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$ightharpoonup \underline{B}$ $ightharpoonup \underline{C1}$ REGULATION (EC) No 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

on persistent organic pollutants and amending Directive 79/117/EEC ◀

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► <u>M1</u>	Council Regulation (EC) No 1195/2006 of 18 July 2006	L 217	1	8.8.2006
► <u>M2</u>	Council Regulation (EC) No 172/2007 of 16 February 2007	L 55	1	23.2.2007
<u>M3</u>	Commission Regulation (EC) No 323/2007 of 26 March 2007	L 85	3	27.3.2007
► <u>M4</u>	Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009	L 87	109	31.3.2009
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REGULATION (EC) No 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

on persistent organic pollutants and amending Directive 79/117/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty (2),

Whereas:

- (1) This Regulation primarily concerns environmental protection and the protection of human health. The legal basis is therefore Article 175(1) of the Treaty.
- (2) The Community is seriously concerned by the continuous release of persistent organic pollutants into the environment. These chemical substances are transported across international boundaries far from their sources and they persist in the environment, bioaccumulate through the food web, and pose a risk to human health and the environment. Further measures need therefore to be taken in order to protect human health and the environment against these pollutants.
- (3) In view of its responsibilities for the protection of the environment, the Community signed on 24 June 1998 the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, hereinafter 'the Protocol', and on 22 May 2001 the Stockholm Convention on Persistent Organic Pollutants, hereinafter 'the Convention'.
- (4) While legislation at Community level relating to persistent organic pollutants has been put in place, its main deficiencies are that there is an absence of, or incomplete legislation on, prohibition of the production and use of any of the currently listed chemicals, that there is no framework to subject additional persistent organic pollutant substances to prohibitions, restrictions or elimination, nor any framework to prevent the production and use of new substances that exhibit persistent organic pollutant characteristics. No emission reduction targets, as such, have been set at Community level and the current release inventories do not cover all sources of persistent organic pollutants.
- (5) In order to ensure coherent and effective implementation of the Community's obligations under the Protocol and the Convention, it is necessary to establish a common legal framework, within

⁽¹⁾ OJ C 32, 5.2.2004, p. 45.

⁽²⁾ Opinion of the European Parliament of 26 February 2004 (not yet published in the Official Journal) and Decision of the Council of 26 April 2004.

- which to take measures designed in particular to eliminate the production, placing on the market and use of intentionally produced persistent organic pollutants. Furthermore, persistent organic pollutants' characteristics should be taken into consideration in the framework of the relevant Community assessment and authorisation schemes.
- (6) Coordination and coherence should be ensured when implementing at Community level the provisions of the Rotterdam (¹), Stockholm and Basel Conventions (²) and when participating in the development of the Strategic Approach to International Chemicals Management (SAICM) within the United Nations framework.
- (7) Moreover, considering that the provisions of this Regulation are underpinned by the precautionary principle as set forth in the Treaty, and mindful of Principle 15 of the Rio Declaration on Environment and Development and in view of the aim of elimination, where feasible, of the release of persistent organic pollutants into the environment, it is appropriate in certain cases to provide for control measures stricter than those under the Protocol and the Convention.
- (8) In the future, the proposed REACH Regulation could be an appropriate instrument by which to implement the necessary control measures on production, placing on the market and use of the listed substances and the control measures on existing and new chemicals and pesticides exhibiting persistent organic pollutants' characteristics. However, without prejudice to the future REACH Regulation and since it is important to implement these control measures on the listed substances of the Protocol and the Convention as soon as possible, this Regulation should for now implement those measures.
- In the Community, the placing on the market and use of most of the persistent organic pollutants listed in the Protocol or the Convention has already been phased out as a result of the prohibitions laid down in Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (3) and Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (4). However, in order to fulfil the Community's obligations under the Protocol and the Convention and to minimise the release of persistent organic pollutants, it is necessary and appropriate also to prohibit the production of those substances and to restrict exemptions to a minimum so that exemptions only apply where a substance fulfils an essential function in a specific application.
- (10) Exports of substances covered by the Convention and exports of lindane are regulated by 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 (5).
- (11) The production and use of hexachlorocyclohexane (HCH), including lindane, is subject to restrictions under the Protocol

⁽¹⁾ Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

⁽²⁾ Convention on the control of transboundary movements of hazardous wastes and their disposal.

