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EUROPEAN COMMISSION

Brussels, 5.5.2011  
COM(2011) 245 final

2011/0105 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**concerning the export and import of dangerous chemicals**

**(recast)**

**(Text with EEA relevance)**

**(presented by the Commission)**

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### 1.1. Grounds for and objectives of the proposal

Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals<sup>1</sup> ('the Regulation') implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for certain hazardous chemicals and pesticides in international trade.

The following reasons lead to the proposal to recast Regulation (EC) No 689/2008:

- The Regulation includes references to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, which are or will be replaced and repealed by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006<sup>2</sup>. It is, therefore, necessary to align the Regulation with Regulation (EC) No 1272/2008.
- In order to support the Commission in its tasks as a common designated authority foreseen under the Regulation, it is proposed to involve the European Chemicals Agency ("the Agency") in certain administrative, technical and scientific tasks necessary for the implementation of the Regulation.
- In the light of Regulation (EC) No 1272/2008 and of the experience of the functioning of the procedures under Regulation (EC) No 689/2008, it is appropriate to include certain technical amendments to the operative provisions such as clarify the definitions of a substance, a mixture and an article, and request the use of the reference identification number for exports that are not subject to export notification.
- In the light of the experience gained with the implementation of the explicit consent procedure provided for by Regulation (EC) No 689/2008 it is appropriate to provide for additional conditions that may allow exports to proceed in the absence of a reply from the importing country whilst not lowering the protection afforded to importing countries.
- In view of the changes introduced by the Lisbon Treaty, it is necessary to clarify provisions relating to the external representation of the European Union and to adapt the provisions concerning comitology. In particular, it should be specified which

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<sup>1</sup> OJ L 204, 31.7.2008, p. 1

<sup>2</sup> OJ L 353, 31. 12. 2008, p. 1

rules are subject to implementing acts and clarified which conditions apply to the adoption of delegated acts.

## **1.2. General context**

The Rotterdam Convention was adopted in September 1998. It entered into force on 24 February 2004. The aim of the Rotterdam Convention is to promote shared responsibility and co-operative efforts among the Parties in the international trade of dangerous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use. This is done by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.

Regulation (EC) No 689/2008 implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for certain hazardous chemicals and pesticides in international trade. The provisions of the Regulation go beyond those of the Convention and offer more protection to importing countries since they are addressed to all countries and not just Parties to the Convention. The scope of the Regulation is not limited to chemicals that are banned or severely restricted under the Convention but also covers chemicals that are banned or severely restricted at EU level. In addition the Regulation ensures that all chemicals are appropriately packed and labelled when exported.

## **1.3. Existing provisions in the area of the proposal**

As noted above, the current Union rules relating to the export and import of dangerous chemicals are laid down in Regulation (EC) No 689/2008, as most recently amended by Commission Regulation (EU) No 196/2010<sup>3</sup>.

The Regulation goes significantly beyond the requirements of the Convention. The key differences can be summarised as follows:

1. The rules apply to exports to all countries, whether or not they are Parties to the Convention;
2. The Regulation stipulates the obligation of an annual export notification for a wider range of chemicals. For the purposes of determining which chemicals should be subject to the procedure, the two use categories (pesticides and industrial chemicals) foreseen by the Convention are divided into two subcategories each (plant protection products and other pesticides such as biocides; and chemicals for professional use and chemicals for consumer use). Moreover export notification has to be made irrespective of the chemical's intended use and whether or not that use is banned or severely restricted in the EU. Furthermore, chemicals subject to the international PIC procedure ('PIC chemicals') and certain articles containing such chemicals are also covered;
3. PIC chemicals and chemicals that are banned or severely restricted in the Union in a Convention use category cannot be exported without the explicit consent of importing countries;

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<sup>3</sup> OJ L 60, 10.3.2010, p. 5

4. Certain articles and chemicals (such as those chemicals that are also subject to the Stockholm Convention on Persistent Organic Pollutants) are banned for export;
5. All dangerous chemicals exported to third countries have to be labelled and packaged in the same way as they must be within the Union unless third countries require otherwise.

#### **1.4. Consistency with the other policies and objectives of the Union**

The proposal is fully in line with existing policies and objectives aimed at protecting human health and the environment globally.

## **2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT**

### **2.1. Consultation of interested parties**

#### *Consultation methods, main sectors targeted and the general background*

Due to the nature of the recast, which introduces only minor technical amendments to the operative provisions, it was not deemed necessary to carry out a formal consultation of stakeholders.

Relevant stakeholders have been informed within the framework of the meetings of Designated National Authorities (DNAs) under Regulation (EC) No 689/2008 about the intended modifications. Participants have included stakeholders such as industry and NGOs as well as Member States, all of whom have had an opportunity to give their opinions and to make comments.

#### *Summary of responses and how these have been taken into account*

All Member States and other stakeholders participating in the meetings of Designated National Authorities (DNAs) under Regulation (EC) No 689/2008 supported the intended changes including the transfer of tasks to the Agency.

### **2.2. Collection and use of expertise**

As no substantive changes are proposed in the context of this review, it was not deemed necessary to make use of external expertise.

### **2.3. Impact assessment**

The current rules set out in the Regulation are generally working well and only minor technical modifications are necessary to facilitate the implementation. The main changes aim to align the Regulation to the Lisbon Treaty and general chemicals legislation as well as to involve the Agency in the tasks foreseen under the Regulation. As the overall impact of the review is expected to be limited, it was not considered imperative to carry out an impact assessment. The main effects of the changes can be summarised as follows:

- As a result of the proposed changes, there will be more clarity, transparency and increased legal certainty for all parties involved in the implementation of the Regulation;

- The proposal will not add any additional administrative burden for exporters or the competent authorities involved in the implementation of the Regulation. On the contrary, with respect to exports that are exempted from export notification the proposed amendments will lead to a reduction of administrative burdens;
- Some tasks will be transferred from the Commission to the European Chemicals Agency, which is expected to reduce the overall costs and to increase the scientific knowledge available for implementation;
- The current high level of protection of human health and the environment will be maintained.

### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### **3.1. Summary of the proposed action**

The proposed new Regulation would essentially maintain all provisions of the current Regulation, including those that go beyond the requirements of the Convention. However, certain technical amendments are deemed necessary to improve the clarity and functioning of the Regulation. The main changes are as follows:

- Changes and clarifications as regards certain definitions (Article 3)  
 Definitions are amended in order to align this Regulation with Regulation (EC) No 1272/2008. The term ‘preparation’ has been replaced by ‘mixture’ to reflect the changes in the general chemicals legislation and a definition for ‘substance’ is added.
- Changes to the so-called 'explicit consent' procedure (Article 14(7))

In around 30% of the cases to date, despite the efforts made by the DNAs of the exporting Member States and the Commission to obtain explicit consent, no response is forthcoming from the importing country, in some cases for many months or even years. As a result, exports cannot proceed, despite the fact that the substances are often not banned or severely restricted in the importing countries. The current system thus causes difficulties for exporters and the DNAs of exporting Member States without necessarily affording greater protection to importing countries. The situation as regards chemicals listed in part 2 of Annex I (chemicals banned or severely restricted in the Union within a Convention use category and thus qualifying for PIC notification but that are not yet PIC chemicals) is particularly problematic because authorities in importing countries are not always aware of EU procedures or do not always have the mandate or the means to respond.

Against this background, certain limited possibilities for exports to proceed on a temporary basis, while further efforts are being made to obtain explicit consent, seem appropriate. It is proposed to allow the export to proceed if there is documentary evidence from official sources showing that the chemical has been imported or used in the last 5 years and no regulatory action has been taken, if, despite all reasonable efforts by the exporter’s DNA, the Agency and the Commission, there is no response from the importing country within 2 months. The evidence showing that the chemical is imported in the country can be regarded as sufficient indication of consent for exports to proceed ad interim for a period of 12 months pending a response. This

would be compatible with the so-called "status quo" provisions of Article 11(2) of the Convention, but would be more restrictive. Moreover import licenses are frequently specific to a given product or supplier or importer so that the possibility for exports to proceed would be limited accordingly.

- Involvement of the European Chemicals Agency (Articles 6 and 24)

The involvement of the Agency in the implementation of this Regulation is because of its expertise and experience with the implementation of the general chemicals legislation and international agreements on chemicals considered particularly desirable, in particular regarding the management of the European Database on Export and Import of dangerous chemicals and some related administrative tasks.

- Adaptation of provisions related to the external representation of the Union and of the comitology procedures to the Lisbon Treaty (Articles 5 and 26 to 29)

The provisions related to the external representation of the Union have been aligned with the Lisbon Treaty. The provisions in which certain powers are conferred upon the European Commission have also been revised in order to reflect the entry into force of the Lisbon Treaty.

### **3.2. Legal basis**

In line with the judgment of the Court in case C-178/03 (*Commission v Parliament and Council*)<sup>4</sup>, the proposed Regulation will be based on Article 192(1) (relating to Environmental Protection) of the Treaty on the functioning of the European Union and Article 207 (relating to the Common Commercial Policy).

### **3.3. Subsidiarity principle**

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the European Union. The proposal fully complies with the principle of subsidiarity since its objectives cannot be achieved by the Member States because a harmonised approach is needed to ensure that the Union, as a Party to the Convention, meets its international obligations.

### **3.4. Proportionality principle**

The proposal complies with the proportionality principle since it does not go beyond what is necessary to achieve its objectives. It concentrates on changes only where they are deemed necessary and appropriate for its proper functioning or where they are necessary due to changes in other legislation.

Furthermore, the proposal aims to reduce the administrative burden without compromising the level of protection afforded to human health and the environment.

### **3.5. Choice of instrument**

Given that the existing legislation to be replaced is in the form of a regulation, this is the most appropriate instrument.

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<sup>4</sup> ECR (2006), I-107.

#### **4. BUDGETARY IMPLICATION**

The proposal is not expected to have important budgetary implications since no new tasks were introduced compared to Regulation (EC) 689/2008. The transfer of certain tasks from the Commission to the European Chemicals Agency is expected to reduce the overall costs of implementation. Further reductions may be achieved in a long-term perspective considering the potential for synergies with other tasks of the Agency.

The financing of the tasks carried out by the European Chemicals Agency will be provided in form of a subsidy from the Union budget.

#### **5. OPTIONAL ELEMENTS**

##### **5.1. Review/revision/sunset clause**

The proposal includes a review clause, which is limited to the possibility to charge fees for services provided by the Agency. However, the Commission is obliged to regularly report on the implementation of the Regulation to the European Parliament and the Council.

##### **5.2. Recasting**

The proposal involves recasting.

↓ 689/2008 (adapted)  
⇒ new

2011/0105 (COD)

**REGULATION (EU) No ~~689/2008~~ OF THE EUROPEAN PARLIAMENT AND OF  
THE COUNCIL**

**of 17 June 2008**

**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  ~~establishing the European Community~~, and in particular  Article 192(1) and Article 207  ~~Articles 133 and 175(1)~~ 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<sup>5</sup>,

Having regard to the opinion of  ~~After consulting~~ the Committee of the Regions,

Acting in accordance with the  ordinary legislative  procedure ~~laid down in Article 251 of the Treaty~~<sup>6</sup>,

Whereas:

↓ new

(1) A number of substantial changes should be made to Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals<sup>7</sup>. In the interest of clarity, Regulation (EC) No 689/2008 should be recast.

<sup>5</sup> OJ C 175, 27.7.2007, p. 40.

<sup>6</sup> Opinion of the European Parliament of 15 January 2008 (not yet published in the Official Journal) and Council Decision of 5 June 2008.

<sup>7</sup> OJ L 204, 31.7.2008, p. 1.

↓ 689/2008 recital (1)

~~(2)~~ Regulation (EC) No 689/2008 ~~304/2003~~ of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals<sup>8</sup> implements~~ed~~ the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade<sup>9</sup>, hereinafter ‘the Convention’, which entered into force on 24 February 2004, and ~~replaces Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals<sup>10</sup> replaced Council Regulation (EEC) No 2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals<sup>11</sup>.~~

↓ 689/2008 recital (2)

~~(2)~~ In its judgment of 10 January 2006 in Case C-178/03 (*Commission v Parliament and Council*)<sup>12</sup> the Court of Justice of the European Communities annulled Regulation (EC) No 304/2003 as it was based solely on Article 175(1) of the Treaty, ruling that both Articles 133 and 175(1) were the appropriate legal bases. However the Court also ruled that the effects of the Regulation were to be maintained until the adoption, within a reasonable period, of a new Regulation founded on appropriate legal bases. That also implies that obligations that were already fulfilled under Regulation (EC) No 304/2003 do not need to be accomplished again.

↓ new

(3) For reasons of clarity and consistency with other relevant Union legislation, certain definitions should be introduced or clarified and terminology should be aligned with that used in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC<sup>13</sup>, on the one hand, and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006<sup>14</sup> on the other hand.

<sup>8</sup> ~~OJ L 63, 6.3.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 1376/2007 (OJ L 307, 24.11.2007, p. 14).~~

<sup>9</sup> OJ L 63, 6.3.2003, p. 29.

<sup>10</sup> OJ L 63, 6.3.2003, p. 1

<sup>11</sup> ~~OJ L 251, 29.8.1992, p. 13. Regulation as last amended by Commission Regulation (EC) No 300/2002 (OJ L 52, 22.2.2002, p. 1).~~

<sup>12</sup> ECR [2006], I 107.

<sup>13</sup> OJ L 396, 30.12.2006, p. 1.

<sup>14</sup> OJ L 353, 31. 12. 2008, p. 1.

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↓ 689/2008 recital (3)

~~(3) In accordance with Regulation (EC) No 304/2003, the Commission has submitted a report to the European Parliament and the Council on the operation of Regulation (EC) No 304/2003 from 2003 to 2005. Overall the procedures have worked well. However, the report identifies a number of technical amendments that appear to be necessary. It is therefore appropriate to incorporate those elements in this Regulation.~~

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↓ 689/2008 recital (4) (adapted)  
⇒ new

(4) The Convention allows Parties the right to take action that is more stringently protective of human health and the environment than that called for in the Convention, provided that such action is consistent with the provisions of the Convention and is in accordance with international law. It is necessary and appropriate, in order ~~not~~ to ensure a higher ~~weaken the~~ level of protection ~~of~~ ~~afforded to~~ the environment and ~~to~~ the general public of importing countries ~~under Regulation (EEC) No 2455/92~~, to go further than the provisions of the Convention in certain respects.

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↓ 689/2008 recital (5)

(5) As regards the participation of the ~~Union Community~~ in the Convention, it is essential to have a single contact point for ~~Union Community~~ interaction with the Secretariat and other Parties to the Convention as well as with other countries. The Commission should act as that contact point.

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↓ new

(6) There is a need to ensure the effective coordination and management of technical and administrative aspects of this Regulation at Union level. The European Chemicals Agency ("the Agency") established by Regulation (EC) No 1907/2006 has the competence and experience in implementing Union legislation on chemicals and international agreements on chemicals. The Agency should, therefore, carry out tasks with regard to the administrative, technical and scientific aspects of the implementation of this Regulation and the exchange of information. In addition, the Agency should support the Commission in implementing the Union's international obligations under the Convention.

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↓ 689/2008 recital (12) (adapted)  
⇒ new

(7) ⇒ Given that certain tasks of the Commission should be transferred to the Agency, the European Database on Export and Import of Dangerous Chemicals initially ~~The database~~ established by the Commission ⇒ should be further developed and maintained by the Agency. ~~is an important tool which should underpin the application of this Regulation and its control.~~

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↓ 689/2008 recital (6) (adapted)

~~(86)~~ Exports of dangerous chemicals that are banned or severely restricted within the Union Community should continue to be subject to a common export notification procedure. Accordingly, dangerous chemicals, whether in the form of substances on their own or in  mixtures  ~~preparations~~ or in articles, which have been banned or severely restricted by the Union Community as plant protection products, as other forms of pesticides, or as industrial chemicals for use by professional users or by the public, should be subject to export notification rules similar to those applicable to such chemicals when they are banned or severely restricted within either or both of the use categories laid down in the Convention, namely as pesticides or chemicals for industrial use. In addition, chemicals subject to the international prior informed consent (PIC) procedure should also be subject to the same rules. This export notification procedure should apply to Union Community exports to all third countries, whether or not they are Parties to the Convention or participate in its procedures. Member States should be permitted to charge administrative fees, in order to cover their costs in carrying out this procedure.

