/2009 <sup>5</sup>;
  - (e) food and food additives covered by Regulation (EC) No 882/2004 of the European Parliament and of the Council <sup>6</sup>;
  - (f) feedingstuffs covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>7</sup> including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

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<sup>1</sup> OJ L 22, 26.1.2005, p. 1.

<sup>2</sup> OJ L 159, 29.6.1996, p. 1.

<sup>3</sup> OJ L 114, 27.4.2006, p. 9.

<sup>4</sup> OJ L 312, 22.11.2008, p. 3.

<sup>5</sup> OJ L 134, 29.5.2009, p. 1.

<sup>6</sup> OJ L 165, 30.4.2004, p. 1.

<sup>7</sup> OJ L 31, 1.2.2002, p. 1.

- (g) genetically modified organisms covered by Directive 2001/18/EC of the European Parliament and of the Council <sup>8</sup>;
  - (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 <sup>9</sup> and Directive 2001/82/EC of the European Parliament and of the Council <sup>10</sup>.
3. This Regulation shall not apply to chemicals in quantities unlikely to affect health or the environment, and in any event to chemicals in quantities not more than 10 kg per chemical from each exporter to each importing country per calendar year [...] provided that they are [...] exported for the purpose of research and development or analysis.

However, exporters of the chemicals referred to in the first subparagraph shall obtain and provide a reference identification number in accordance with paragraphs 2 and 3 of Article 19.

### *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 2 of Article 7 of Regulation (EC) No 1907/2006;

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<sup>8</sup> OJ L 106, 17.4.2001, p. 1.

<sup>9</sup> OJ L 311, 28.11.2001, p. 67.

<sup>10</sup> OJ L 311, 28.11.2001, p. 1.

3. 'mixture' means a mixture or a solution as defined in point 8 of Article 2 of Regulation (EC) No 1907/2006;
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 points 2 or 3;
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 <sup>11</sup>;
  - (b) other pesticides, such as biocidal products under Directive 98/8/EC of the European Parliament and of the Council <sup>12</sup> and such as disinfectants, insecticides and parasiticides covered by Directive 2001/82/EC and Directive 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;

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<sup>11</sup> OJ L 309, 24.11.2009, p. 1.

<sup>12</sup> OJ L 123, 24.4.1998, p. 1.

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;
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 <sup>13</sup>;
16. 'export' means the following:
- (a) the permanent or temporary export of a chemical meeting the conditions of Article 28(2) of the Treaty;
  - (b) the re-export of a chemical not meeting the conditions of Article 28(2) of the Treaty 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 when 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;

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<sup>13</sup> OJ L 302, 19.10.1992, p. 1.



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. 'the Agency' means the European Chemicals Agency established under Regulation (EC) No 1907/2006;
23. 'the Secretariat' means the Secretariat of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade unless otherwise specified in this Regulation.

*Article 4*

*Designated national authorities of the Member States*

Each Member State shall designate the authority or authorities, hereinafter '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 [OJ: please insert the date: 3 months after publication] if it has not been done before the entry into force of this Regulation or in case of any change of the designated national authority.<sup>14</sup>

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<sup>14</sup> Alternative wording: "It shall inform the Commission of such designation and any change of the designated national authority by [OJ: please insert the date: 3 months after publication] unless it has already done so before the entry into force of this Regulation."

*Article 5*  
*Participation of the **Union** in the Convention*

1. 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 submission to the Secretariat of the Convention, hereinafter ‘the Secretariat’, of notifications of relevant final regulatory actions concerning chemicals qualifying for PIC notification pursuant to Article 11;
- (b) the transmission of information concerning other final regulatory actions involving chemicals not qualifying for PIC notification in accordance with Article 12;
- (c) 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 any of the following:

- (a) the Convention;
  - (b) the preparation of the Conference of the Parties established by Article 18 of the Convention;
  - (c) the Chemical Review Committee established in accordance with Article 18(6) of the Convention;
  - (d) other subsidiary bodies.
2. The Commission and the Member States shall take the necessary initiatives to ensure appropriate coordination in the various bodies implementing the Convention.

*Article 6*  
*Tasks of the European Chemicals 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 of this Regulation, 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 the designated national authorities of the Member States, with the agreement of the Commission, with assistance and technical and scientific guidance in order to ensure the effective application of this Regulation;
  - (e) assist the Commission, in the cooperation with Member States, in the drafting of decision guidance documents referred to in Article 7(3) of the Convention and other technical documents related to the implementation of the Convention, and where appropriate, establish an expert group of Member States for that purpose [...];
  - (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 covered by the provisions of this Regulation relating to export notification, PIC notification and the PIC procedure respectively shall be as listed in Annex I.

2. Chemicals in Annex I shall be assignable to one or more of three groups of chemicals, set out as Parts 1, 2 and 3 of Annex I.

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.

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 referred to in paragraph 2 shall be made available to the public by means of the Agency's Database available on its website.