⁽³⁾ OJ L 33, 8.2.1979, p. 36. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

⁽⁴⁾ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2004/21/EC (OJ L 57, 25.2.2004, p. 4).

⁽⁵⁾ OJ L 63, 6.3.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 775/2004 (OJ L 123, 27.4.2004, p. 27).

but not totally prohibited. That substance is still used in some Member States and therefore it is not possible to prohibit immediately all existing uses. However, in view of the harmful properties of HCH and the possible risks related to its release into the environment, its production and uses should be confined to a minimum and ultimately phased out by the end of 2007 at the latest.

- Obsolete or carelessly managed stockpiles of persistent organic (12)pollutants may seriously endanger the environment and human health through, for instance, contamination of soil and ground water. It is appropriate, therefore, to adopt provisions that go beyond the provisions laid down in the Convention. Stockpiles of prohibited substances should be treated as waste, while stockpiles of substances the production or use of which is still allowed should be notified to the authorities and properly supervised. In particular, existing stockpiles which consist of or contain banned persistent organic pollutants should be managed as waste as soon as possible. If other substances are banned in the future, their stocks should also be destroyed without delay and no new stockpiles should be built up. In view of the particular problems of certain new Member States, adequate financial and technical assistance should be provided through existing Community financial instruments, such as the Cohesion and Structural Funds.
- (13) In line with the Communication from the Commission on the Community Strategy for Dioxins, Furans and Polychlorinated Biphenyls (PCBs) (¹), and with the Protocol and the Convention, releases of persistent organic pollutants which are unintentional by-products of industrial processes should be identified and reduced as soon as possible with the ultimate aim of elimination, where feasible. Appropriate national action plans, covering all sources and measures, including those provided for under existing Community legislation, should be drawn up and implemented to reduce the releases continuously and cost-effectively as soon as possible. To this end, appropriate tools should be developed in the framework of the Convention.
- (14) In line with that Communication, appropriate programmes and mechanisms should be established to provide adequate monitoring data on the presence of dioxins, furans and PCBs in the environment. However, it is necessary to ensure that appropriate tools are available and can be used under economically and technically viable conditions.
- (15) Under the Convention, the persistent organic pollutant content in waste is to be destroyed or irreversibly transformed into substances that do not exhibit similar characteristics, unless other operations are environmentally preferable. Since current Community legislation on waste does not lay down specific rules as regards those substances, they should be laid down in this Regulation. To ensure a high level of protection, common concentration limits for the substances in waste should be established before 31 December 2005.
- (16) The importance of identifying and separating waste consisting of, containing or contaminated by persistent organic pollutants at source in order to minimise the spreading of these chemicals into other waste is recognised. Council Directive 91/689/EEC of 12 December 1991 on hazardous waste (2) established Community rules on the management of hazardous waste obliging Member States to take the necessary measures to require that establishments and undertakings which dispose of,

⁽¹⁾ OJ C 322, 17.11.2001, p. 2.

⁽²⁾ OJ L 377, 31.12.1991, p. 20. Directive as amended by Directive 94/31/EC (OJ L 168, 2.7.1994, p. 28).