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↓ 689/2008 recital (7)

~~(97)~~ Exporters and importers should be obliged to provide information concerning the quantities of chemicals in international trade covered by this Regulation so that the impact and effectiveness of the arrangements laid down therein can be monitored and assessed.

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↓ 689/2008 recital (8)

~~(108)~~ Notifications to the Secretariat of the Convention of Union Community or Member State final regulatory actions banning or severely restricting chemicals, with a view to their inclusion in the international PIC procedure, should be submitted by the Commission and should relate to those cases meeting the criteria laid down in the Convention in this regard. Additional information to support such notifications should be sought where necessary.

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↓ 689/2008 recital (9)

~~(119)~~ In cases where Union Community or Member State final regulatory actions do not qualify for notification because they do not meet the criteria, information concerning the actions should nevertheless be conveyed to the Convention Secretariat and other Parties to the Convention in the interests of information exchange.

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↓ 689/2008 recital (10)

~~(124)~~ It is also necessary to ensure that the Union Community take decisions with regard to the import into the Union Community of chemicals that are subject to the international PIC procedure. These decisions should be based on applicable Union Community legislation and take into account bans or severe restrictions imposed by Member States. Where justified, amendments to Union Community legislation should be proposed.

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↓ 689/2008 recital (11)

~~(134)~~ Arrangements are needed to ensure that Member States and exporters are aware of the decisions of importing countries as regards chemicals that are subject to the international PIC procedure, and that exporters comply with those decisions. Furthermore, in order to prevent undesired exports, no chemicals banned or severely restricted within the Union Community that meet the Convention criteria or that are covered under the international PIC procedure should be exported unless the explicit consent of the importing country concerned has been sought and obtained, whether or not that country is a Party to the Convention. At the same time, a waiver from this obligation is appropriate in relation to exports of certain chemicals to countries that are members of the Organisation for Economic Cooperation and Development (OECD) provided that certain conditions are met. Furthermore a procedure is needed to deal with cases in which, despite all reasonable efforts, no response is obtained from the importing country, so that exports of certain chemicals may proceed on a temporary basis under specified conditions. It is also necessary to provide for periodic review of all such cases as well as those in which explicit consent is obtained.

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↓ 689/2008 recital (13)

~~(144)~~ It is also important that all chemicals exported have an adequate shelf-life so that they may be used effectively and safely. As regards pesticides, in particular and especially those exported to developing countries, it is essential that information about appropriate storage conditions be provided and that suitable packaging and sizes of containers are used to avoid creating obsolete stocks.

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↓ 689/2008 recital (14)

~~(154)~~ Articles containing chemicals do not fall within the scope of the Convention. Nevertheless, it seems appropriate that articles containing chemicals that could be released under certain conditions of use or disposal and that are banned or severely restricted in the Union Community within one or more of the use categories laid down in the Convention or are subject to the international PIC procedure should also be subject to the export notification rules. Furthermore, certain chemicals and articles containing specific chemicals falling outside the scope of the Convention but giving rise to particular concern should not be exported at all.

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↓ 689/2008 recital (15)

~~(164)~~ In accordance with the Convention, information on transit movements of chemicals subject to the international PIC procedure should be provided to Parties to the Convention who request such information.

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↓ 689/2008 recital (16)

⇒ new

~~(174)~~ Union Community rules on packaging and labelling and other safety information should apply to all dangerous chemicals when intended for export to Parties and other countries unless those provisions would conflict with any specific requirements of

those countries, taking into account relevant international standards. ⇒ In order to ensure the full effectiveness of this Regulation, those rules should also apply to chemicals under customs supervision with a view to their re-exportation. Since Regulation (EC) No 1272/2008 established new provisions on classification, labelling and packaging of substances and mixtures, a reference to that Regulation should be included. ⇐

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↓ 689/2008 recital (17) (adapted)  
⇒ new

~~(1817)~~ In order to ensure effective control and enforcement of the rules, Member States should designate authorities such as customs authorities that should have the responsibility of controlling imports and exports of chemicals covered by this Regulation. The Commission and the Member States have a key role to play and should act in a targeted and coordinated way. Member States should provide for appropriate sanctions in the event of infringements.

(19) ☒ In order ☒ ~~to~~ facilitate customs control<sub>2</sub> and to reduce the administrative burden for both exporters and authorities, a system of codes ~~confirming compliance with the rules~~ to be used in export declarations should be established. ⇒ The codes should also be used for chemicals exported for the purpose of research or analysis in quantities not likely to affect health or the environment, and in any event not more than 10 kg per year. ⇐ ~~In order to allow all parties time to become accustomed to this system before it becomes mandatory a short transitional period should be provided for.~~

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↓ 689/2008 recital (18)

~~(2018)~~ Information exchange, shared responsibility and cooperative efforts between the Union Community and the Member States and third countries should be promoted with a view to ensuring sound management of chemicals, whether or not those third countries are Parties to the Convention. In particular, technical assistance to developing countries and countries with economies in transition should be provided directly by the Commission and the Member States, or indirectly via support for projects by non-governmental organisations, especially assistance seeking to enable those countries to implement the Convention.

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↓ 689/2008 recital (19)  
⇒ new

~~(2119)~~ There should be regular monitoring of the operation of the procedures if they are to be effective. To this end, Member States ⇒ and the Agency ⇐ should regularly submit reports to the Commission, which should in turn regularly report to the European Parliament and the Council.

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↓ 689/2008 recital (20)  
⇒ new

~~(2220)~~ Technical notes for guidance should be drawn up ⇒ by the Agency ⇐ to assist the competent authorities, including such authorities as customs controlling exports, ⇒ exporters and importers ⇐ in the application of this Regulation.

↓ 689/2008 recital (22) (adapted)  
⇒ new

~~(232)~~ ~~In particular~~ The Commission should be empowered to adopt ~~⇒ delegated acts in accordance with Article 290 of the Treaty in respect of the following: modifications of the lists of chemicals in Annex I, ⇐ measures to include a chemical in Parts 1 or 2 of Annex I following final regulatory action at Community level,~~ ☒ inclusion of ☒ ~~measures to include~~ 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<sup>15</sup> in Part 1 of Annex V, ~~measures to amend Annex I, including modifications to existing entries,~~ ☒ inclusion of ☒ ~~measures to include~~ a chemical already subject to an export ban at Union Community level in Part 2 of Annex V, ☒ modifications of ☒ ~~measures to amend~~ Annexes II, III, IV and VI, and ☒ modifications of ☒ ~~measures to modify existing~~ entries in Annex V. ~~Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC,~~

↓ 689/2008 recital (21) (adapted)  
⇒ new

~~(242)~~ ⇒ In order to ensure uniform conditions ⇐ ~~The measures necessary for the implementation of this Regulation, should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers~~ ☒ should be ☒ conferred on the Commission<sup>16</sup>. ⇒ Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers<sup>17</sup>. ⇐

↓ new

(25) In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, the objectives of ensuring coherent and effective implementation of the Union's obligations under the Convention cannot be sufficiently achieved by the Member States and can therefore, by reason of the necessity to harmonise the rules concerning imports and exports of chemicals, be better achieved by the Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

↓ new

(26) Regulation (EC) No 689/2008 should be repealed.

<sup>15</sup> OJ L 158, 30.4.2004, p. 7. ~~Regulation as last amended by Commission Regulation (EC) No 323/2007 (OJ L 85, 27.3.2007, p. 3).~~

<sup>16</sup> OJ L 184, 17.7.1999, p. 23. ~~Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).~~

<sup>17</sup> OJ L 55, 28.2.2011, p. 13.

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↓ new

(27) It is appropriate to provide for the deferred application of this Regulation so as to allow the Agency sufficient time to prepare its new role and to the industry to familiarise itself with the new procedures,

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↓ 689/2008

HAVE ADOPTED THIS REGULATION:

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↓ 689/2008 Article 1  
⇒ new

### *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 Community 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 provisions ~~of Council Directive 67/548/EEC<sup>18</sup> and of Directive 1999/45/EC of the European Parliament and of the Council<sup>19</sup> regarding the classification, packaging and labelling of chemicals dangerous to man or to the environment when they are placed on the market in the Community~~ ⇒ and, where applicable,

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<sup>18</sup> ~~Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L96, 16.8.1967, p. 1). Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850). Corrected version in OJ L 136, 29.5.2007, p. 281.~~

<sup>19</sup> ~~Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1). Directive as last amended by Regulation (EC) No 1907/2006 (OJ L 396, 30.12.2006, p. 1). Corrected version in OJ L 136, 29.5.2007, p. 3.~~

Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>⇐</sup> also 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.

↓ 689/2008 Article 2  
⇒ new

## 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 Community 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>20</sup> ~~of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors;~~
  - (b) radioactive materials and substances covered by Council Directive 96/29/Euratom<sup>21</sup> ~~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;~~
  - (c) wastes covered by Directive 2006/12/EC of the European Parliament and of the Council<sup>22</sup> ~~of 5 April 2006 on waste~~ and Council Directive 91/689/EEC<sup>23</sup> ~~of 12 December 1991 on hazardous waste;~~
  - (d) chemical weapons covered by Council Regulation (EC) No 1334/2000<sup>24</sup> ~~of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology;~~

<sup>20</sup> OJ L 22, 26.1.2005, p. 1.

<sup>21</sup> OJ L 159, 29.6.1996, p. 1.

<sup>22</sup> OJ L 114, 27.4.2006, p. 9.

<sup>23</sup> OJ L 377, 31.12.1991, p. 20. ~~Directive as last amended by Regulation (EC) No 166/2006 of the European Parliament and of the Council (OJ L 33, 4.2.2006, p. 1).~~

<sup>24</sup> OJ L 159, 30.6.2000, p. 1. ~~Regulation as last amended by Regulation (EC) No 1183/2007 (OJ L 278, 22.10.2007, p. 1).~~

- (e) food and food additives covered by Regulation (EC) No 882/2004 of the European Parliament and of the Council<sup>25</sup> ~~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;~~
- (f) feedingstuffs covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>26</sup> ~~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 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<sup>27</sup> ~~of 12 March 2001 on the deliberate release into the environment of genetically modified organisms;~~
- (h) save to the extent covered by Article 3(54)(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>28</sup> ~~of 6 November 2001 on the Community code relating to medicinal products for human use and Directive 2001/82/EC of the European Parliament and of the Council<sup>29</sup> of 6 November 2001 on the Community code relating to veterinary medicinal products.~~
3. (±) ⇒ This Regulation shall not apply to ⇐ chemicals in quantities not likely to affect health or the environment, and in any event not more than 10 kg ⇒ per year, per exporter and per importing country ⇐, provided that they are imported or exported for the purpose of research 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. ⇐

↓ 689/2008 Article 3 (adapted)  
⇒ new

### Article 3 Definitions

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

- <sup>25</sup> OJ L 165, 30.4.2004, p. 1. ~~Corrected version in OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Council Regulation (EC) No 301/2008 (OJ L 97, 9.4.2008, p. 85).~~
- <sup>26</sup> OJ L 31, 1.2.2002, p. 1. ~~Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).~~
- <sup>27</sup> OJ L 106, 17.4.2001, p. 1. ~~Directive as last amended by Directive 2008/27/EC (OJ L 81, 20.3.2008, p. 45).~~
- <sup>28</sup> OJ L 311, 28.11.2001, p. 67. ~~Directive as last amended by Directive 2008/29/EC (OJ L 81, 20.3.2008, p. 51).~~
- <sup>29</sup> OJ L 311, 28.11.2001, p. 1. ~~Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).~~

1. ‘chemical’ means a substance ~~as defined in Directive 67/548/EEC~~, whether by itself or in a  mixture  preparation, or a  mixture  preparation, 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. ~~2.~~  mixture  preparation means a mixture or a solution  as defined in point 8 of Article 2 of Regulation (EC) No 1272/2008 ~~composed of two or more substances~~;
4. ~~2.~~ ‘article’ means a finished product containing or including a chemical, the use of which has been banned or severely restricted by Union Community legislation in that particular product ⇒ where that product does not fall under points 2 or 3 ⇐ ;
5. ~~4.~~ ‘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>30</sup> ~~Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market~~;
  - (b) other pesticides, such as biocidal products under Directive 98/8/EC of the European Parliament and of the Council<sup>31</sup> ~~of 16 February 1998 concerning the placing of biocidal products on the market~~ and such as disinfectants, insecticides and parasiticides covered by Directive 2001/82/EC and Directive 2001/83/EC;
6. ~~5.~~ ‘industrial chemicals’ means chemicals in either of the following subcategories:
  - (a) chemicals for use by professionals;
  - (b) chemicals for use by the public;
7. ~~6.~~ ‘chemical subject to export notification’ means any chemical that is banned or severely restricted within the Union Community 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. ~~7.~~ ‘chemical qualifying for PIC notification’ means any chemical that is banned or severely restricted within the Union Community or a Member State within one or

<sup>30</sup> OJ L 309, 24.11.2009, p. 1.

<sup>31</sup> OJ L 123, 24.4.1998, p. 1. ~~Directive as last amended by Directive 2008/31/EC of the European Parliament and of the Council (OJ L 81, 20.3.2008, p. 57).~~

more categories. Chemicals banned or severely restricted in the Union Community within one or more categories are listed in Part 2 of Annex I;

9. ~~8.~~ '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. ~~9.~~ '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 Community, 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 Community 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. ~~10.~~ '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 Community 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 Community 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. ~~11.~~ '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. ~~12.~~ 'final regulatory action' means a  legally binding  legislative act the purpose of which is to ban or severely restrict a chemical;
14. ~~13.~~ '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>32</sup>.
16. ~~14.~~ 'export' means the following:
- (a) the permanent or temporary export of a chemical meeting the conditions of Article ~~283~~(2) of the Treaty;

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<sup>32</sup> OJ L 302, 19.10.1992, p. 1

- (b) the re-export of a chemical not meeting the conditions of Article ~~282~~(2) of the Treaty which is placed under a customs procedure other than the external Union Community transit procedure for movement of goods through the customs territory of the Union Community;
17. ~~15.~~ 'import' means the physical introduction into the customs territory of the Union Community of a chemical that is placed under a customs procedure other than the external Union Community transit procedure for movement of goods through the customs territory of the Union Community;
18. ~~16.~~ '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 Community;
- (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 Community;
- (c) where the benefit of a right to dispose of the chemical belongs to a person established outside the Union Community pursuant to the contract on which the export is based, the contracting party established in the Union Community;
19. ~~17.~~ 'importer' means any natural or legal person who at the time of import into the customs territory of the Union Community is the consignee for the chemical;
20. ~~18.~~ '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. ~~19.~~ 'other country' means any country that is not a Party.
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↓ 689/2008 Article 4

*Article 4*  
*Designated national authorities*

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]~~1 November 2008~~.

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

1. ~~1. The participation of the Community 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. ~~12.~~ ☒ The Commission shall act as a common designated authority ☒ ~~With regard to the Community's participation in the Convention,~~ for the administrative functions of the Convention with reference to the PIC procedure ~~and the export notification, the Commission shall act as a common designated authority~~ 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 Community export notifications to Parties and other countries pursuant to Article 7;~~
- ~~(a)~~ (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 ~~1110~~;
- ~~(b)~~ (b) the transmission of information concerning other final regulatory actions involving chemicals not qualifying for PIC notification in accordance with Article ~~1211~~;
- ~~(c)~~ (c) the receiving of information from the Secretariat more generally.

The Commission shall also provide the Secretariat with Union Community import responses for chemicals subject to the PIC procedure pursuant to Article ~~1312~~.

In addition, the Commission shall coordinate the Union Community 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.