#### *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 shall apply regardless of the expected 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, no later than 30 [...] days before the export of the chemical is due to take place. Thereafter the exporter shall notify the designated national authority of the Member State of the first export of such chemical each calendar year no later than 20 [...] days before the export takes place. The notifications shall comply with the requirements set out in Annex II and shall be made available by means of the Agency's Database on its website.

The designated national authority of the 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 20 days before the expected date for the 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 before the first export in any subsequent calendar year. [...]

The Agency shall register each export notification and assign it a reference identification number in its 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 on its website.

3. If the Agency does not receive from the importing Party or other country an acknowledgement of receipt of the first export notification given after the chemical is included in the 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 as provided for in paragraph 2 shall be given for exports which take place subsequent to changes 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 requirements set out in Annex II and shall indicate that it is a revision of a previous notification.
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, the requirements of paragraphs 2, 3 and 4 may be waived wholly or partly at the duly justified request of the exporter or the importing Party or other country and at the discretion of the designated national authority of the exporting Member State, in consultation with the Commission assisted by the Agency.
6. Without prejudice to the obligations set out in paragraphs 2 and 3 of Article 19, the obligations set out in paragraphs 2, 3 and 4 of this Article shall cease when the following conditions are fulfilled:
  - (a) the chemical has become a chemical subject to the PIC procedure;
  - (b) the importing country being a Party to the Convention 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;
  - (c) the Commission has been informed of that response by the Secretariat and has forwarded that information to the Member States and the Agency.

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

Without prejudice to the obligations set out in paragraphs 2 and 3 of Article 19, the obligations set out in paragraphs 2, 3 and 4 of this Article shall also cease when 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;
  - (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 made it available by means of the Database on its website.
7. The Commission, the relevant designated national authorities of the Member States, the Agency and the exporters shall provide importing Parties and other countries with available additional information concerning the exported chemicals, on request[...].
8. Member States may establish, in a transparent manner, systems obliging exporters to pay an administrative fee for each export notification given 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(3), (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 Agency's Database on its website within 15 days.

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, together with all available information. Other Member States shall be entitled to receive copies on request.

2. Should 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:
  - (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 Parts 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 its 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 importer 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. Upon request from the Commission or the designated national authority of its Member State or the Agency, the exporter or importer shall provide any additional information relating to chemicals that is necessary to ensure the effective operation of his 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 on its 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 that qualify for PIC notification.
2. Where further chemicals qualify for PIC notification and are added to Part 2 of Annex I, the Commission shall notify the Secretariat. The notification shall be submitted as soon as possible after adoption of the relevant final Union regulatory action banning or severely restricting the chemical, and no later than 90 days after the date on which the final regulatory action must be applied.
3. The notification shall provide all relevant information as 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 must be applied.

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

6. Upon request from any Party or from 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 shall:
- (a) notify the Secretariat, pursuant to this Article, or
  - (b) provide the information to the Secretariat, pursuant to Article 12.

*Article 12*

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

Where a chemical is listed only in Part 1 of Annex I or following receipt of information from a Member State for the purposes of the second indent 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, in accordance with the advisory procedure referred to in Article 29(2), take 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. It shall then 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 is subject to additional or amended restrictions under Union legislation, the Commission shall revise the import decision in accordance with the advisory procedure referred to in Article 29(2) and 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 on its 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.

*Article 14*

*Obligations in relation to exports of chemicals other than export notification requirements*

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 import decisions, available in its Database, which shall be publicly available on its website, 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 Organization's Harmonized System Nomenclature or in the European Union's Combined Nomenclature for the chemicals concerned.
3. Each Member State shall communicate the responses 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 has first informed the Commission of that response 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 Parts 2 or 3 of Annex I or mixtures containing such substances in a concentration that triggers labelling obligations under Directive 1999/45/EC and, where applicable, under Regulation (EC) No 1272/2008 irrespective of the presence of any other substances shall 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 his designated national authority 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 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), 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 national authority 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 Parts 2 or 3 of Annex I, the designated national authority of the exporter may, in consultation with the Commission assisted by the Agency and on a case-by-case basis, decide that the export may proceed if, after all reasonable efforts, no response to a request for explicit consent pursuant to paragraph 6(a) has been received within 60 days and there is evidence from official sources in the importing Party or other country that the chemical has been licensed, registered or authorised or that it has in the last 5 years been used in, or imported into the importing Party or importing other country and no regulatory action has been taken to prohibit its use.

When deciding on the export of chemicals listed in Part 3 of Annex I, the designated national authority of the exporter in consultation with the Commission assisted by the Agency shall consider the possible impact on human health or the environment of the use of the chemical in the importing Party or other country.

8. The validity of each explicit consent obtained pursuant to paragraph 6(a) or waiver granted 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 paragraph 6(a) 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 waiver granted pursuant to paragraph 7 shall be 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 this paragraph, 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 waivers granted in its Database. Each explicit consent obtained or waived shall be assigned a reference identification number and shall be listed with all relevant information concerning any conditions attached, such as validity dates. The non-confidential information shall be made publicly available on the Agency's Database.
10. No chemical shall be exported later than six months before its expiry date, when 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 risks 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 containing chemicals*

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 Parts 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. When 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 Member State in which he is established 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 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.