- recover, collect or transport hazardous waste do not mix different categories of hazardous waste or mix hazardous waste with non-hazardous waste.
- (17) The Convention provides that each Party is to draw up a plan for the implementation of its obligations under the Convention. Member States should provide opportunities for public participation in drawing up their implementation plans. Since the Community and the Member States share competence in that regard, implementation plans should be drawn up both at national and Community level. Cooperation and an exchange of information between the Commission and the authorities of the Member States should be promoted.
- (18) In accordance with the Convention and the Protocol, information on persistent organic pollutants should be provided to other Parties. The exchange of information with third countries not party to those Agreements should also be promoted.
- (19) Public awareness of the hazards that persistent organic pollutants pose to the health of present and future generations as well as to the environment, particularly in developing countries, is often lacking, and wide-scale information is therefore needed to increase the level of caution and gain support for restrictions and bans. In accordance with the Convention, public awareness programmes on these substances, especially for the most vulnerable groups, as well as training of workers, scientists, educators, technical and managerial personnel should be promoted and facilitated, as appropriate.
- (20) Upon request and within available resources, the Commission and the Member States should cooperate in providing appropriate and timely technical assistance designed especially to strengthen the capacity of developing countries and countries with economies in transition to implement the Convention. Technical assistance should include the development and implementation of suitable alternative products, methods and strategies, inter alia, to the use of DDT in disease vector control which, under the Convention, can only be used in accordance with World Health Organisation recommendations and guidelines and when locally safe, effective and affordable alternatives are not available to the country in question.
- (21) There should be regular evaluation of the effectiveness of the measures taken to reduce releases of persistent organic pollutants. To that end, Member States should report regularly to the Commission, in particular as regards release inventories, notified stockpiles and the production and placing on the market of restricted substances. The Commission, in cooperation with Member States, should develop a common format for Member States' reports.
- (22) The Convention and the Protocol provide that Parties thereto may propose other substances for international action and consequently additional substances may be listed under those Agreements, in which case this Regulation should be amended accordingly. Furthermore, it should be possible to modify the existing entries in Annexes to this Regulation, inter alia for the purposes of adapting them to scientific and technical progress.
- (23) When Annexes to this Regulation are amended to implement any listings of an additional, intentionally produced persistent organic pollutant in the Protocol or in the Convention, it should be included in Annex II, instead of Annex I, only in exceptional cases and when duly justified.
- (24) 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 conferred on the Commission (1).
- (25) In order to ensure transparency, impartiality and consistency at the level of enforcement activities, Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive, since non-compliance can result in damage to human health and the environment. Information on infringements of the provisions of this Regulation should be made public, where appropriate.
- (26) Since the objectives of this Regulation, namely to protect the environment and human health from persistent organic pollutants, cannot be sufficiently achieved by the Member States, owing to the transboundary effects of those pollutants, and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. 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.
- (27) In the light of the above, Directive 79/117/EEC should be amended,

HAVE ADOPTED THIS REGULATION:

Article 1

Objective and scope

- 1. Taking into account, in particular, the precautionary principle, the objective of this Regulation is to protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting the production, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants, hereinafter 'the Convention', or the 1998 Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, hereinafter 'the Protocol', and by minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of these substances.
- 2. Articles 3 and 4 shall not apply to waste consisting of, containing or contaminated by any substance listed in Annexes I or II.

Article 2

Definitions

For the purposes of this Regulation:

- (a) 'placing on the market' means supplying or making available to third persons against payment or free of charge. Imports into the customs territory of the Community shall also be deemed to be placed on the market;
- (b) 'article' means an object composed of one or more substances and/or preparations which during production is given a specific

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

- shape, surface or design determining its end use function to a greater extent than its chemical composition does;
- (c) 'substance' is as defined in Article 2 of Council Directive 67/548/EEC (¹);
- (d) 'preparation' is as defined in Article 2 of Directive 67/548/EEC;
- (e) 'waste' is as defined in Article 1(a) of Council Directive 75/442/EEC (2);
- (f) 'disposal' is as defined in Article 1(e) of Directive 75/442/EEC;
- (g) 'recovery' is as defined in Article 1(f) of Directive 75/442/EEC.

Control of production, placing on the market and use

- 1. The production, placing on the market and use of substances listed in Annex I, whether on their own, in preparations or as constituents of articles, shall be prohibited.
- 2. The production, placing on the market and use of substances listed in Annex II, whether on their own, in preparations or as constituents of articles, shall be restricted in accordance with the conditions set out in that Annex.
- 3. Member States and the Commission shall, within the assessment and authorisation schemes for existing and new chemicals and pesticides under the relevant Community legislation, take into consideration the criteria set out in paragraph 1 of Annex D to the Convention and take appropriate measures to control existing chemicals and pesticides and prevent the production, placing on the market and use of new chemicals and pesticides, which exhibit characteristics of persistent organic pollutants.