~~A network of Member State rapporteurs shall be established, as appropriate, to deal with the preparation of technical documents such as decision guidance documents as referred to in Article 7(3) of the Convention.~~

3. ~~23.~~ The Commission and the Member States shall take the necessary initiatives to ensure appropriate  $\Rightarrow$  coordination  $\Leftarrow$  ~~representation of the Community~~ in the various bodies implementing the Convention.
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↓ new

#### 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, 18, 19, 20, 21, 22 and 25 of this Regulation, carry out the following tasks:
  - (a) maintain, further develop and regularly update the Database on Export and Import of Dangerous Chemicals ("the Database");
  - (b) make the Database publicly available on its website;
  - (c) where appropriate, provide, with the agreement of the Commission, 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, with the agreement of the Commission, with assistance and technical and scientific guidance in order to ensure the effective application of this Regulation;
  - (e) where requested by the Commission and in cooperation with Member States, prepare decision guidance documents referred to in Article 7(3) of the Convention and other technical documents related to the implementation of the Convention which shall be subject to approval by the Commission;
  - (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 ~~76~~*

*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 ~~87~~, 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 ~~87~~, qualify for the PIC notification procedure set out in Article ~~1140~~, 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 ⇐ ~~electronic means~~.

*Article ~~87~~*

*Export notifications forwarded to Parties and other countries*

1. In the case of substances listed in Part 1 of Annex I or ⊗ mixtures ⇐ ~~preparations~~ containing such substances in a concentration that ⇒ triggers ⇐ ~~could trigger~~ labelling obligations under Directive 1999/45/EC ⇒ and, where applicable, under Regulation (EC) No 1272/2008 ⇐ irrespective of the presence of any other substances, paragraphs 2 to 8 shall apply.
2. When an exporter is due to export a chemical referred to in paragraph 1 from the Union Community 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 ⊗ 20 working ⇐ ~~30~~ days before the export of the chemical is due to take place.

Thereafter the exporter shall notify the designated national authority of the first export of such chemical each calendar year no later than ~~⇒ 20 working~~ ~~⇐ 15~~ 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 shall check compliance of the information with Annex II and ~~promptly~~ forward the notification received from the exporter to the ~~⇒ Agency within 5 working days~~ ~~⇐ Commission~~.

The ~~⇒ Agency~~ ~~⇐ Commission~~ shall ~~take the measures necessary to ensure that~~ ~~⇒~~ , 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 ~~⊗ 10 working~~ ~~⊗ 15~~ days before the first intended export of the chemical and thereafter before the first export in any subsequent calendar year. This shall apply regardless of the expected use of the chemical in the importing Party or other country.

~~⇒ The Agency shall register~~ ~~⇐ each~~ ~~Each~~ export notification ~~shall be registered~~ and ~~⊗~~ assign it ~~⊗ assigned an export~~ a reference identification number in ~~⊗~~ its ~~⊗ a Database.~~ ~~database at the Commission,~~ ~~⇒ The Agency~~ ~~⇐~~ ~~⊗~~ shall also make available to the public and the designated national authorities of the Member States, as appropriate, ~~⊗ and~~ 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~~ ~~⇐ shall be kept available to the public and distributed to the designated national authorities of the Member States as appropriate.~~

3. If the ~~⇒ Agency~~ ~~⇐ Commission~~ 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 ~~⊗ 20 working~~ ~~⊗ 30~~ days of the dispatch of such notification, it shall ~~⇒~~ , on behalf of the Commission, ~~⇐~~ submit a second notification. The ~~⇒ Agency~~ ~~⇐ Commission~~ 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 Community legislation concerning the marketing, use or labelling of the substances in question or whenever the composition of the ~~⊗~~ mixture ~~⊗ preparation~~ in question changes so that the labelling of such ~~⊗~~ mixture ~~⊗ preparation~~ 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 ⇐ ~~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 ☒ ~~The first subparagraph shall not apply~~ 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 ⇐ ~~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 ⇐ ~~and~~ made it available ⇒ by means of the Database on its website ⇐ ~~on the Internet~~.

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, when requested.

8. Member States may establish 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 ☒ ~~to them~~ of carrying out the procedures set out in paragraphs 2, ~~3~~ and 4 of this Article and in Article ~~1413~~(3), (6) and (7).

↓ 689/2008 Article 8  
⇒ new

#### Article ~~98~~

##### *Export notifications received from Parties and other countries*

1. Export notifications received by the ⇒ Agency ⇐ ~~Commission~~ from the designated national authorities of Parties or the appropriate authorities of other countries

concerning the export to the Union Community 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 ⇐ by electronic means through the database maintained by the Commission.~~

The ~~⇒ Agency ⇐ Commission~~ 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 ⇐~~ 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 ⇐ Commission~~ together with all available information.

↓ 689/2008 Article 9 (adapted)  
⇒ new

#### *Article 109*

#### *Information on export and import of chemicals*

1. Each exporter of:

- ~~(a=)~~ substances listed in Annex I,
- ~~(b=)~~  mixtures ~~⇐ preparations~~ containing such substances in a concentration that ~~⇒ triggers ⇐ could trigger~~ labelling obligations under Directive 1999/45/EC ~~⇒~~ and, where applicable, 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 ~~⇐ preparations~~ containing such substances in a concentration that ~~⇒ triggers ⇐ could trigger~~ 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, 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 ~~⇐ preparations~~ 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 ~~1413~~(7).

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

2. Upon request from the Commission or the designated national authority of its Member State  $\Rightarrow$  or the Agency  $\Leftarrow$ , 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  $\Rightarrow$  Agency  $\Leftarrow$  ~~Commission~~ each year with aggregated information in accordance with Annex III. The  $\Rightarrow$  Agency  $\Leftarrow$  ~~Commission~~ shall summarise that information at Union Community level and shall make the non-confidential information publicly available on its  $\boxtimes$  Database  $\boxtimes$  ~~database via the Internet~~.

↓ 689/2008 Article 10 (adapted)  
 $\Rightarrow$  new

#### *Article ~~11~~10*

##### *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 Community 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.  
 $\boxtimes$  Where  $\boxtimes$  ~~When~~ 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 Community level in order to prevent any unacceptable risks to human health or the environment within the Union Community.

8. Where a Member State takes national final regulatory action in accordance with the relevant Union Community 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 1211.

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↓ 689/2008 Article 11 (adapted)

*Article 1211*

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

⊗ Where ~~⊗ When~~ 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 1110(8), the Commission shall provide the Secretariat with information concerning the relevant final regulatory actions, so that that information can be disseminated to other Parties to the Convention as appropriate.

*Article 13~~2~~*  
*Obligations in relation to imports 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 294(2), take an import decision, in the form of a final or interim import response on behalf of the Union Community, 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 Community legislation, the Commission shall revise the import decision in accordance with the advisory procedure referred to in Article 294(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 within the Union Community 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 Community level in order to prevent any unacceptable risks to human health or the environment within the Union Community, taking into account the information given in the decision guidance document.

*Article 14~~3~~*

*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 ~~⇐~~ ~~Commission~~ ~~⇐~~ shall assign each import decision a reference identification number and keep ~~⇐~~ ~~shall keep~~ all information regarding import decisions, ~~which shall each be assigned an import decision reference identification number~~, available in its Database ~~database~~, which shall be publicly available on ~~⇐~~ its website ~~⇐~~ ~~the Internet~~, 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 ~~Community'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 ~~Community'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 ~~⇐~~ ~~to obtain~~ further information ~~⇐~~ needed to prepare ~~⇐~~ ~~to help them to make~~ 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 ~~⇐~~ ~~preparations~~ containing such substances in a concentration that ~~⇒~~ triggers ~~⇐~~ ~~could trigger~~ 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~~ ~~Commission or the designated national authority of the exporter~~ has not received a response to ~~the~~ ~~its~~ request within 30 days, the ~~Agency~~ ~~Commission~~ 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~~ ~~Commission~~ 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 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.

~~All new requests shall be channelled through the Commission.~~

9. The  Agency  Commission shall register all requests for explicit consent, responses obtained and waivers granted in its Database ~~database~~. Each explicit consent obtained or waived shall be assigned  a  ~~an explicit consent~~ reference identification number and shall be listed with all relevant information concerning any conditions attached,  such as  validity dates, ~~etc.~~ The non-confidential information shall be made publicly available on the  Agency's Database  Internet.
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 Community legislation.

689/2008 Article 14 (adapted)  
 new

#### *Article 154*

##### *Export of certain chemicals and articles containing chemicals*

1. Articles ~~containing substances listed in Parts 2 or 3 of Annex I in unreacted form or preparations containing such substances in a concentration that could trigger~~ labelling obligations under Directive 1999/45/EC ~~irrespective of the presence of any other substances~~ shall be subject to the export notification procedure laid down in Article ~~87~~  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 Directive 1999/45/EC   and, where applicable, 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 Community for the protection of human health or the environment, as listed in Annex V, shall not be exported.

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↓ 689/2008 Article 15  
⇒ new

*Article 16~~5~~*  
*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.

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↓ 689/2008 Article 16 (adapted)  
⇒ new

*Article 17~~6~~*  
*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, ~~Directive 67/548/EEC~~, Directive 1999/45/EC, Regulation (EC) No 1107/2009, ~~Directive 91/414/EEC and~~ Directive 98/8/EC ⇒ and, where applicable, Regulation (EC) No 1272/2008, ⇐ or any other ☒ relevant ⇐ ~~specific Union Community~~ legislation.

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↓ new

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.

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↓ 689/2008 Article 16 (adapted)

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 ~~of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency<sup>33</sup>~~ 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.

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↓ 689/2008 Article 17 (adapted)  
⇒ new

#### Article 18~~7~~

#### *Obligations of the authorities of the Member States ~~and exporters~~ for controlling imports and exports*

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 ⇒ and the Agency ⇐ shall act in a targeted and coordinated way in monitoring exporters' compliance with this Regulation.

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↓ new

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

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↓ 689/2008 Article 17

3. Each Member State shall, in its regular reports on the operation of procedures pursuant to Article ~~2221~~(1), include details of the activities of its authorities in that regard.

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<sup>33</sup> OJ L 396, 30.12.2006, p. 1. Corrected version in OJ L 136, 29.5.2007, p. 3. Regulation as amended by Council Regulation (EC) No 1354/2007 (OJ L 304, 22.11.2007, p. 1).

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↓ 689/2008 Article 17 (adapted)  
⇒ new

⇒ Article 19

*Obligations of exporters for controlling imports and exports* ⇐

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 of 12 October 1992 establishing the Community Customs Code<sup>34</sup> the applicable reference identification numbers referred to in Article 7(2) or Article 13(1) or (9) of this Regulation as appropriate confirming compliance with the obligations to which they relate.

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↓ new

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 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 shall use the Agency's Database for the submission of information required for the fulfilment of their obligations under this Regulation.

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↓ 689/2008 Article 19  
⇒ new

*Article 20~~19~~*

*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:

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<sup>34</sup> ~~OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).~~

- (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, ~~and~~ the Member States  $\Rightarrow$  and the Agency  $\Leftarrow$  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>35</sup> ~~of 28 January 2003 on public access to environmental information~~, 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 regularly by the  $\Rightarrow$  Agency  $\Leftarrow$  ~~Commission~~ on the basis of the contributions by Member States  $\Rightarrow$  and the Commission  $\Leftarrow$ .

$\Downarrow$  689/2008 Article 20 (adapted)  
 $\Rightarrow$  new

*Article ~~21~~<sup>20</sup>*  
*Technical assistance*

The Commission, ~~and~~ the designated national authorities of the Member States  $\Rightarrow$  and the Agency  $\Leftarrow$  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.

<sup>35</sup> OJ L 41, 14.2.2003, p. 26.

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  $\Rightarrow$  international activities in capacity-building in chemicals management  $\Leftarrow$  ~~the Information Network on Capacity Building set up by the Intergovernmental Forum on Chemical Safety~~, 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.

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$\Downarrow$  689/2008 Article 21  
 $\Rightarrow$  new

*Article ~~2221~~*  
*Monitoring and reporting*

1. Member States  $\Rightarrow$  and the Agency  $\Leftarrow$  shall regularly forward to the Commission information concerning the operation of the procedures provided for in this Regulation, including customs controls, infringements, penalties and remedial action,  $\Rightarrow$  as appropriate  $\Leftarrow$ .
  2. The Commission shall regularly compile 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  $\Rightarrow$  and the Agency  $\Leftarrow$  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  $\Rightarrow$ , the Agency  $\Leftarrow$  and the Commission shall comply with relevant obligations to protect the confidentiality of data and ownership.
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$\Downarrow$  689/2008 Article 22 (adapted)  
 $\Rightarrow$  new

*Article ~~2322~~*  
*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 ~~Community~~ law and under the Convention.

2. When determining whether a final regulatory action at Union Community 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 Community level constitutes a ban or a severe restriction such that the chemical concerned qualifies for PIC notification under Article ~~1110~~, 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 entry 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: ⇐ ~~The following measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(3):~~

(a)  inclusion of  ~~measures to include~~ a chemical in Parts 1 or 2 of Annex I pursuant to paragraph 2 following final regulatory action at Union Community level  and amendments of Annex I, including modifications to existing entries  ;

(b)  inclusion of  ~~measures to include~~ a chemical that is subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council<sup>36</sup> in Part 1 of Annex V;

~~(c) other measures to amend Annex I, including modifications to existing entries;~~

~~(cd)~~  inclusion of  ~~measures to include~~ a chemical already subject to an export ban at Union Community level in Part 2 of Annex V;

~~(d)~~  modifications to  ~~measures to modify~~ existing entries in Annex V~~;~~

(e)  amendments of  ~~measures to amend~~ Annexes II, III, IV and VI~~;~~

↓ 689/2008 Article 23

#### ~~Article 23~~

#### ~~Technical notes for guidance~~

~~The Commission, in accordance with the advisory procedure referred to in Article 24(2), shall draw up technical notes for guidance to facilitate the day to day application of this Regulation.~~

<sup>36</sup> OJ L 158, 30.4.2004, p. 7.

~~The technical notes shall be published in the ‘C’ series of the Official Journal of the European Union.~~

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↓ new

#### 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.
- 

↓ new

#### 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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↓ new

#### 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.

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↓ new

*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*.

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↓ new

*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.

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↓ 689/2008 Article 24 (adapted)  
⇒ new

*Article 29~~4~~*  
*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 and Article 7 ⇒ of Regulation (EU) No 182/2011 ⇐ of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. ~~Where reference is made to this paragraph, Article 5(a)(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.~~

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↓ new

*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.

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↓ 689/2008 Article 18 (adapted)

*Article 31~~18~~*  
*Penalties*

Member States shall ☒ lay down the rules on ☒ ~~determine the~~ 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 ☒ ~~shall~~ 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 ~~of those measures~~ by [OJ: please insert the date: 1 year after publication] 1 August 2009 ☒ at the latest and ☒ ~~They~~ shall ~~also~~ notify it ☒ without delay ☒ of any ☒ subsequent amendment affecting them ☒ ~~further modifications as soon as possible after their adoption.~~

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

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↓ 689/2008 Article 25 (adapted)  
⇒ new

*Article ~~3225~~*

⇒ Repeal ⇐ ~~References to Regulation (EC) No 304/2003~~

⇒ Regulation (EC) No 689/2008 shall be repealed with effect from 31 March 2013. ⇐

References to Regulation (EC) No ☒ 689/2008 ☒ ~~304/2003~~ shall be construed as references to this Regulation ⇒ and shall be read in accordance with the correlation table in Appendix 1 ⇐.

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↓ 689/2008 Article 26 (adapted)  
⇒ new

*Article ~~3326~~*

*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*.