#### *Article 17*

#### *Information to accompany exported chemicals*

1. Chemicals that are intended for export shall be subject to the measures 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.

By way of derogation from point (b) of Article 1(2) of Regulation (EC) No 1272/2008, chemicals that are intended for export and subject to customs supervision which do not undergo any treatment or processing and are in temporary storage or in a free zone or free warehouse with a view to re-exportation, shall be subject to the measures on packaging and labelling established in, or pursuant to, Regulation (EC) No 1272/2008.

The first two subparagraphs of this paragraph shall be without prejudice to any specific requirements of the importing Party or other country taking into account relevant international standards.

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 importer.
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 and the Member States, supported by the Agency, 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*

*Obligations of exporters for controlling import[...] and export[...]*

1. Exporters of chemicals subject to the obligations set out in paragraphs 2 and 4 of Article 8 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 Council Regulation (EEC) No 2913/92.
2. Exporters of chemicals exempted by paragraphs 5 or 6 of Article 8 from the obligations set out in paragraphs 2 and 4 of that Article shall obtain a special reference identification number using the Database available on the Agency's website and provide that reference identification number in their export declaration.
3. Where no export declaration is required, all exporters shall provide the reference identification number in the summary declaration lodged at the customs office of exit.
4. Where requested by the Agency, exporters or their designated national authorities shall use the Agency's 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:

- (a) the provision of publicly available information concerning regulatory actions relevant to the objectives of the Convention; and
  - (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 <sup>15</sup>, 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.

A compilation of the information transmitted shall be prepared every two years by the Agency on the basis of the contributions by Member States and the Commission.

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<sup>15</sup> OJ L 41, 14.2.2003, p. 26.

*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.

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 every three years forward to the Commission information concerning the operation of the procedures provided for in this Regulation, including customs controls, infringements, penalties and remedial action, as appropriate.

2. The Commission shall [...] compile every three years a report 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 Member States, the Agency and the Commission shall comply with relevant obligations to protect the confidentiality of data and ownership.

### *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 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 amend their entries where appropriate, shall be taken without undue delay.

4. The Commission may, for the purpose of adapting this Regulation to technical progress, adopt, by means of delegated acts in accordance with Article 26, the following measures:
  - (a) inclusion of a chemical in Parts 1 or 2 of Annex I pursuant to paragraph 2 following final regulatory action at Union level and 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 <sup>16</sup> 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 the date referred to in the second subparagraph of Article 33 and, if necessary, submit a relevant proposal.

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<sup>16</sup> OJ L 158, 30.4.2004, p. 7.

## *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.

## *Article 26*

### *Exercise of the delegation*

1. The powers to adopt the delegated acts referred to in Article 23(4) shall be conferred on the Commission for an indeterminate period of time.
2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 27 and 28.

## *Article 27*

### *Revocation of the delegation*

1. The delegation of power referred to in Article 23(4) may be revoked at any time by the European Parliament or by the Council.
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which would be subject to revocation and possible reasons for a revocation.



3. The decision of revocation shall put an end to the delegation of powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

#### *Article 28*

##### *Objections to delegated acts*

1. The European Parliament and the Council may object to the delegated act within a period of two months from the date of notification. At the initiative of the European Parliament or the Council this period shall be extended by one month.
2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the *Official Journal of the European Union* and shall enter into force at the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

#### *Article 29*

##### *Committee*

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 3 of Regulation (EU) No 182/2011 shall apply.

### *Article 30*

#### *Amendments to Annexes under Regulation (EC) No 689/2008*

The Commission shall ensure, by means of delegated acts in accordance with Article 26, that all amendments to the Annexes to Regulation (EC) No 689/2008 adopted prior to 1 April 2013 are incorporated in this Regulation by 31 March 2013.

### *Article 31*

#### *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 *[OJ: please insert the date: 1 year after publication]* at the latest and shall notify it without delay of any subsequent amendment affecting them.

Member States shall make all information regarding penalties available upon request.

### *Article 31a*

#### *Transitional period on the classification, labelling and packaging of chemicals*

Without prejudice to Article 1(2), the rules concerning classification, labelling and packaging specified in Article 61 of Regulation (EC) No 1272/2008 shall apply to chemicals intended for export until 1 June 2015.

These rules shall also apply to chemicals that are intended for export and subject to customs supervision which do not undergo any treatment or processing and are in temporary storage or in a free zone or free warehouse with a view to re-exportation.

*Article 32*

*Repeal*

Regulation (EC) No 689/2008 shall be repealed with effect from 1 April 2013 / [one year after the publication in the Official Journal] [*OJ: please insert the date*].

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 Appendix 1.

*Article 33*

*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*.

This Regulation shall apply as from 1 April 2013 / [one year after the publication in the Official Journal] [*OJ: please insert the date*].

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

Done at [...],

*For the European Parliament*

*The President*

*For the Council*

*The President*