Article 4

Exemptions from control measures

- 1. Article 3 shall not apply in the case of:
- (a) a substance used for laboratory-scale research or as a reference standard;
- (b) a substance occurring as an unintentional trace contaminant in substances, preparations or articles.
- 2. Article 3 shall not apply in respect of substances occurring as a constituent of articles produced before or on the date of entry into force of this Regulation until six months after the date of its entry into force.

Article 3 shall not apply in the case of a substance occurring as a constituent of articles already in use before or on the date of entry into force of this Regulation.

However, immediately upon becoming aware of articles referred to in the first and second subparagraph, a Member State shall inform the Commission accordingly.

⁽¹) 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 P 196, 16.8.1967, p. 1). Directive as last amended by Council Regulation (EC) No 807/2003.

⁽²⁾ Council Directive 75/442/EEC of 15 July 1975 on waste (OJ L 194, 25.7.1975, p. 39). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

Whenever the Commission is so informed or otherwise learns of such articles, it shall, where appropriate, notify the Secretariat of the Convention accordingly without further delay.

3. Where a substance is listed in Part A of Annex I or in Part A of Annex II, a Member State wishing to permit, until the deadline specified in the relevant Annex, the production and use of that substance as a closed-system site-limited intermediate shall notify accordingly the Secretariat of the Convention.

However, such notification may be made only if the following conditions are satisfied:

- (a) an annotation has been entered in the relevant Annex expressly to the effect that such production and use of that substance may be permitted;
- (b) the manufacturing process will transform the substance into one or more other substances that do not exhibit the characteristics of a persistent organic pollutant;
- (c) it is not expected that either humans or the environment will be exposed to any significant quantities of the substance during its production and use, as shown through assessment of that closed system in accordance with Commission Directive 2001/59/EC (¹).

The notification shall be communicated also to the other Member States and to the Commission and shall give details of actual or estimated total production and use of the substance concerned and the nature of the closed-system site-limited process, specifying the amount of any non-transformed and unintentional trace contamination by any persistent organic pollutant starting material in the final product.

The deadlines referred to in the first subparagraph may be amended in cases where, following a repeat notification from the Member State concerned to the Secretariat of the Convention, express or tacit consent is issued under the Convention for the continued production and use of the substance for another period.

Article 5

Stockpiles

- 1. The holder of a stockpile, which consists of or contains any substance listed in Annex I or Annex II, for which no use is permitted, shall manage that stockpile as waste and in accordance with Article 7.
- 2. The holder of a stockpile greater than 50 kg, consisting of or containing any substance listed in Annex I or Annex II, and the use of which is permitted shall provide the competent authority of the Member State in which the stockpile is established with information concerning the nature and size of that stockpile. Such information shall be provided within 12 months of the entry into force of this Regulation and of amendments to Annexes I or II and annually thereafter until the deadline specified in Annex I or II for restricted use.

The holder shall manage the stockpile in a safe, efficient and environmentally sound manner.

3. Member States shall monitor the use and management of notified stockpiles.

⁽¹) Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 225, 21.8.2001, p. 1).

Release reduction, minimisation and elimination

- 1. Within two years of the date of entry into force of this Regulation, Member States shall draw up and maintain release inventories for the substances listed in Annex III into air, water and land in accordance with their obligations under the Convention and the Protocol.
- 2. A Member State shall communicate its action plan on measures to identify, characterise and minimise with a view to eliminating where feasible as soon as possible the total releases developed in accordance with its obligations under the Convention, to both the Commission and the other Member States as part of its national implementation plan, pursuant to Article 8.

The action plan shall include measures to promote the development and, where it deems appropriate, shall require the use of substitute or modified materials, products and processes to prevent the formation and release of the substances listed in Annex III.

3. Member States shall, when considering proposals to construct new facilities or significantly to modify existing facilities using processes that release chemicals listed in Annex III, without prejudice to Council Directive 1996/61/EC (¹), give priority consideration to alternative processes, techniques or practices that have similar usefulness but which avoid the formation and release of substances listed in Annex III.

Article 7

Waste management

- 1. Producers and holders of waste shall undertake all reasonable efforts to avoid, where feasible, contamination of this waste with substances listed in Annex IV.
- 2. Notwithstanding Directive 96/59/EC (²), waste consisting of, containing or contaminated by any substance listed in Annex IV shall be disposed of or recovered, without undue delay and in accordance with Annex V, part 1 in such a way as to ensure that the persistent organic pollutant content is destroyed or irreversibly transformed so that the remaining waste and releases do not exhibit the characteristics of persistent organic pollutants.