~~Article 17(2), however, shall apply as from 1 November 2008.~~

⇒ This Regulation shall apply as from 1 April 2013. ⇐

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

☒ 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*

- ↓ 689/2008 Annex I (adapted)
- <sub>1</sub> 15/2010 Art. 1 and Annex .1(a)
- <sub>2</sub> 196/2010 Art. 1 and Annex .1(a)
- <sub>3</sub> 196/2010 Art. 1 and Annex .1(b)
- <sub>4</sub> 15/2010 Art. 1 and Annex .1(b)
- <sub>5</sub> 15/2010 Art. 1 and Annex .2(a)
- <sub>6</sub> 196/2010 Art. 1 and Annex .2(b)
- <sub>7</sub> 196/2010 Art. 1 and Annex .2(a)
- <sub>8</sub> 15/2010 Art. 1 and Annex .2(b)
- <sub>9</sub> 196/2010 Art. 1 and Annex .3

**ANNEX I**

**LIST OF CHEMICALS**

(referred to in Article ~~76~~)

**PART 1**

**List of chemicals subject to export notification procedure**

(referred to in Article ~~87~~)

It should be noted that where chemicals listed in this part of the Annex are subject to the PIC procedure, the export notification obligations set out in Article ~~87~~(2), (3) and (4) shall not apply provided that the conditions laid down in  points  ~~Article 7(6)~~ (b) and (c)  of Article 8(6)  have been fulfilled. Such chemicals, which are identified by the symbol ‘#’ in the list below, are listed again in Part 3 of this Annex for ease of reference.

It should also be noted that where the chemicals listed in this part of the Annex qualify for PIC notification because of the nature of the Union's ~~Community's~~ final regulatory action, those chemicals are also listed in Part 2 of this Annex. Such chemicals are identified by the symbol ‘+’ in the list below.

Chemical	CAS No	Einecs No	CN code	Subcategory (*)	Use limitation	Countries for which no
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					(**)	notification is required
1,1,1-Trichloroethane	71-55-6	200-756-3	29031910	i(2)	b	
1,2-Dibromoethane (Ethylene dibromide) #	106-93-4	203-444-5	29033100	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
1,2-Dichloroethane (ethylene dichloride) #	107-06-2	203-458-1	29031500	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
				i(2)	b	
Cis- 1,3-dichloropropene ((1Z)-1,3-dichloroprop-1-ene)	10061-01-5	233-195-8	29032900	p(1)-p(2)	b-b	
→ <sub>1</sub> 1,3-dichloropropene <sup>37</sup> ←	→ <sub>1</sub> 542-75-6 ←	→ <sub>1</sub> 208-826-5 ←	→ <sub>1</sub> 29032900 ←	→ <sub>1</sub> p(1) ←	→ <sub>1</sub> b ←	
2-aminobutane	13952-84-6	237-732-7	29211980	p(1)-p(2)	b-b	
2-Naphthylamine (naphthalen-2-amine) and its salts +	91-59-8, 553-00-4, 612-52-2 and others	202-080-4, 209-030-0, 210-313-6 and others	29214500	i(1)	b	
				i(2)	b	
→ <sub>2</sub> 2-Naphthyloxyacetic acid ←	→ <sub>2</sub> 120-23-0 ←	→ <sub>2</sub> 204-380-0 ←	→ <sub>2</sub> 29189990 ←	→ <sub>2</sub> p(1) ←	→ <sub>2</sub> b ←	
2,4,5-T and its salts and esters #	93-76-5 and others	202-273-3 and others	29189100	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
4-Aminobiphenyl (biphenyl-4-amine) and its salts +	92-67-1,	202-177-1	29214980	i(1)	b	

<sup>37</sup> This entry does not affect the existing entry for cis-1,3-dichloropropene (CAS No 10061-01-5).

	2113-61-3 and others	and others		i(2)	b	
4-Nitrobiphenyl +	92-93-3	202-204-7	29042000	i(1)	b	
				i(2)	b	
Acephate +	30560-19-1	250-241-2	29309085	p(1)-p(2)	b-b	
Acifluorfen	50594-66-6	256-634-5	29163900	p(1)-p(2)	b-b	
Alachlor +	15972-60-8	240-110-8	29242995	p(1)	b	
Aldicarb +	116-06-3	204-123-2	29309085	p(1)-p(2)	sr-b	
Ametryn	834-12-8	212-634-7	29336980	p(1)-p(2)	b-b	
→ <sub>3</sub> Amitraz + ←	→ <sub>3</sub> 33089- 61-1 ←	→ <sub>3</sub> 251- 375-4 ←	→ <sub>3</sub> 29252 900 ←	→ <sub>3</sub> p(1)- p(2) ←	→ <sub>3</sub> b-b ←	
→ <sub>2</sub> Anthraquinone ←	→ <sub>2</sub> 84-65- 1 ←	→ <sub>2</sub> 201- 549-0 ←	→ <sub>2</sub> 29146 100 ←	→ <sub>2</sub> p(1)- p(2) ←	→ <sub>2</sub> b-b ←	
Arsenic compounds				p(2)	sr	
Asbestos Fibres +:	1332-21-4 and others					Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Crocidolite #	12001-28-4		25241000	i	b	
Amosite #	12172-73-5		25249000	i	b	
Antophyllite #	77536-67-5		25249000	i	b	

Actinolite #	77536-66-4		25249000	i	b	
Tremolite #	77536-68-6		25249000	i	b	
Chrysotile +	12001-29-5 or 132207- 32-0		25249000	i	b	
→ <sub>3</sub> Atrazine + ←	→ <sub>3</sub> 1912-24- 9 ←	→ <sub>3</sub> 217- 617-8 ←	→ <sub>3</sub> 29336 910 ←	→ <sub>3</sub> p(1) ←	→ <sub>3</sub> b ←	
Azinphos-ethyl	2642-71-9	220-147-6	29339990	p(1)-p(2)	b-b	
Azinphos-methyl	86-50-0	201-676-1	29339990	p(1)	b	
→ <sub>1</sub> Benfuracarb ←	→ <sub>1</sub> 82560- 54-1 ←		→ <sub>1</sub> 29329 900 ←	→ <sub>1</sub> p(1) ←	→ <sub>1</sub> b ←	
Bensultap	17606-31-4		29309085	p(1)-p(2)	b-b	
Benzene <sup>(1)</sup>	71-43-2	200-753-7	29022000	i(2)	sr	
Benzidine and its salts + Benzidine derivatives +	92-87-5, 36341-27-2 and others	202-199-1, 252-984-8 and others	29215990	i(1)-i(2)  i(2)	sr-b  b	
	—	—				
Binapacryl #	485-31-4	207-612-9	29161950	p(1)-p(2)  i(2)	b-b  b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
→ <sub>2</sub> Butralin ←	→ <sub>2</sub> 33629- 47-9 ←	→ <sub>2</sub> 251- 607-4 ←	→ <sub>2</sub> 29214 900 ←	→ <sub>2</sub> p(1) ←	→ <sub>2</sub> b ←	

Cadmium and its compounds	7440-43-9 and others	231-152-8 and others	8107 32064930 and others	i(1)	sr	
Cadusafos +	95465-99-9	n.a.	29309085	p(1)	b	
Calciferol	50-14-6	200-014-9	29362990	p(1)	b	
Captafol #	2425-06-1	219-363-3	29305000	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Carbaryl +	63-25-2	200-555-0	29242995	p(1)-p(2)	b-b	
Carbofuran +	1563-66-2	216-353-0	29329985	p(1)	b	
Carbon tetrachloride	56-23-5	200-262-8	29031400	i(2)	b	
Carbosulfan +	55285-14-8	259-565-9	29329985	p(1)	b	
Cartap	15263-53-3		29302000	p(1)-p(2)	b-b	
Chinomethionat	2439-01-2	219-455-3	29349990	p(1)-p(2)	b-b	
Chlordecone	143-50-0	205-601-3	29147000	p(2)	sr	
Chlordimeform #	6164-98-3	228-200-5	29252100	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Chlorfenapyr +	122453-73-0		29339990	p(1)	b	
Chlorfenvinphos	470-90-6	207-432-0	29199090	p(1)-p(2)	b-b	
Chlormephos	24934-91-6	246-538-1	29309085	p(1)-p(2)	b-b	

Chlorobenzilate #	510-15-6	208-110-2	29181800	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Chloroform	67-66-3	200-663-8	29031300	i(2)	b	
Chlozolate +	84332-86-5	282-714-4	29349990	p(1)-p(2)	b-b	
Cholecalciferol	67-97-0	200-673-2	29362990	p(1)	b	
Coumafuryl	117-52-2	204-195-5	29322985	p(1)-p(2)	b-b	
Creosote and creosote related substances	8001-58-9	232-287-5	27079100			
	61789-28-4	263-047-8				
	84650-04-4	283-484-8	38070090			
	90640-84-9	292-605-3				
	65996-91-0	266-026-1		i(2)	b	
	90640-80-5	292-602-7				
	65996-85-2	266-019-3				
	8021-39-4	232-419-1				
	122384-78-5	310-191-5				
Crimidine	535-89-7	208-622-6	29335995	p(1)	b	
Cyanazine	21725-46-2	244-544-9	29336980	p(1)-p(2)	b-b	
Cyhalothrine	68085-85-8	268-450-2	29269095	p(1)	b	

DBB (Di- $\mu$ -oxo-di-n-butylstannio-hydroxyborane/dioxastannaboretan-4-ol)	75113-37-0	401-040-5	29310095	i(1)	b	
Diazinon	333-41-5	206-373-8	29335910	p(1)	b	
Dichlorvos	62-73-7	200-547-7	29199090	p(1)	b	
→ <sub>2</sub> Dicofol ←	→ <sub>2</sub> 115-32-2 ←	→ <sub>2</sub> 204-082-0 ←	→ <sub>2</sub> 29062900 ←	→ <sub>2</sub> p(1)-p(2) ←	→ <sub>2</sub> b-b ←	
Dicofol containing < 78 % p, p'-Dicofol or 1 g/kg of DDT and DDT related compounds +	115-32-2	204-082-0	29062900	p(1)-p(2)	b-b	
Dimethenamid +	87674-68-8	n.a.	29349990	p(1)	b	
→ <sub>2</sub> Diniconazole-M ←	→ <sub>2</sub> 83657-18-5 ←	→ <sub>2</sub> n.a. ←	→ <sub>2</sub> 29339980 ←	→ <sub>2</sub> p(1) ←	→ <sub>2</sub> b ←	
Dinitro-ortho-cresol (DNOC) and its salts (such as ammonium salt, potassium salt and sodium salt) #	534-52-1 2980-64-5 5787-96-2 2312-76-7	208-601-1 221-037-0 — 219-007-7	29089990	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Dinobuton	973-21-7	213-546-1	29209010	p(1)-p(2)	b-b	
Dinoseb and its salts and esters #	88-85-7 and others	201-861-7 and others	29089100 29153600	p(1)-p(2) i(2)	b-b b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Dinoterb +	1420-07-1	215-813-8	29089990	p(1)-p(2)	b-b	
→ <sub>4</sub> --- ←	→ <sub>4</sub> --- ←	→ <sub>4</sub> --- ←	→ <sub>4</sub> --- ←	→ <sub>4</sub> --- ←	→ <sub>4</sub> --- ←	

Dustable powder formulations containing a combination of:			38089990			Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Benomyl at or above 7 %	17804-35-2	241-775-7	29339990	p(1)	b	
Carbofuran at or above 10 %	1563-66-2	216-353-0	29329985	p(2)	b	
and Thiram at or above 15 % #	137-26-8	205-286-2	29303000			
Endosulfan +	115-29-7	204-079-4	29209085	p(1)	b	
Ethion	563-12-2	209-242-3	29309085	p(1)-p(2)	b-b	
Ethylene oxide (Oxirane) #	75-21-8	200-849-9	29101000	p(1)	b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
→ <sub>1</sub> Fenarimol + ←	→ <sub>1</sub> 60168-88-9 ←	→ <sub>1</sub> 262-095-7 ←	→ <sub>1</sub> 29335995 ←	→ <sub>1</sub> p(1) ←	→ <sub>1</sub> b ←	
Fenitrothion	122-14-5	204-524-2	29201900	p(1)	b	
Fenpropathrin	39515-41-8	254-485-0	29269095	p(1)-p(2)	b-b	
Fenthion +	55-38-9	200-231-9	29309085	p(1)	sr	
Fentin acetate +	900-95-8	212-984-0	29310095	p(1)-p(2)	b-b	
Fentin hydroxide +	76-87-9	200-990-6	29310095	p(1)-p(2)	b-b	
Fenvalerate	51630-58-1	257-326-3	29269095	p(1)	b	
Ferbam	14484-64-1	238-484-2	29302000	p(1)-p(2)	b-b	
Fluoroacetamide #	640-19-7	211-363-1	29241200	p(1)	b	Please refer to PIC

						circular at <a href="http://www.pic.int/">www.pic.int/</a>
Flurenol	467-69-6	207-397-1	29181985	p(1)-p(2)	b-b	
→ <sub>2</sub> Flurprimidol ←	→ <sub>2</sub> 56425-91-3 ←	→ <sub>2</sub> n.a. ←	→ <sub>2</sub> 29335995 ←	→ <sub>2</sub> p(1) ←	→ <sub>2</sub> b ←	
Furathiocarb	65907-30-4	265-974-3	29329985	p(1)-p(2)	b-b	
Haloxyfop-R +	95977-29-0	n.a.	29333999	p(1)	b	
(Haloxyfop-P-methyl ester)	(72619-32-0)	(406-250-0)	(29333999)			
HCH/Hexachlorocyclohexane (mixed isomers) #	608-73-1	210-168-9	29035100	p(1)-p(2)	b-sr	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Hexachloroethane	67-72-1	200-666-4	29031980	i(1)	sr	
Hexazinone	51235-04-2	257-074-4	29336980	p(1)-p(2)	b-b	
Iminoctadine	13516-27-3	236-855-3	29252900	p(1)-p(2)	b-b	
Isoxathion	18854-01-8	242-624-8	29349990	p(1)	b	
Lindane (γ-HCH) #	58-89-9	200-401-2	29035100	p(1)-p(2)	b-sr	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Malathion	121-75-5	204-497-7	29309085	p(1)	b	
(a) Maleic hydrazide, and its salts, other than choline, potassium and sodium salts	123-33-1	204-619-9	29339990	p(1)	b	
(b) Choline, potassium and sodium salts of maleic hydrazide containing more than 1 mg/kg of free	61167-10-0, 51542-52-0,	257-261-0,	29339990			

hydrazine expressed on the basis of the acid equivalent	28330-26-9	248-972-7				
Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds #	10112-91-1, 21908-53-2 and others	233-307-5, 244-654-7 and others	28520000	p(1)-p(2)	b-sr	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
→ <sub>1</sub> Methamidophos <sup>38</sup> + ←	→ <sub>1</sub> 10265-92-6 ←	→ <sub>1</sub> 233-606-0 ←	→ <sub>1</sub> 29305000 ←	→ <sub>1</sub> p(1) ←	→ <sub>1</sub> b ←	
Methamidophos (Soluble liquid formulations of the substance that exceed 600 g active ingredient/l) #	10265-92-6	233-606-0	29305000 38085000	p(2)	b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Methidathion	950-37-8	213-449-4	29349990	p(1)-p(2)	b-b	
→ <sub>1</sub> Methomyl ←	→ <sub>1</sub> 16752-77-5 ←	→ <sub>1</sub> 240-815-0 ←	→ <sub>1</sub> 29309085 ←	→ <sub>1</sub> p(1)-p(2) ←	→ <sub>1</sub> b-b ←	
Methyl-parathion + #	298-00-0	206-050-1	29201100	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Metoxuron	19937-59-8	243-433-2	29242190	p(1)-p(2)	b-b	
Monocrotophos #	6923-22-4	230-042-7	29241200	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Monolinuron	1746-81-2	217-129-5	29280090	p(1)	b	
Monomethyl-dibromo-diphenyl methane Tradename: DBBT +	99688-47-8	402-210-1	29036990	i(1)	b	

<sup>38</sup> This entry does not affect the existing entry for soluble liquid formulations of methamidophos that exceed 600 g active ingredient/l.

Monomethyl-Dichloro-Diphenyl methane; Tradename: Ugilec 121 or Ugilec 21 +	—	400-140-6	29036990	i(1)-i(2)	b-b	
Monomethyl-Tetrachlorodiphenyl methane; Tradename: Ugilec 141 +	76253-60-6	278-404-3	29036990	i(1)-i(2)	b-b	
Monuron	150-68-5	205-766-1	29242190	p(1)	b	
→ <sub>2</sub> Nicotine ←	→ <sub>2</sub> 54-11-5 ←	→ <sub>2</sub> 200-193-3 ←	→ <sub>2</sub> 29399900 ←	→ <sub>2</sub> p(1) ←	→ <sub>2</sub> b ←	
Nitrofen +	1836-75-5	217-406-0	29093090	p(1)-p(2)	b-b	
Nonylphenols C <sub>6</sub> H <sub>4</sub> (OH)C <sub>9</sub> H <sub>19</sub> +	25154-52-3 (phenol, nonyl-),	246-672-0	29071300	i(1)	sr	
	84852-15-3 (phenol, 4- nonyl- branched)	284-325-5				
	11066-49-2 (isononylphe nol),	234-284-4				
	90481-04-2, (phenol, nonyl- branched),	291-844-0				
	104-40-5(p-	203-199-4				

	nonylphenol) and others	and others				
Nonylphenol ethoxylates (C <sub>2</sub> H <sub>4</sub> O) <sub>n</sub> C <sub>15</sub> H <sub>24</sub> O +	9016-45-9, 26027-38-3, 68412-54-4, 37205-87-1, 127087-87-0 and others		34021300	i(1) p(1)-p(2)	sr b-b	
Octabromodiphenyl ether +	32536-52-0	251-087-9	29093038	i(1)	sr	
Omethoate	1113-02-6	214-197-8	29309085	p(1)-p(2)	b-b	
Oxydemeton-methyl +	301-12-2	206-110-7	29309085	p(1)	b	
→ <sub>1</sub> Paraquat + ←	→ <sub>1</sub> 4685-14-7 ←	→ <sub>1</sub> 225-141-7 ←	→ <sub>1</sub> 29333 999 ←	→ <sub>1</sub> p(1) ←	→ <sub>1</sub> b ←	
Parathion #	56-38-2	200-271-7	29201100	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Pebulate	1114-71-2	214-215-4	29302000	p(1)-p(2)	b-b	
Pentabromodiphenyl ether +	32534-81-9	251-084-2	29093031	i(1)	sr	
Pentachlorophenol and its salts and esters #	87-86-5 and others	201-778-6 and others	29081100 29081900 and others	p(1)-p(2)	b-sr	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Perfluorooctane sulfonates	1763-23-1	n.a.	29049020	i(1)	sr	
(PFOS)	2795-39-3		29049020			

C8F17SO2X	and others		and others			
(X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers) + <sup>(a)</sup>						
Permethrin	52645-53-1	258-067-9	29162000	p(1)	b	
Phosalone +	2310-17-0	218-996-2	29349990	p(1)	b	
Phosphamidon (soluble liquid formulations of the substance that exceed 1000 g active ingredient/l) #	13171-21-6 (mixture, (E) & (Z) isomers)	236-116-5	29241200  38085000	p(1)-p(2)	b-b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
	23783-98-4 ((Z)-isomer)					
	297-99-4 ((E)-isomer)					
Polybrominated biphenyls (PBB) #	13654-09-6 36355-01-8 27858-07-7 and others	237-137-2 252-994-2 248- 696-7	29036990 and others	i(1)	sr	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Polychlorinated terphenyls (PCT) #	61788-33-8	262-968-2	29036990	i(1)	b	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
→ <sub>1</sub> Procymidone + ←	→ <sub>1</sub> 32809-16-8 ←	→ <sub>1</sub> 251-233-1 ←	→ <sub>1</sub> 29251 995 ←	→ <sub>1</sub> p(1) ←	→ <sub>1</sub> b ←	
→ <sub>2</sub> Propachlor ←	→ <sub>2</sub> 1918-16-7 ←	→ <sub>2</sub> 217-638-2 ←	→ <sub>2</sub> 29242 998 ←	→ <sub>2</sub> p(1) ←	→ <sub>2</sub> b ←	

→ <sub>2</sub> Propanil ←	→ <sub>2</sub> 709-98-8 ←	→ <sub>2</sub> 211-914-6 ←	→ <sub>2</sub> 29242998 ←	→ <sub>2</sub> p(1) ←	→ <sub>2</sub> b ←	
Propham	122-42-9	204-542-0	29242995	p(1)	b	
Pyrazophos +	13457-18-6	236-656-1	29335995	p(1)-p(2)	b-b	
Quintozene +	82-68-8	201-435-0	29049085	p(1)-p(2)	b-b	
Scilliroside	507-60-8	208-077-4	29389090	p(1)	b	
→ <sub>3</sub> Simazine + ←	→ <sub>3</sub> 122-34-9 ←	→ <sub>3</sub> 204-535-2 ←	→ <sub>3</sub> 29336910 ←	→ <sub>3</sub> p(1)-p(2) ←	→ <sub>3</sub> b-b ←	
Strychnine	57-24-9	200-319-7	29399900	p(1)	b	
Tecnazene +	117-18-0	204-178-2	29049085	p(1)-p(2)	b-b	
Terbufos	13071-79-9	235-963-8	29309085	p(1)-p(2)	b-b	
Tetraethyl lead #	78-00-2	201-075-4	29310095	i(1)	sr	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Tetramethyl lead #	75-74-1	200-897-0	29310095	i(1)	sr	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Thallium sulphate	7446-18-6	231-201-3	28332990	p(1)	b	
Thiocyclam	31895-22-4	250-859-2	29349990	p(1)-p(2)	b-b	
Thiodicarb +	59669-26-0	261-848-7	29309085	p(1)	b	
→ <sub>1</sub> Tolyfluanid + ←	→ <sub>1</sub> 731-27-1 ←	→ <sub>1</sub> 211-986-9 ←	→ <sub>1</sub> 29309085 ←	→ <sub>1</sub> p(1) ←	→ <sub>1</sub> b ←	

Triazophos	24017-47-8	245-986-5	29339990	p(1)-p(2)	b-b	
→ <sub>2</sub> All tributyltin compounds, including: ←			→ <sub>2</sub> 29310 095 ←	→ <sub>2</sub> p(2) ←	→ <sub>2</sub> b ←	→ <sub>2</sub> Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a> ←
→ <sub>2</sub> Tributyltin oxide ←	→ <sub>2</sub> 56-35- 9 ←	→ <sub>2</sub> 200- 268-0 ←	→ <sub>2</sub> 29310 095 ←			
→ <sub>2</sub> Tributyltin fluoride ←	→ <sub>2</sub> 1983-10- 4 ←	→ <sub>2</sub> 217- 847-9 ←	→ <sub>2</sub> 29310 095 ←			
→ <sub>2</sub> Tributyltin methacrylate ←	→ <sub>2</sub> 2155-70- 6 ←	→ <sub>2</sub> 218- 452-4 ←	→ <sub>2</sub> 29310 095 ←			
→ <sub>2</sub> Tributyltin benzoate ←	→ <sub>2</sub> 4342-36- 3 ←	→ <sub>2</sub> 224- 399-8 ←	→ <sub>2</sub> 29310 095 ←			
→ <sub>2</sub> Tributyltin chloride ←	→ <sub>2</sub> 1461-22- 9 ←	→ <sub>2</sub> 215- 958-7 ←	→ <sub>2</sub> 29310 095 ←			
→ <sub>2</sub> Tributyltin linoleate ←	→ <sub>2</sub> 24124- 25-2 ←	→ <sub>2</sub> 246- 024-7 ←	→ <sub>2</sub> 29310 095 ←			
→ <sub>2</sub> Tributyltin naphthenate # ←	→ <sub>2</sub> 85409- 17-2 ←	→ <sub>2</sub> 287- 083-9 ←	→ <sub>2</sub> 29310 095 ←			
Trichlorfon +	52-68-6	200-149-3	29310095	p(1)-p(2)	b-b	
→ <sub>2</sub> Tricyclazole ←	→ <sub>2</sub> 41814- 78-2 ←	→ <sub>2</sub> 255- 559-5 ←	→ <sub>2</sub> 29349 990 ←	→ <sub>2</sub> p(1) ←	→ <sub>2</sub> b ←	
Tridemorph	24602-86-6	246-347-3	29349990	p(1)-p(2)	b-b	

→ <sub>1</sub> Trifluralin ←	→ <sub>1</sub> 1582-09-8 ←	→ <sub>1</sub> 216-428-8 ←	→ <sub>1</sub> 29214 300 ←	→ <sub>1</sub> p(1) ←	→ <sub>1</sub> b ←	
→ <sub>3</sub> Triorganostannic compounds other than tributyltin compounds + ←	→ <sub>3</sub> — ←	→ <sub>3</sub> — ←	→ <sub>3</sub> 29310 095 and others ←	→ <sub>3</sub> p(2) i(2) ←	→ <sub>3</sub> sr sr ←	
Tris (2,3-Dibromopropyl) phosphate #	126-72-7	204-799-9	29191000	i(1)	sr	Please refer to PIC circular at <a href="http://www.pic.int/">www.pic.int/</a>
Tris-aziridinyl-phosphin oxide (1,1',1'-phosphoryltriairidine) +	545-55-1	208-892-5	29339990	i(1)	sr	
Vamidotion	2275-23-2	218-894-8	29309085	p(1)-p(2)	b-b	
Vinclozolin	50471-44-8	256-599-6	29349990	p(1)	b	
Zineb	12122-67-7	235-180-1	29302000 or 38249097	p(1)	b	

(\*) Sub- Category: p(1) – pesticide in the group of plant protection products, p(2) – other pesticide including biocides. i(1) - industrial chemical for professional use and i(2) – industrial chemical for public use.

(\*\*) Use limitation: sr - severe restriction, b – ban (for the sub-category or sub-categories concerned) according to Union Community legislation.

(<sup>1</sup>) Except motor fuels subject to Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels (OJ L 350, 28.12.1998, p.58). ~~Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).~~

CAS No = Chemical Abstracts Service Registry Number.

# Chemical subject or partially subject to the PIC procedure.

+ Chemical qualifying for PIC notification.

## PART 2

### List of chemicals qualifying for PIC notification

(referred to in Article 1140)

This list comprises chemicals qualifying for PIC notification. It ~~generally~~ does not include chemicals that are already subject to the PIC procedure, which are listed in Part 3 of this Annex.

Chemical	CAS No <del>RN</del>	Einecs No	CN code	Category (*)	Use limitation (**)
2-Naphthylamine (naphthalen-2-amine) and its salts	91-59-8, 553-00-4, 612-52-2 and others	202-080-4, 209-030-0, 210-313-6 and others	29214500	i	b
4-Aminobiphenyl (biphenyl-4-amine) and its salts	92-67-1, 2113-61-3 and others	202-177-1 and others	29214980	i	b
4-Nitrobiphenyl	92-92-3	202-204-7	29042000	i	b
Acephate	30560-19-1	250-241-2	29309085	p	b
Alachlor	15972-60-8	240-110-8	29242995	p	b
Aldicarb	116-06-3	204-123-2	29309085	p	sr
→ <sub>5</sub> Amitraz ←	→ <sub>5</sub> 33089-61-1 ←	→ <sub>5</sub> 251-375-4 ←	→ <sub>5</sub> 29252900 ←	→ <sub>5</sub> p ←	→ <sub>5</sub> b ←
→ <sub>6</sub> Anthraquinone ←	→ <sub>6</sub> 84-65-1 ←	→ <sub>6</sub> 201-549-0 ←	→ <sub>6</sub> 29146100 ←	→ <sub>6</sub> p ←	→ <sub>6</sub> b ←
Asbestos fibres: Chrysotile	12001-29-5 or 132207-32-0		25249000	i	b
→ <sub>5</sub> Atrazine ←	→ <sub>5</sub> 1912-24-9 ←	→ <sub>5</sub> 217-617-8 ←	→ <sub>5</sub> 29336910 ←	→ <sub>5</sub> p ←	→ <sub>5</sub> b ←

→ <sub>7</sub> Azinphos-methyl ←	→ <sub>7</sub> 86-50-0 ←	→ <sub>7</sub> 201-676-1 ←	→ <sub>7</sub> 29339980 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> b ←
Benzidine and its salts	92-87-5, 36341-27-2 and others	202-199-1, 252-984-8 and others	29215990	i	sr
	—	—			
Benzidine derivatives					
→ <sub>6</sub> Butralin ←	→ <sub>6</sub> 33629-47-9 ←	→ <sub>6</sub> 251-607-4 ←	→ <sub>6</sub> 29214900 ←	→ <sub>6</sub> p ←	→ <sub>6</sub> b ←
→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←
Carbaryl	63-25-2	200-555-0	29242995	p	b
→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←
→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←
Chlorfenapyr	122453-73-0		29339990	p	sr
Chlozolate	84332-86-5	282-714-4	29349990	p	b
→ <sub>7</sub> Diazinon ←	→ <sub>7</sub> 333-41-5 ←	→ <sub>7</sub> 206-373-8 ←	→ <sub>7</sub> 29335910 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> sr ←
→ <sub>7</sub> Dichlorvos ←	→ <sub>7</sub> 62-73-7 ←	→ <sub>7</sub> 200-547-7 ←	→ <sub>7</sub> 29199000 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> sr ←
→ <sub>6</sub> Dicofol ←	→ <sub>6</sub> 115-32-2 ←	→ <sub>6</sub> 204-082-0 ←	→ <sub>6</sub> 29062900 ←	→ <sub>6</sub> p ←	→ <sub>6</sub> b ←
Dicofol containing < 78 % p, p'-Dicofol or 1 g/kg of DDT and DDT related compounds	115-32-3	204-082-0	29062900	p	b
Dimethenamid	87674-68-8	n.a.	29349990	p	b
→ <sub>6</sub> Diniconazole-M ←	→ <sub>6</sub> 83657-18-5 ←	→ <sub>6</sub> n.a. ←	→ <sub>6</sub> 29339980 ←	→ <sub>6</sub> p ←	→ <sub>6</sub> b ←

Dinoterb	1420-07-1	215-813-8	29089990	p	b
Endosulfan	115-29-7	204-079-4	29209085	p	b
→ <sub>7</sub> Fenarimol ←	→ <sub>7</sub> 60168-88-9 ←	→ <sub>7</sub> 262-095-7 ←	→ <sub>7</sub> 29335995 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> b ←
→ <sub>7</sub> Fenitrothion ←	→ <sub>7</sub> 122-14-5 ←	→ <sub>7</sub> 204-524-2 ←	→ <sub>7</sub> 29201900 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> sr ←
Fenthion	55-38-9	200-231-9	29309085	p	sr
Fentin acetate	900-95-8	212-984-0	29310095	p	b
Fentin hydroxide	76-87-9	200-990-6	29310095	p	b
→ <sub>6</sub> Flurprimidol ←	→ <sub>6</sub> 56425-91-3 ←	→ <sub>6</sub> n.a. ←	→ <sub>6</sub> 29335995 ←	→ <sub>6</sub> p ←	→ <sub>6</sub> b ←
→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←
→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←	→ <sub>8</sub> --- ←		
→ <sub>7</sub> Methamidophos <sup>39</sup> ←	→ <sub>7</sub> 10265-92-6 ←	→ <sub>7</sub> 233-606-0 ←	→ <sub>7</sub> 29305000 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> b ←
Methyl parathion #	298-00-0	206-050-1	29201100	p	b
Monomethyl-dibromo-diphenyl methane Tradename: DBBT	99688-47-8	401-210-1	29036990	i	b
Monomethyl-Dichloro-Diphenyl methane; Tradename: Ugilec 121 or Ugilec 21	—	400-140-6	29036990	i	b
Monomethyl-Tetrachlorodiphenyl methane; Tradename: Ugilec 141	76253-60-6	278-404-3	29036990	i	b