In carrying out such a disposal or recovery, any substance listed in Annex IV may be isolated from the waste, provided that this substance is subsequently disposed of in accordance with the first subparagraph.

- 3. Disposal or recovery operations that may lead to recovery, recycling, reclamation or re-use of the substances listed in Annex IV shall be prohibited.
- 4. By way of derogation from paragraph 2:

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(a) waste containing or contaminated by any substance listed in Annex IV may be otherwise disposed of or recovered in accordance with the relevant Community legislation, provided that the content of the listed substances in the waste is below the concentration limits to be specified in Annex IV. Those measures, designed to amend non-essential elements of this Regu-

⁽¹⁾ Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26. Directive as last amended by Regulation (EC) No 1882/2003.

last amended by Regulation (EC) No 1882/2003.

(2) Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) (OJ L 243, 24.9.1996, p. 31).

▼M4

lation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 17(3). Until such time as concentration limits are established in accordance with such procedure, the competent authority of a Member State may adopt or apply concentration limits or specific technical requirements in respect of the disposal or recovery of waste under this point.

▼C1

- (b) a Member State or the competent authority designated by that Member State may, in exceptional cases, allow wastes listed in Annex V, part 2 containing or contaminated by any substance listed in Annex IV up to concentration limits to be specified in Annex V, part 2, to be otherwise dealt with in accordance with a method listed in Annex V, part 2 provided that:
 - (i) the holder concerned has demonstrated to the satisfaction of the competent authority of the Member State concerned that decontamination of the waste in relation to substances listed in Annex IV was not feasible, and that destruction or irreversible transformation of the persistent organic pollutant content, performed in accordance with best environmental practice or best available techniques, does not represent the environmentally preferable option and the competent authority has subsequently authorised the alternative operation;
 - (ii) this operation is in accordance with the relevant Community legislation and the conditions laid down in relevant additional measures referred to in paragraph 6; and
 - (iii) the Member State concerned has informed the other Member States and the Commission of its authorisation and the justification for it.
- ►M4 Concentration limits in Annex V, part 2 shall be established by the Commission for the purposes of paragraph 4(b) of this Article. Those 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 17(3). ◀

Until such time as these concentration limits are established:

- (a) the competent authority may adopt or apply concentration limits or specific technical requirements in respect of waste being dealt with under paragraph 4(b);
- (b) where waste is being dealt with under paragraph 4(b), the holders concerned shall provide information on the persistent organic pollutant content of the waste to the competent authority.
- The Commission may, where appropriate, and taking into consideration technical developments and relevant international guidelines and decisions and any authorisations granted by a Member State, or the competent authority designated by that Member State in accordance with paragraph 4 and Annex V, adopt additional measures relating to the implementation of this Article. The Commission shall define a format for the submission of the information by Member States in accordance with paragraph 4(b)(iii). Such measures shall be decided in accordance with the procedure laid down in Article 17(2).
- The Commission shall, before 31 December 2009, review the derogations in paragraph 4 in the light of international and technical developments, in particular with regard to their environmental preferability.

Implementation plans

- 1. When preparing their national implementation plans, Member States shall, in accordance with their national procedures, give the public early and effective opportunities to participate in this process.
- As soon as a Member State has adopted its national implementation plan in accordance with its obligations under the Convention, it shall communicate it both to the Commission and to the other Member States.
- 3. When preparing their implementation plans, the Commission and the Member States shall exchange information on the content, as appropriate.
- 4. The Commission shall, within two years of the entry into force of this Regulation, draw up a plan for the implementation of Community obligations under the Convention.

As soon as the Commission has adopted the Community implementation plan, it shall communicate it to the Member States.

The Commission shall review and update the Community implementation plan, as appropriate.

Article 9

Monitoring

The Commission and the Member States shall establish, in close cooperation, appropriate programmes and mechanisms, consistent with the state of the art, for the regular provision of comparable monitoring data on the presence of dioxins, furans and PCBs as identified in Annex III in the environment. When establishing such programmes and mechanisms, due account shall be taken of developments under the Protocol and the Convention.