<sup>39</sup> →<sub>7</sub> This entry does not affect the entry in Annex I Part 3 for soluble liquid formulations of methamidophos that exceed 600 g active ingredient/l. ←

→ <sub>6</sub> Nicotine ←	→ <sub>6</sub> 54-11-5 ←	→ <sub>6</sub> 200-193-3 ←	→ <sub>6</sub> 29399900 ←	→ <sub>6</sub> p ←	→ <sub>6</sub> b ←
Nitrofen	1836-75-5	217-406-0	29093090	p	b
Nonylphenols C <sub>6</sub> H <sub>4</sub> (OH)C <sub>9</sub> H <sub>19</sub>	25154-52-3 (phenol, nonyl-),	246-672-0	29071300	i	sr
	84852-15-3 (phenol, 4-nonyl-, branched),	284-325-5			
	11066-49-2 (isononylphenol),	234-284-4			
	90481-04-2, (phenol, nonyl-, branched),	291-844-0			
	104-40-5 (P-nonylphenol) and others	203-199-4 and others			
Nonylphenol ethoxylates (C <sub>2</sub> H <sub>4</sub> O) <sub>n</sub> C <sub>15</sub> H <sub>24</sub> O	9016-45-9, 26027-38-3, 68412-54-4, 37205-87-1, 127087-87-0 and others		34021300	i p	sr b
Octabromodiphenyl ether	32536-52-0	251-087-9	29093038	i	sr
Oxydemeton-methyl	301-12-2	206-110-7	29309085	p	b
→ <sub>7</sub> Paraquat ←	→ <sub>7</sub> 1910-42-5 ←	→ <sub>7</sub> 217-615-7 ←	→ <sub>7</sub> 29333999 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> b ←
Pentabromodiphenyl ether	32534-81-9	251-084-2	29093031	i	sr
Perfluorooctane sulfonates	1763-23-1	n.a.	29049020	i	sr

(PFOS) C8F17SO2X (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)	2795-39-3 and others		29049020 and others		
Phosalone	2310-17-0	218-996-2	29349990	p	b
→ <sub>7</sub> Procymidone ←	→ <sub>7</sub> 32809-16-8 ←	→ <sub>7</sub> 251-233-1 ←	→ <sub>7</sub> 29251995 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> b ←
→ <sub>6</sub> Propachlor ←	→ <sub>6</sub> 1918-16-7 ←	→ <sub>6</sub> 217-638-2 ←	→ <sub>6</sub> 29242998 ←	→ <sub>6</sub> p ←	→ <sub>6</sub> b ←
Pyrazophos	13457-18-6	236-656-1	29335995	p	b
Quintozene	82-68-8	201-435-0	29049085	p	b
→ <sub>5</sub> Simazine ←	→ <sub>5</sub> 122-34-9 ←	→ <sub>5</sub> 204-535-2 ←	→ <sub>5</sub> 29336910 ←	→ <sub>5</sub> p ←	→ <sub>5</sub> b ←
Tecnazene	117-18-0	204-178-2	29049085	p	b
Thiodicarb	59669-26-0	261-848-7	29309085	p	b
→ <sub>7</sub> Tolyfluanid ←	→ <sub>7</sub> 731-27-1 ←	→ <sub>7</sub> 211-986-9 ←	→ <sub>7</sub> 29309085 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> sr ←
Trichlorfon	52-68-6	200-149-3	29310095	p	b
→ <sub>5</sub> Triorganostannic compounds other than tributyltin compounds ←	→ <sub>5</sub> — ←	→ <sub>5</sub> — ←	→ <sub>5</sub> 29310095 and others ←	→ <sub>5</sub> p ←	→ <sub>5</sub> sr ←
→ <sub>7</sub> Vinclozolin ←	→ <sub>7</sub> 50471-44-8 ←	→ <sub>7</sub> 256-599-6 ←	→ <sub>7</sub> 29349990 ←	→ <sub>7</sub> p ←	→ <sub>7</sub> b ←

(\*) Category: p – pesticides; i – industrial chemical.

(\*\*) Use limitation: sr – severe restriction, b – ban (for the category or categories concerned).

CAS No = Chemical Abstracts Service Registry Number.

# Chemical subject or partially subject to the international PIC procedure.

### PART 3

#### List of chemicals subject to the PIC procedure under the Rotterdam Convention

(referred to in Articles 1312 and 1413)

(The categories shown are those referred to in the Convention)

Chemical	Relevant CAS number(s)	HS code Pure substance	HS code Mixtures, <del>preparations</del> containing substance	Category
2,4,5-T and its salts and esters	93-76-5 #	2918.91	3808.50	Pesticide
Aldrin (*)	309-00-2	2903.52	3808.50	Pesticide
Binapacryl	485-31-4	2916.19	3808.50	Pesticide
Captafol	2425-06-1	2930.50	3808.50	Pesticide
Chlordane (*)	57-74-9	2903.52	3808.50	Pesticide
Chlordimeform	6164-98-3	2925.21	3808.50	Pesticide
Chlorobenzilate	510-15-6	2918.18	3808.50	Pesticide
DDT (*)	50-29-3	2903.62	3808.50	Pesticide
Dieldrin (*)	60-57-1	2910.40	3808.50	Pesticide

Dinitro-ortho-cresol (DNOC) and its salts (such as ammonium salt, potassium salt and sodium salt)	534-52-1, 2980-64-5, 5787-96-2, 2312-76-7	2908.99	3808.91 3808.92 3808.93	Pesticide
Dinoseb and its salts and esters	88-85-7 #	2908.91	3808.50	Pesticide
1,2-dibromoethane (EDB)	106-93-4	2903.31	3808.50	Pesticide
Ethylene dichloride (1,2-dichloroethane)	107-06-2	2903.15	3808.50	Pesticide
Ethylene oxide	75-21-8	2910.10	3808.50 3824.81	Pesticide
Fluoroacetamide	640-19-7	2924.12	3808.50	Pesticide
HCH (mixed isomers)	608-73-1	2903.51	3808.50	Pesticide
Heptachlor (*)	76-44-8	2903.52	3808.50	Pesticide
Hexachlorobenzene (*)	118-74-1	2903.62	3808.50	Pesticide
Lindane	58-89-9	2903.51	3808.50	Pesticide
Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds	10112-91-1, 21908-53-2 and others See also: <a href="http://www.pic.int/">www.pic.int/</a>	2852.00	3808.50	Pesticide
Monocrotophos	6923-22-4	2924.12	3808.50	Pesticide
Parathion	56-38-2	2920.11	3808.50	Pesticide
Pentachlorophenol and its salts and esters	87-86-5 #	2908.11 2908.19	3808.50 3808.91 3808.92	Pesticide

			3808.93 3808.94 3808.99	
Toxaphene (*)	8001-35-2	—	3808.50	Pesticide
Dustable powder formulations containing a combination of: Benomyl at or above 7 %, Carbofuran at or above 10 % and Thiram at or above 15 %	17804-35-2 1563-66-2 137-26-8	—	3808.92	Severely hazardous pesticide formulation
Methamidophos (soluble liquid formulations of the substance that exceed 600 g active ingredient/l)	10265-92-6	2930.50	3808.50	Severely hazardous pesticide formulation
Methyl-parathion (emulsifiable concentrates (EC) at or above 19,5 % active ingredient and dusts at or above 1,5 % active ingredient)	298-00-0	2920.11	3808.50	Severely hazardous pesticide formulation
Phosphamidon (soluble liquid formulations of the substance that exceed 1000 g active ingredient/l)		2924.12	3808.50	Severely hazardous pesticide formulation
Mixture (E) & (Z) isomers	13171-21-6			
(Z)-isomer	23783-98-4			
(E)-isomer	297-99-4			
Asbestos fibres:		2524.10 2524.90	6811.40 6812.80 6812.91 6812.92 6812.93 6812.99 6813.20	Industrial

Crocidolite	12001-28-4	2524.10		
Actinolite	77536-66-4	2524.90		
Anthophyllite	77536-67-5	2524.90		
Amosite	12172-73-5	2524.90		
Tremolite	77536-68-6	2524.90		
Polybrominated biphenyls (PBB)				
– (hexa-)	36355-01-8	—	3824.82	
				Industrial
– (octa-)	27858-07-7			
– (deca-)	13654-09-6			
Polychlorinated biphenyls (PCB) (*)	1336-36-3	—	3824.82	Industrial
Polychlorinated terphenyls (PCT)	61788-33-8	—	3824.82	Industrial
Tetraethyl lead	78-00-2	2931.00	3811.11	Industrial
Tetramethyl lead	75-74-1	2931.00	3811.11	Industrial
→ <sub>9</sub> All tributyltin compounds, including: ←		→ <sub>9</sub> 2931.00 ←	→ <sub>9</sub> 3808.99 ←	→ <sub>9</sub> Pesticide ←
→ <sub>9</sub> Tributyltin oxide ←	→ <sub>9</sub> 56-35-9 ←	→ <sub>9</sub> 2931.00 ←	→ <sub>9</sub> 3808.99 ←	
→ <sub>9</sub> Tributyltin fluoride ←	→ <sub>9</sub> 1983-10-4 ←	→ <sub>9</sub> 2931.00 ←	→ <sub>9</sub> 3808.99 ←	

→ <sub>9</sub> Tributyltin methacrylate ←	→ <sub>9</sub> 2155-70-6 ←	→ <sub>9</sub> 2931.00 ←	→ <sub>9</sub> 3808.99 ←	
→ <sub>9</sub> Tributyltin benzoate ←	→ <sub>9</sub> 4342-36-3 ←	→ <sub>9</sub> 2931.00 ←	→ <sub>9</sub> 3808.99 ←	
→ <sub>9</sub> Tributyltin chloride ←	→ <sub>9</sub> 1461-22-9 ←	→ <sub>9</sub> 2931.00 ←	→ <sub>9</sub> 3808.99 ←	
→ <sub>9</sub> Tributyltin linoleate ←	→ <sub>9</sub> 24124-25-2 ←	→ <sub>9</sub> 2931.00 ←	→ <sub>9</sub> 3808.99 ←	
→ <sub>9</sub> Tributyltin naphthenate ←	→ <sub>9</sub> 85409-17-2 ←	→ <sub>9</sub> 2931.00 ←	→ <sub>9</sub> 3808.99 ←	
Tris (2,3-dibromopropyl) phosphate	126-72-7	2919.10	3824.83	Industrial

(\*) These substances are subject to an export ban in accordance with ~~the provisions of Article 1514~~(2) of and Annex V to this Regulation.

# Only the CAS numbers of parent compounds are listed.

## ANNEX II

### EXPORT NOTIFICATION

The following information is  ~~Information~~ required pursuant to Article 87:

1. Identity of the substance to be exported:
  - (a) name in nomenclature of the International Union of Pure and Applied Chemistry;
  - (b) other names (e.g. ISO name, usual names, trade names, and abbreviations);
  - (c) European Inventory of Existing Chemical Substances (Einecs) number and Chemical Abstracts Services (CAS) number;
  - (d) CUS number (European Customs Inventory of Chemical Substances) and Combined Nomenclature code;
  - (e) main impurities of the substance, when particularly relevant.
2. Identity of the  mixture  ~~preparation~~ to be exported:
  - (a) trade name and/or designation of the  mixture  ~~preparation~~;
  - (b) for each substance listed in Annex I, percentage and details as specified under item 1;
  - (c) CUS number (European Customs Inventory of Chemical Substances) and Combined Nomenclature code.
3. Identity of the article to be exported:
  - (a) trade name and/or designation of the article;
  - (b) for each substance listed in Annex I, percentage and details as specified under item 1.
4. Information on the export:
  - (a) country of destination;
  - (b) country of origin;
  - (c) expected date of first export this year;
  - (d) estimated amount of the chemical to be exported to the country concerned this year;

- (e) intended use in the country of destination, if known, including information on the category(ies) under the Rotterdam Convention under which the use falls;
  - (f) name, address and other relevant particulars of the importer or importing company;
  - (g) name, address and other relevant particulars of the exporter or exporting company.
5. Designated national authorities:
- (a) the name, address, telephone and telex, fax number or e-mail of the designated authority in the European Union from which further information may be obtained;
  - (b) the name, address, telephone and telex, fax number or e-mail of the designated authority in the importing country.
6. Information on precautions to be taken, including category of danger and risk and safety advice.
7. A summary on physicochemical, toxicological and ecotoxicological properties.
8. Use of the chemical in the European Union:
- (a) uses, category(ies) under the Rotterdam Convention and Union Community subcategory(ies) subject to control measure (ban or severe restriction);
  - (b) uses for which the chemical is not severely restricted or banned (use categories and subcategories as defined in Annex I of the Regulation);
  - (c) estimation, where available, of quantities of the chemical produced, imported, exported and used.
9. Information on precautionary measures to reduce exposure to, and emission of, the chemical.
10. Summary of regulatory restrictions and reasons for them.
11. Summary of information given in Annex IV under point 2(a), (c) and (d).
12. Additional information provided by the exporting Party because considered of concern or further information specified in Annex IV when requested by the importing Party.

**ANNEX III**

**Information to be supplied to the Commission by the designated national authorities of the Member States in accordance with Article 109**

1. Summary of quantities of chemicals (in the form of substances,  mixtures  ~~preparations~~ and articles) subject to Annex I exported during the previous year.

(a) Year in which exports took place.

(b) Table summarising quantities of exported chemicals (in the form of substances,  mixtures  ~~preparations~~ and articles) as outlined below.

Chemical	Importing country	Quantity of substance

2. List of importers

Chemical	Importing country	Importer or importing company	Address and other relevant particulars of the importer or the importing company

**ANNEX IV**

**Notification of the Secretariat of the Convention of a banned or severely restricted chemical**

**INFORMATION REQUIREMENTS FOR NOTIFICATIONS PURSUANT TO ARTICLE 1110**

Notifications shall include:

1. properties, identification and uses
  - (a) common name;
  - (b) chemical name according to an internationally recognised nomenclature (for example International Union of Pure and Applied Chemistry (IUPAC)), where such nomenclature exists;
  - (c) trade names and names of  mixtures  preparations;
  - (d) code numbers: Chemical Abstracts Service (CAS) number, Harmonised System Customs Code and other numbers;
  - (e) information on hazard classification, where the chemical is subject to classification requirements;
  - (f) use or uses of the chemical:
    - in the European Union,
    - elsewhere (if known);
  - (g) the physicochemical, toxicological and ecotoxicological properties;
2. final regulatory action
  - (a) information specific to the final regulatory action:
    - (i) summary of the final regulatory action;
    - (ii) reference to the regulatory document;
    - (iii) date of entry into force of the final regulatory action;
    - (iv) indication of whether the final regulatory action was taken on the basis of a risk or hazard evaluation and, if so, information on such an evaluation, covering a reference to the relevant documentation;
    - (v) reasons for the final regulatory action relevant to human health, including the health of consumers and workers, or the environment;

- (vi) summary of the hazards and risks presented by the chemical to human health, including the health of consumers and workers, or the environment and the expected effect of the final regulatory action;
- (b) category or categories where the final regulatory action has been taken, and for each category:
  - (i) use or uses prohibited by the final regulatory action;
  - (ii) use or uses that remain allowed;
  - (iii) estimation, where available, of quantities of the chemical produced, imported, exported and used;
- (c) an indication, to the extent possible, of the likely relevance of the final regulatory action to other States and regions;
- (d) other relevant information that may cover:
  - (i) assessment of socioeconomic effects of the final regulatory action;
  - (ii) information on alternatives and their relative risks, where available, such as:
    - integrated pest management strategies,
    - industrial practices and processes, including cleaner technology.

**ANNEX V**

**Chemicals and articles subject to export ban**

(referred to in Article 1514)

**PART 1**

Persistent organic pollutants as listed in Annexes A and B of the Stockholm Convention on Persistent Organic Pollutants according to the provisions thereof.

Description of chemicals/article(s) subject to export ban	Additional details, where relevant (e.g. name of chemical, EC No, CAS No, etc.)	
	Aldrin	EC No 206-215-8, CAS No 309-00-2, CN code 29035200
	Chlordane	EC No 200-349-0, CAS No 57-74-9, CN code 29035200
	Dieldrin	EC No 200-484-5, CAS No 60-57-1, CN code 29104000
	DDT (1,1,1-trichloro-2,2-bis (p-chlorophenyl) ethane	EC No 200-024-3, CAS No 50-29-3, CN code 29036200
	Endrin	EC No 200-775-7, CAS No 72-20-8, CN code 29109000
	Heptachlor	EC No 200-962-3, CAS No 76-44-8, CN code 29035200
	Hexachlorobenzene	EC No 200-273-9, CAS No 118-74-1, CN code 29036200
	Mirex	EC No 219-196-6, CAS No 2385-85-5, CN code 29035980
	Toxaphene (camphechlor)	EC No 232-283-3,

		CAS No 8001-35-2, CN code 38085000
	Polychlorinated biphenyls (PCBs)	EC No 215-648-1 and others, CAS No 1336-36-3 and others, CN code 29036990

## PART 2

Chemicals other than persistent organic pollutants as listed in Annexes A and B of the Stockholm Convention on Persistent Organic Pollutants according to the provisions thereof.

Description of chemicals/article(s) subject to export ban	Additional details, where relevant (e.g. name of chemical, EC No, CAS No, etc.)
Cosmetic soaps containing mercury	CN codes 34011100, 34011900, 34012010, 34012090, 34013000

**ANNEX VI**

**List of Parties to the Convention requiring information concerning transit movements of chemicals subject to the PIC procedure**

**(referred to in Article 1615)**

Country	Required information

**APPENDIX 1**

**CORRELATION TABLE**

This Regulation	Regulation (EC) No 689/2008
Article 1	
1.1	Article 1.1
1.2	Article 1.2
Article 2	
2.1	Article 2.1
2.2	Article 2.2
2.3	
Article 3	Article 3
Article 4	Article 4
Article 5	
5.1	Article 5.2
5.2	Article 5.3
Article 6	
6.1	
6.2	
Article 7	
7.1	Article 6.1
7.2	Article 6.2
7.3	Article 6.3
Article 8	
8.1	Article 7.1
8.2	Article 7.2
8.3	Article 7.3
8.4	Article 7.4
8.5	Article 7.5
8.6	Article 7.6
8.7	Article 7.7
8.8	Article 7.8
Article 9	
9.1	Article 8.1
9.2	Article 8.2
Article 10	
10.1	Article 9.1
10.2	Article 9.2
10.3	Article 9.3
Article 11	
11.1	Article 10.1
11.2	Article 10.2
11.3	Article 10.3
11.4	Article 10.4
11.5	Article 10.5
11.6	Article 10.6
11.7	Article 10.7

11.8	Article 10.8
Article 12	Article 11
Article 13	
13.1	Article 12.1
13.2	Article 12.2
13.3	Article 12.3
13.4	Article 12.4
13.5	Article 12.5
13.6	Article 12.6
Article 14	
14.1	Article 13.1
14.2	Article 13.2
14.3	Article 13.3
14.4	Article 13.4
14.5	Article 13.5
14.6	Article 13.6
14.7	Article 13.7
14.8	Article 13.8
14.9	Article 13.9
14.10	Article 13.10
14.11	Article 13.11
Article 15	
15.1	Article 14.1
15.2	Article 14.2
Article 16	
16.1	Article 15.1
16.2	Article 15.2
16.3	Article 15.3
16.4	Article 15.4
Article 17	
17.1	Article 16.1
17.2	Article 16.2
17.3	Article 16.3
17.4	Article 16.4
Article 18	
18.1	Article 17.1
18.2	
18.3	Article 17.1
Article 19	
19.1	Article 17.2
19.2	
19.3	
19.4	
Article 20	
20.1	Article 19.1
20.2	Article 19.2
20.3	Article 19.3
Article 21	Article 20
Article 22	

22.1	Article 21.1
22.2	Article 21.2
22.3	Article 21.3
Article 23	
23.1	Article 22.1
23.2	Article 22.2
23.3	Article 22.3
23.4	Article 22.4
Article 24	
24.1	
24.2	
24.3	
Article 25	
Article 26	
26.1	
26.2	
26.3	
Article 27	
27.1	
27.2	
27.3	
Article 28	
28.1	
28.2	
28.3	
Article 29	
29.1	Article 24.1
29.2	Article 24.2
Article 30	
Article 31	Article 18
Article 32	Article 25
Article 33	Article 26
Annex I	Annex I
Annex II	Annex II
Annex III	Annex III
Annex IV	Annex IV
Annex V	Annex V
Annex VI	Annex VI

## **LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS**

### **1. FRAMEWORK OF THE PROPOSAL/INITIATIVE**

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management method(s) envisaged

### **2. MANAGEMENT MEASURES**

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

### **3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
  - 3.2.1. *Summary of estimated impact on expenditure*
  - 3.2.2. *Estimated impact on operational appropriations*
  - 3.2.3. *Estimated impact on appropriations of an administrative nature*
  - 3.2.4. *Compatibility with the current multiannual financial framework*
  - 3.2.5. *Third-party participation in financing*
- 3.3. Estimated impact on revenue

## LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS

### 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

#### 1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council concerning the export and import of dangerous chemicals

#### 1.2. Policy area(s) concerned in the ABM/ABB structure<sup>40</sup>

Policy area 07 Environment

Activity Code 07 03 : Implementation of Union environmental policy and legislation

#### 1.3. Nature of the proposal/initiative

- The proposal/initiative relates to a **new action**
- The proposal/initiative relates to a **new action following a pilot project/preparatory action**<sup>41</sup>
- The proposal/initiative relates to **the extension of an existing action**
- The proposal/initiative relates to **an action redirected towards a new action**

#### 1.4. Objectives

##### 1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

This proposal targets two of the Commission's strategic objectives:

- Managing risk in the modern world
- Global solidarity

by ensuring information exchange with and national decision making of third countries concerning the trade of dangerous substances and mixtures in line with the Rotterdam Convention.

##### 1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

Specific objective No.

**Environmental quality, chemicals & industrial emissions**

ABM/ABB activity(ies) concerned

<sup>40</sup> ABM: Activity-Based Management – ABB: Activity-Based Budgeting.  
<sup>41</sup> As referred to in Article 49(6)(a) or (b) of the Financial Regulation.



### 1.4.3. *Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

The objective of the proposal is to recast Regulation (EC) No 689/2008 to take into account:

- (1) the implementation of the Globally Harmonised System (GHS) of classification and labelling into Union legislation through the adoption of Regulation (EC) No 1272/2008;
- (2) the establishment of the European Chemicals Agency ("the Agency") under Regulation (EC) No 1907/2006;
- (3) the changes stemming from the Lisbon Treaty;
- (4) the experience of practical implementation achieved so far.

The expected results/effects are therefore:

- (1) an increase in access to and understanding of information, in particular for developing countries, on the dangerous substances subject to the proposal by implementation of GHS;
- (2) increased synergies with the implementation of REACH and CLP and later Biocides (see proposal for a new Regulation COM (2009) 267), by transferring administrative, technical and scientific work from the Commission to the Agency;
- (3) some proposed amendments will lead to a reduction of administrative burdens regarding exports that are exempted from export notification.

The proposal will therefore continue to meet the aims of the Rotterdam Convention, namely to promote shared responsibility and co-operative efforts among the Parties in the international trade of dangerous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use. This is done by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties

### 1.4.4. *Indicators of results and impact*

*Specify the indicators for monitoring implementation of the proposal/initiative.*

The proposed regulation, as is the case of the current regulation, aims at providing information to third countries and taking into account their decision on the import of substances exported from the EU although banned or severely restricted domestically. Indicators for monitoring the implementation of the proposal are therefore:

- the number of export notifications dispatched and import notifications received;
- the number of explicit consents requested;

- the number of problems encountered in the implementation of the proposed regulation and reported to the network of designated national authorities coordinated by the Commission;
- the number of violations of the provisions of the proposed regulation as identified by the national enforcement authorities

These indicators will be summarised in the reporting carried out by the Member states, the Agency and the Commission.

## **1.5. Grounds for the proposal/initiative**

### *1.5.1. Requirement(s) to be met in the short or long term*

The main requirement to be met is to align Regulation (EC) No 689/2008, which refers to specific classification and labelling provisions of Directive 67/548/EEC and Directive 1999/45/EC with the new provisions for classification and labelling set out in Regulation (EC) No 1272/2008, implementing the Globally Harmonised System (GHS) of classification and labelling into Union legislation, enabling operators to apply one consistent system of classification and labelling.

In addition the transfer of tasks from the Commission to the Agency ensures a more appropriate setting for carrying out the administrative, scientific and technical support to the implementation

### *1.5.2. Added value of EU involvement*

The proposed regulation does not alter any of the objectives set in Regulation (EC) No 689/2008 and hence the added value of EU involvement is identical to that of the current regulation.

Regulation (EC) No 689/2008 implements the Union's responsibilities as agreed in the Rotterdam Convention. As was seen at the time of adoption of Regulation (EC) No 689/2008 an EU regulation was the most efficient means of meeting those obligations

### *1.5.3. Lessons learned from similar experiences in the past*

The experience gained from the implementation of Regulation (EC) No 689/2008 shows that it is appropriate to include certain technical amendments to the operative provisions such as clarify the definitions of a substance, a mixture and an article, and the reference identification number required for exports that are not subject to export notification.

The scientific and technical work related to the implementation of Regulation (EC) No 689/2008 is being performed by the Commission's Joint Research Centre, due to its unique mandate within the Commission of providing scientific and technical support for the conception, development, implementation and monitoring of EU policies. Other scientific and technical work was also performed by the JRC in the past concerning industrial chemicals (Directive No 67/548/EEC, Regulation (EEC) No 793/93, Directive No 98/8/EC and Regulation No (EC) 1907/2006), but this has been or is in the process of being transferred to the Agency in Helsinki.

The creation of the Agency and the transfer of tasks from the JRC to the Agency were based on an extensive feasibility study, which concluded that an independent Agency was in the longer term the preferred structure to carry out the scientific and technical tasks needed for implementing the chemicals legislation in comparison to maintaining the work within the JRC. The feasibility study concluded that the decision could not be made due to any underlying differences in costs, but could be made based on structural differences:

- An independent Agency is better placed to receive and use fee income for performing specific tasks;
- An independent Agency is better placed to ensure long term stability in the number of staff allocated to specific tasks;
- An independent Agency can better ensure long term planning and resource availability for routine scientific tasks which need to be performed over a longer period of time.

The JRC was then seen to have the advantage that synergies could be achieved with other work being done on chemical legislation implementation, leading the feasibility study to conclude that an independent Agency located at the relevant site of the JRC would be the ideal solution.

The analysis and conclusions made in establishing the Agency for certain chemicals policy areas is equally valid and relevant for Regulation (EC) No 689/2008, with two important differences:

(1) the current recast of Regulation (EC) No 689/2008 does not foresee fees to be collected, albeit it will consider the feasibility at a later stage;

(2) not the JRC but the Agency now houses the competences for implementing certain other chemical policies.

It can therefore be concluded that the scientific and technical work necessary for implementing Regulation (EC) No 689/2008 can best be done by an independent Agency, in particular if at a later stage fees will be collected and that the best location of that Agency would be in Helsinki, to utilise the synergies which can be obtained from the Agency's other chemicals work. Clearly adding the tasks to an existing Agency will be more efficient than creating a new Agency, as the functioning administrative infrastructure can be used and synergies in terms of staff and infrastructure can be expected.

#### 1.5.4. *Coherence and possible synergy with other relevant instruments*

The proposal is fully in line with existing policies and objectives aimed at protecting human health and the environment globally such as those laid down in the 6th Environmental Action Programme.

By placing the scientific and technical work related to the implementation of the proposed regulation at the Agency, synergies are expected with the implementation work carried out by the Agency on REACH, CLP and also in the future Biocides (proposal for a new Regulation COM (2009) 267).

## 1.6. Duration and financial impact

Proposal/initiative of **limited duration**

–  Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

–  Financial impact from YYYY to YYYY

Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from 2012 to 2013,

– followed by full-scale operation from 01.04.2013 (estimated).

## 1.7. Management mode(s) envisaged<sup>42</sup>

**Centralised direct management** by the Commission

**Centralised indirect management** with the delegation of implementation tasks to:

–  executive agencies

–  bodies set up by the Communities<sup>43</sup>

–  national public-sector bodies/bodies with public-service mission

–  persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

**Shared management** with the Member States

**Decentralised management** with third countries

**Joint management** with international organisations (*to be specified*)

*If more than one management mode is indicated, please provide details in the "Comments" section.*

Comments

<sup>42</sup> Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: [http://www.cc.cec/budg/man/budgmanag/budgmanag\\_en.html](http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html)

<sup>43</sup> As referred to in Article 185 of the Financial Regulation.

## **2. MANAGEMENT MEASURES**

### **2.1. Monitoring and reporting rules**

*Specify frequency and conditions.*

(1) Member States and the Agency will regularly forward to the Commission information concerning the operation of the Regulation, including customs controls, infringements, penalties and remedial action.

(2) The Commission in turn will regularly compile a report on the operation of the Regulation for which it is responsible and shall incorporate it into a synthesis report integrating the information provided by the Member States and the Agency. Furthermore, the Commission will prepare a summary of the report for the purpose of publication on the Internet and forward it to the European Parliament and to the Council.

(3) The Member States, the Agency and the Commission will protect where necessary the confidentiality of data and its ownership.

### **2.2. Management and control system**

#### *2.2.1. Risk(s) identified*

The main risks are:

- failure of exporters to comply with their obligations;
- non uniform implementation of the proposal in Member States;
- insufficient control systems, e.g. customs controls, in Member States;
- failure of the Agency to carry out its tasks.

#### *2.2.2. Control method(s) envisaged*

Multiple management and control systems are in place or will be put in place to ensure the appropriate implementation of the proposed regulation:

- Member States are requested to designate authorities responsible for controlling exports and imports;
- The technical and scientific coordination of the EU's work is monitored through the meeting of the designated national authorities, chaired by the Commission;
- The day-to-day management of the Agency's tasks fall under the responsibility of the Executive Director, who in turn reports to the Agency's Management Board.

In addition this financial fiche gives the basis for the subsidy necessary for the Agency to carry out its tasks.

### 2.3. Measures to prevent fraud and irregularities

*Specify existing or envisaged prevention and protection measures.*

The standard measures in place to prevent fraud and irregularities in the Commission apply for the tasks carried out by the Commission under this proposal.

In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1037/1999 apply without restrictions to this Agency.

The Agency has acceded to the Inter-institutional Agreement of May 25, 1999 concerning internal investigations by Olaf and has issued the appropriate provisions applicable to its entire staff.

The decisions concerning funding and the implementing agreements and instruments resulting from them stipulate that the Court of Auditors and Olaf may carry out, if necessary, on-the-spot checks of the recipients of the Agency's funding and the agents responsible for allocating it.

### 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

#### 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description.....]	DA/NDA <sup>(44)</sup>	from EFTA <sup>45</sup> countries	from candidate countries <sup>46</sup>	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
	[XX.YY.YY.YY]	DA/ND A	YES/N O	YES/N O	YES/N O	YES/NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading.....]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
2	07. 03 70 01 Chemicals Agency – Activities in the Field of Legislation on PIC – subsidy under Titles 1&2	Diff	YES	NO	NO	NO
2	07. 03 70 02 Chemicals Agency – Activities in the Field of Legislation on PIC– subsidy under Title 3	Diff	YES	NO	NO	NO

<sup>44</sup> DA= Differentiated appropriations / NDA= Non-Differentiated Appropriations

<sup>45</sup> EFTA: European Free Trade Association.