Article 10

Information exchange

- 1. The Commission and the Member States shall facilitate and undertake the exchange within the Community and with third countries of information relevant to the reduction, minimisation or elimination, where feasible, of the production, use and release of persistent organic pollutants and to alternatives to those substances, specifying the risks and the economic and social costs related to such alternatives.
- 2. The Commission and Member States, as appropriate, shall promote and facilitate with regard to persistent organic pollutants:
- (a) awareness programmes, including relating to their health and environmental effects and their alternatives and on the reduction or elimination of their production, use and release, especially for:
 - (i) policy and decision makers,
 - (ii) particularly vulnerable groups;
- (b) the provision of public information;
- (c) training, including workers, scientists, educators and technical and managerial personnel.

▼<u>C1</u>

3. Without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information (¹), information on health and safety of humans and the environment shall not be regarded as confidential. The Commission and the Member States that exchange other information with a third country shall protect any confidential information as mutually agreed.

Article 11

Technical assistance

In accordance with Articles 12 and 13 of the Convention, the Commission and the Member States shall cooperate in providing appropriate and timely technical and financial assistance to developing countries and countries with economies in transition to assist them, upon request and within available resources and taking into account their particular needs, to develop and strengthen their capacity to fully implement their obligations under the Convention. Such support may also be channelled through non-governmental organisations.

Article 12

Reporting

- 1. Member States shall every three years forward to the Commission information on the application of this Regulation, including information on infringements and penalties.
- 2. Member States shall provide the Commission every year with statistical data on the actual or estimated total production and placing on the market of any substance listed in Annex I or II.
- 3. Within three years of the date of entry into force of this Regulation and every three years thereafter, Member States shall provide the Commission with:
- (a) summary information compiled from the notifications, concerning stockpiles, received pursuant to Article 5(2);
- (b) summary information compiled from the release inventories drawn up pursuant to Article 6(1);
- (c) summary information on the presence of dioxins, furans and PCBs as identified in Annex III in the environment, as compiled pursuant to Article 9.
- 4. As regards the data and information to be provided by Member States pursuant to paragraphs 1, 2 and 3, the Commission shall develop in advance a common format in accordance with the procedure referred to in Article 16(2).
- 5. Regarding the substances listed in the Convention, the Commission shall, at intervals to be determined by the Conference of the Parties of the Convention, compile a report on the basis of the information provided by the Member States in accordance with paragraph 2 and communicate it to the Secretariat of the Convention.

6. The Commission shall every three years compile a report on the application of this Regulation and shall integrate it with the information already available in the context of the EPER, as established by Commission Decision 2000/479/EC (¹), and CORINAIR Emission Inventory of EMEP (Cooperative Programme for Monitoring and Evaluation of the Long-Range Transmission of Air Pollutants in Europe), and with the information provided by the Member States under paragraphs 1, 2 and 3 to form a synthesis report. This report shall include information on the use of derogations as referred to in Article 7(4). It shall forward a summary of the synthesis report to the European Parliament and to the Council and make it available to the public without delay.

Article 13

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission one year after entry into force of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

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Article 14

Amendment of Annexes

1. Whenever a substance is listed in the Convention or the Protocol, the Commission shall, where appropriate, amend Annexes I, II and III accordingly.

Those 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 16(3).

2. Whenever a substance is listed in the Convention or the Protocol, the Commission shall, where appropriate, amend Annex IV accordingly.

Those 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 17(3).

3. The Commission shall adopt modifications to the existing entries in Annexes I, II and III, including their adaptation to scientific and technical progress.

Those 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 16(3).

4. The Commission shall adopt modifications to the existing entries in Annex IV and modifications to Annex V, including their adaptation to scientific and technical progress.

Those 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 17(3).

⁽¹) Commission Decision 2000/479/EC of 17 July 2000 on the implementation of a European pollutant emission register (EPER) according to Article 15 of Council Directive 96/61/EC concerning integrated pollution prevention and control (IPPC) (OJ L 192, 28.7.2000, p. 36).