<sup>46</sup> Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

### 3.2. Estimated impact on expenditure

#### 3.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places)

<b>Heading of multiannual financial framework:</b>	Number	2. Preservation and Management of Natural Resources
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DG: Environment			2012	2013	2014	2015	2016 <sup>47</sup>	TOTAL	
• Operational appropriations									
07.03.70.01	Commitments	(1)	0,349	0,620	0,718	0,744	0,772		
	Payments	(2)	0,349	0,620	0,718	0,744	0,772		
07.03.70.02	Commitments	(1a)	1,122	1,012	0,563	0,463	0,363		
	Payments	(2a)	1,122	1,012	0,563	0,463	0,363		
Appropriations of an administrative nature financed from the envelop of specific programs <sup>48</sup>									
Number of budget line			(3)						
<b>TOTAL appropriations for DG Environment</b>			Commitments	=1+1a +3	1,470	1,632	1,281	1,207	1,135
			Payments	=2+2a +3	1,470	1,632	1,281	1,207	1,135

<sup>47</sup> The yearly budget remains unchanged from 2018 onwards

<sup>48</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)	1,470	1,632	1,281	1,207	1,135	
	Payments	(5)	1,470	1,632	1,281	1,207	1,135	
• TOTAL appropriations of an administrative nature financed from the envelop of specific programs		(6)						
<b>TOTAL appropriations under HEADING 2</b> of the multiannual financial framework	Commitments	=4+ 6	1,470	1,632	1,281	1,207	1,135	
	Payments	=5+ 6	1,470	1,632	1,281	1,207	1,135	

**If more than one heading is affected by the proposal / initiative:**

• TOTAL operational appropriations	Commitments	(4)						
	Payments	(5)						
• TOTAL appropriations of an administrative nature financed from the envelop of specific programs		(6)						
<b>TOTAL appropriations under HEADINGS 1 to 4</b> of the multiannual financial framework (Reference amount)	Commitments	=4+ 6						
	Payments	=5+ 6						

<b>Heading of multiannual financial framework:</b>	<b>5</b>	" Administrative expenditure "
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EUR million (to 3 decimal places)

		2012	2013	2014	2015	TOTAL
DG: Environment						
• Human resources		0,191	0,191	0,191	0,191	
• Other administrative expenditure		0,025	0,025	0,025	0,025	
<b>TOTAL DG Environment</b>	Appropriations	0,216	0,216	0,216	0,216	
DG: JRC						
• Human resources		0,058	0,039			
• Other administrative expenditure		0,088	0,059			
<b>TOTAL DG JRC</b>	Appropriations	0,146	0,098			

<b>TOTAL appropriations under HEADING 5 of the multiannual financial framework</b>	(Total commitments = Total payments)	0,362	0,314	0,216	0,216				
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EUR million (to 3 decimal places)

						TOTAL
<b>TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework</b>	Commitments	1,832	1,946	1,497	1,423	
	Payments	1,832	1,946	1,497	1,423	

3.2.2. *Estimated impact on operational appropriations*

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs  ↓			Year 2012	Year 2013	Year 2014	Year 2015	... enter as many years as necessary to show the duration of the impact (see point 1.6)										<b>TOTAL</b>			
	<b>OUTPUTS</b>																			
	Type of output <sup>49</sup>	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE No 1 <sup>50</sup> ...																				
- IT system			1	1,000	1	0,800	1	0,350	1	0,250										
- Export notifications				0,406	2000	0,768	5300	0,867	5800	0,893										
- DGDs + PIC notifications				0,064	2	0,064	7	0,064	7	0,064										
Sub-total for specific objective N°1				1,470		1,632		1,281		1,207										
SPECIFIC OBJECTIVE No 2...																				
- Output																				
Sub-total for specific objective N°2																				

<sup>49</sup> Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).  
<sup>50</sup> As described in Section 1.4.2. "Specific objective(s)..."

<b>TOTAL COST</b>		1,470		1,632		1,281		1,207								
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Current costs for the administrative, scientific and technical work that are covered by the operational budget 2010 -2011 (070307) amount to 444.000€ in 2010 and 400.000€ in 2011, and cover an Administrative Arrangement with the JRC and a service contract. The transfer to the Agency is expected to create high costs in 2012 and 2013 for development of new software, which would also be necessary for either alternative approach due to the age of the current database. After this initial phase, operating costs are expected to only slightly increase proportionally to the increase of the workload. An investment and transition phase is necessary in 2012-2013 in particular for IT investments by the Agency. Once the Agency activities have started in 2013, the overall expenditure of the Agency will be stable, while an increase in export notifications and requests for explicit consent processed is expected – the "unit cost" per output will therefore decrease from 163€ in 2014 to 106€ in 2020.

### 3.2.3. Estimated impact on appropriations of an administrative nature

#### 3.2.3.1. Summary

- The proposal/initiative does not require the use of administrative appropriations
- The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	Year 2012 <sup>51</sup>	Year 2013	Year 2014	Year 2015	... enter as many years as necessary to show the duration of the impact (see point 1.6)				<b>TOTAL</b>
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<b>DG ENV HEADING 5 of the multiannual financial framework</b>									
Human resources	0,191	0,191	0,191	0,191					
Other administrative expenditure	0,025	0,025	0,025	0,025					
<b>Subtotal DG ENV HEADING 5 of the multiannual financial framework</b>	<b>0,216</b>	<b>0,216</b>	<b>0,216</b>	<b>0,216</b>					

<b>DG JRC HEADING 5<sup>52</sup> of the multiannual financial framework</b>									
Human resources	0,058	0,039							
Other expenditure of an administrative nature	0,088	0,059							
<b>Subtotal DG JRC HEADING 5 of the multiannual financial framework</b>	<b>0,146</b>	<b>0,098</b>							

<b>TOTAL</b>	<b>0,362</b>	<b>0,314</b>	<b>0,216</b>	<b>0,216</b>					
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<sup>51</sup> Year N is the year in which implementation of the proposal/initiative starts.

<sup>52</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

The level of administrative expenditure in DG ENV will remain the same under the recast Regulation. JRC administrative expenditure (estimated at EUR 146.000 in 2011 will have to be maintained in 2012 and partly in 2013 in order to ensure continuity of operations until the Agency takes over operation of the system.

### 3.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources
- The proposal/initiative requires the use of human resources, as explained below:

*Estimate to be expressed in full amounts (or at most to one decimal place)*

	Year 2012	Year 2013	Year 2014	Year 2015	... enter as many years as necessary to show the duration of the impact (see point 1.6)		
<b>• Establishment plan posts (officials and temporary agents)</b>							
XX 01 01 01 (Headquarters and Commission's Representation Offices)	1,5	1,5	1,5	1,5			
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
<b>• External personnel (in Full Time Equivalent unit: FTE)<sup>53</sup></b>							
XX 01 02 01 (CA, INT, SNE from the "global envelope")							
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
<b>XX 01 04 yy</b> <sup>54</sup>	- at Headquarters <sup>55</sup>						
	- in delegations						
<b>XX 01 05 02</b> (CA, INT, SNE - Indirect research)							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							
<b>TOTAL</b>							

**XX** is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

The current distribution of tasks in the Commission is as follows:

- DG ENV runs the policy development and is responsible for implementation of the PIC Regulation in the EU, including the adoption of legislation, and for all international

<sup>53</sup> CA= Contract Agent; INT= agency staff ("Intérimaire"); JED= "Jeune Expert en Délégation" (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert;

<sup>54</sup> Under the ceiling for external personnel from operational appropriations (former "BA" lines).

<sup>55</sup> Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

obligations stemming from the Convention. DG ENV represents the European Union at Convention level, including the Chemical Review Committee, and does the international negotiations work.

- The JRC (Ispra) carries out the administrative and technical work relating to the EDEXIM database.

Since DG ENV will keep the complete work package, there are no changes as regards resources required. However, there will be savings in JRC from 2013 onwards due to the transfer of the work to the Agency.

Description of tasks to be carried out:

Officials and temporary agents	DG ENV is responsible for policy development and implementation of the PIC Regulation in the EU, including the adoption of legislation, and for all international obligations stemming from the Convention. DG ENV represents the European Union at Convention level, including the Chemical Review Committee, and does the international negotiations work.
External personnel	

3.2.4. *Compatibility with the current multiannual financial framework*

- Proposal/initiative is compatible with the current multiannual financial framework.
- Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework<sup>56</sup>.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties

The regulation contains a review clause where after no longer than 5 years of operation the Commission will review the possibility of introducing fees to finance the works carried out by the Agency, in contrast to doing so through the subsidy. This review will take into account the impact such fees will have on the economic operators involved. If the Commission decides to introduce fees, then this will be done through an amendment to the current proposal which would require adoption through the ordinary legislative procedure.

Appropriations in EUR million (to 3 decimal places)

	Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)	Total

<sup>56</sup> See points 19 and 24 of the Interinstitutional Agreement.

<i>Specify the co-financing body</i>								
TOTAL appropriations cofinanced								

### 3.3. Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
  - on own resources
  - on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget exercise	Impact of the proposal/initiative <sup>57</sup>					... insert as many columns as necessary in order to reflect the duration of the impact (see point 1.6)		
		Year N	Year N+1	Year N+2	Year N+3				
Article .....									

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

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<sup>57</sup> As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.

## ANNEX 1

### Draft Budget for the European Chemicals Agency (in Euros)

#### Tasks related to Prior Informed Consent

Expenditure	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
<b>Title 1</b>										
Salaries & allocations	251.100	471.800	505.900	523.800	543.800	563.900	570.600	570.600	570.600	570.600
Other personnel costs	33.600	45.600	67.800	70.200	72.900	75.600	76.500	76.500	76.500	76.500
<b>Total Title 1</b>	<b>284.700</b>	<b>517.400</b>	<b>573.700</b>	<b>594.000</b>	<b>616.700</b>	<b>639.500</b>	<b>647.100</b>	<b>647.100</b>	<b>647.100</b>	<b>647.100</b>
<b>Title 2</b>										
20 Rental of building and associated costs*	33.000	50.000	74.900	77.600	80.500	83.500	84.500	84.500	84.500	84.500
21 Information & communication technology**	21.100	33.700	49.700	51.400	53.400	55.400	56.000	56.000	56.000	56.000
22 Movable property and associated costs**	5.100	8.800	10.400	10.700	11.100	11.600	11.700	11.700	11.700	11.700
23 Current administrative expenditure*	4.700	9.900	9.500	9.800	10.200	10.500	10.700	10.700	10.700	10.700
25 Meetings expenditure*	100	200	200	200	200	200	200	200	200	200
<b>Total Title 2</b>	<b>64.000</b>	<b>102.600</b>	<b>144.700</b>	<b>149.700</b>	<b>155.400</b>	<b>161.200</b>	<b>163.100</b>	<b>163.100</b>	<b>163.100</b>	<b>163.100</b>
<b>Title 3</b>										
Development of databases and software tools related to the operation of PIC	1.000.000	800.000	350.000	250.000	150.000	150.000	100.000	100.000	100.000	100.000
Information and publications	10.000	10.000	10.000	10.000	10.000	10.000	10.000	10.000	10.000	10.000
Helpdesk services/Guidance	0	20.000	20.000	20.000	20.000	20.000	20.000	20.000	20.000	20.000
Studies and Consultants	100.000	100.000	100.000	100.000	100.000	100.000	100.000	100.000	100.000	100.000
Mission expenses	5.000	10.000	10.000	10.000	10.000	10.000	10.000	10.000	10.000	10.000
Technical training of staff and stakeholders	900	2.000	2.700	2.700	2.800	3.000	3.000	3.000	3.000	3.000
Meetings of the DNAs and expert groups on PIC implementation	5.700	70.000	70.200	70.200	70.200	70.200	70.200	70.200	70.200	70.200
<b>Total Title 3</b>	<b>1.121.600</b>	<b>1012.000</b>	<b>562.900</b>	<b>462.900</b>	<b>363.000</b>	<b>363.200</b>	<b>313.200</b>	<b>313.200</b>	<b>313.200</b>	<b>313.200</b>
<b>Total</b>	<b>1.470.300</b>	<b>1.632.000</b>	<b>1.281.300</b>	<b>1.206.600</b>	<b>1.135.100</b>	<b>1.163.900</b>	<b>1.123.400</b>	<b>1.123.400</b>	<b>1.123.400</b>	<b>1.123.400</b>
<b>Revenues</b>										
<b>Union subvention</b>	1.470.300	1.632.000	1.281.300	1.206.600	1.135.100	1.163.900	1.123.400	1.123.400	1.123.400	1.123.400
<b>Total</b>	<b>1.470.300</b>	<b>1.632.000</b>	<b>1.281.300</b>	<b>1.206.600</b>	<b>1.135.100</b>	<b>1.163.900</b>	<b>1.123.400</b>	<b>1.123.400</b>	<b>1.123.400</b>	<b>1.123.400</b>

## ANNEX II

### Applied methodology and main underlying assumptions for the financial model of the European Chemicals Agency for activities relating to PIC

#### Computation of staff costs

Due to the fact that the European Chemicals Bureau (ECB) of the Commission JRC in Ispra currently has a major role in implementing Regulation (EC) 689/2008, significant experience exists with regard to how long certain tasks take and what kind of qualifications are needed in order to carry them out (differentiation between different categories of staff).

To this staff additional resource requirements have been added for the management and training of these resources, taking into account economies of scale that can be achieved in particular in support tasks and staff from existing arrangements set up for the implementation of the REACH, CLP and Biocides Regulations (e.g. for international relations, for external communication, helpdesk services, the Legal Department, Audit and Internal Control, Human Resources (HR), Finance, Information Technology (IT) and Building Management). Based on the current staff ratio of the Agency, these additional resources amount to 30% of those required for the operational tasks related to the PIC regulation.

From January 2012, it is proposed that the Agency should be able to start work, primarily on developing the IT system, setting up internal procedures, and set off the recruit procedures for staff for 2012.

For 2012, it is proposed that the Agency should be able to recruit most of the required staff and ensure from the Agency's side a smooth hand-over of the PIC tasks from the Commission.

From 1 April 2013, the Agency would then be responsible for the different tasks set out in the proposal.

Annex III sets out the proposed establishment plan related to this proposal. The budget set out in Annex I takes into account permanent / temporary staff (i.e. that appear in establishment plan).

All the resources computed have been multiplied by the average annual cost by grade and that has led to the total staff costs. In addition, the weighting factor for Helsinki (119.8% – cost of living adjustment applicable to all staff) has been applied.

The other personnel costs in Title 1 have been assumed to represent 10% of salary costs of permanent / temporary staff.

#### **Applied average costs for permanent/temporary staff by grade per annum (source the Agency)**

Grade	Salary
AD 13	243,156
AD 12	195,900
AD 5-11	120,288
AST 7-8	104,778
AST 1-6	66,872

**Applied average costs for contract agents by function group per annum (source the Agency)**

Grade	Salary
FG IV	55,869
FG III	55,287
FG II	37,319
FG I	34,813

Computation of building, equipment and miscellaneous operating expenditure:

All building, equipment, furniture, IT and other administrative expenditure have been computed based on the number of required staff multiplied by average cost figures per person based on the current Agency budget.

Operating expenditure:

The major cost driver for the first years is the development of an IT system to support the PIC implementation. In addition it is foreseen that the Agency hosts one technical meeting with Member States per year, has an expert support groups for the IT development and maintain and can give training to Member State staff.

There is also a continuous expense for consultancies to support in particular the Agency's annual and regular reporting.

Finally, the mission expenses are higher than average per staff compared to the current tasks of the Agency due to the international character of the work and the need for the Commission to have scientific and technical support on site at international meetings.

**ANNEX III**  
**European Chemicals Agency**  
**ESTABLISHMENT PLAN**  
**Additional staff to carry out activities related to PIC**

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
AD 13	0	0	0	0	0	0	0	0	0	0
AD 12	0	0	0	0	0	0	0	0	0	0
AD 5-11	1	1	1	1	1	1	1	1	1	1
AST 7-11	1	3	2	2	2	2	2	2	2	2
AST 1-6	1	1	2,7	3,0	3,3	3,6	3,6	3,6	3,6	3,6
Overall	3	5	6	6	6	7	7	7	7	7