Competent authorities

Each Member State shall designate the competent authority or authorities responsible for the administrative tasks required by this Regulation. It shall inform the Commission of such designation at the latest three months after the entry into force of this Regulation.

Article 16

Committee for general matters

- 1. The Commission shall be assisted by the Committee established by Article 29 of Directive 67/548/EEC for all matters under this Regulation except for those relating to waste.
- 2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

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3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

▼C1

Article 17

Committee for waste matters

- 1. The Commission shall be assisted by the Committee established by Article 18 of Directive 75/442/EEC, for matters relating to waste under this Regulation.
- 2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

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3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

▼<u>C1</u>

Article 18

Amendments to Directive 79/117/EEC

In Part B of the Annex to Directive 79/117/EEC, 'Persistent organochlorine compounds', items 1 to 8 shall be deleted.

Article 19

Entry into force

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

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

ANNEX I

LIST OF SUBSTANCES SUBJECT TO PROHIBITIONS

Part A Substances listed in the Convention and in the Protocol

Substance	CAS No	EC No	SPECIFIC EXEMPTION ON INTER- MEDIATE USE OR OTHER SPECIFI- CATION
Aldrin	309-00-2	206-215-8	-
Chlordane	57-74-9	200-349-0	-
Dieldrin	60-57-1	200-484-5	-
Endrin	72-20-8	200-775-7	-
Heptachlor	76-44-8	200-962-3	-
Hexachlorobenzene	118-74-1	200-273-9	-
Mirex	2385-85-5	219-196-6	-
Toxaphene	8001-35-2	232-283-3	-
Polychlorinated Biphenyls (PCB)	1336-36-3 and others	215-648-1 and others	Without prejudice to Directive 96/59/EC, articles already in use at the time of entry into force of this Regulation are allowed to be used.
DDT (1,1,1-trichloro-2,2-bis(4-chlorophenyl) ethane)	50-29-3	200-024-3	Member States may allow the existing production and use of DDT as a closed-system site-limited intermediate for the production of dicofol until 1 January 2014, in accordance with Article 4(3) of this Regulation. The Commission shall review this exemption by 31.12.2008 in the light of the outcome of the evaluation in the framework of Directive 91/414/ EEC . (1)

⁽¹⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

Part B Substances listed only in the Protocol

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
Chlordecone	143-50-0	205-601-3	_
Hexabromobiphenyl	36355-01-8	252-994-2	_
HCH, including lindane	608-73-1, 58-89-9	210-168-9, 200-401-2	By way of derogation, Member States may allow the following uses (a) until 1.9.2006: — Professional remedial and industrial treatment of lumber, timber and logs; — Indoor industrial and residential applications; (b) until 31.12.2007: — Technical HCH for use as an intermediate in chemical manufacturing; — Products in which at least 99 % of the HCH isomer is in the gamma form (lindane) are restricted for use as public health and veterinary topical insecticide.

ANNEX II

LIST OF SUBSTANCES SUBJECT TO RESTRICTIONS

PART A — Substances listed in the Convention and in the Protocol

Substance	CAS No	EC No	Conditions of restriction	
_				
PART B — Substances listed only in the Protocol				
Substance	CAS No	EC No	Conditions of restriction	

ANNEX III

LIST OF SUBSTANCES SUBJECT TO RELEASE REDUCTION PROVISIONS

Substance (CAS No)

Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)

Hexachlorobenzene (HCB) (CAS No: 118-74-1)

Polychlorinated biphenyls (PCB)

Polycyclic aromatic hydrocarbons (PAHs) (1)

For the purpose of emission inventories, the following four compound indicators shall be used: benzo(a)pyrene, benzo(b) fluoranthene, benzo(k)fluoranthene and indeno(1,2,3-cd)pyrene.

 ${\it ANNEX~IV}$ List of substances subject to waste management provisions set out in article 7

Substance	CAS No	EC No	Concentration limit referred to in Article 7(4)(a)
Aldrin	309-00-2	206-215-8	50 mg/kg
Chlordane	57-74-9	200-349-0	50 mg/kg
Dieldrin	60-57-1	200-484-5	50 mg/kg
Endrin	72-20-8	200-775-7	50 mg/kg
Heptachlor	76-44-8	200-962-3	50 mg/kg
Hexachlorobenzene	118-74-1	200-273-9	50 mg/kg
Mirex	2385-85-5	219-196-6	50 mg/kg
Toxaphene	8001-35-2	232-283-3	50 mg/kg
Polychlorinated Biphenyls (PCB)	1336-36-3 and others	215-648-1	50 mg/kg (*)
DDT (1,1,1-trichloro- 2,2-bis(4-chlorophenyl) ethane)	50-29-3	200-024-3	50 mg/kg
Chlordecone	143-50-0	205-601-3	50 mg/kg
Polychlorinated dibenzo- p-dioxins and dibenzo- furans (PCDD/PCDF)			15 μg/kg (**)
The sum of alpha, beta- and gamma-HCH	58-89-9, 319-84-6, 319-85-7	206-270-8, 206-271-3 and 200-401-2	50 mg/kg
Hexabromobiphenyl	36355-01-8	252-994-2	50 mg/kg

^(*) Where applicable, the calculation method laid down in European standards EN 12766-1 and EN 12766-2 shall be applied. (**) ► M5 The limit is calculated as PCDD and PCDF according to the following toxic equivalency factors (TEFs):

PCDD	TEF
2,3,7,8-TeCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0,1
1,2,3,6,7,8-HxCDD	0,1
1,2,3,7,8,9-HxCDD	0,1
1,2,3,4,6,7,8-HpCDD	0,01
OCDD	0,0003
PCDF	TEF
2,3,7,8-TeCDF	0,1
1,2,3,7,8-PeCDF	0,03
2,3,4,7,8-PeCDF	0,3
1,2,3,4,7,8-HxCDF	0,1
1,2,3,6,7,8-HxCDF	0,1
1,2,3,7,8,9-HxCDF	0,1
2,3,4,6,7,8-HxCDF	0,1
1,2,3,4,6,7,8-HpCDF	0,01
1,2,3,4,7,8,9-HpCDF	0,01
OCDF	0,0003 ◀

ANNEX V

WASTE MANAGEMENT

Part 1 Disposal and recovery under Article 7(2)

The following disposal and recovery operations, as provided for in Annex IIA and IIB of Directive 75/442/EEC, are permitted for the purposes of Article 7(2) when applied in such a way as to ensure that the persistent organic pollutant content is destroyed or irreversibly transformed

- D9 Physico-chemical treatment,
- D10 Incineration on land, and
- R1 Use principally as a fuel or other means to generate energy, excluding waste containing PCBs.

▼M5

R4 Recycling/reclamation of metals and metal compounds, under the following conditions: The operations are restricted to residues from iron- and steel-making processes such as dusts or sludges from gas treatment or mill scale or zinc-containing filter dusts from steelworks, dusts from gas cleaning systems of copper smelters and similar wastes and lead-containing leaching residues of the non-ferrous metal production. Waste containing PCBs is excluded. The operations are restricted to processes for the recovery of iron and iron alloys (blast furnace, shaft furnace and hearth furnace) and non-ferrous metals (Waelz rotary kiln process, bath melting processes using vertical or horizontal furnaces), provided the facilities meet as minimum requirements the emission limit values for PCDDs and PCDFs laid down in Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste (1), whether or not the processes are subject to that Directive, and without prejudice to the other provisions of Directive 2000/76/EC where it applies and to the provisions of Directive 96/61/EC.

▼C1

Pre-treatment operation prior to destruction or irreversible transformation pursuant to this Part of this Annex may be performed, provided that a substance listed in Annex IV that is isolated from the waste during the pre-treatment is subsequently disposed of in accordance with this Part of this Annex. ▶ M5 Where only part of a product or waste, such as waste equipment, contains or is contaminated with persistent organic pollutants, it shall be separated and then disposed of in accordance with the requirements of this Regulation. ◀ In addition, repackaging and temporary storage operations may be performed prior to such pre-treatment or prior to destruction or irreversible transformation pursuant to this part of this Annex.

▼M2

Part 2 Wastes and operations to which Article 7(4)(b) applies

The following operations are permitted for the purposes of Article 7(4)(b) in respect of the wastes specified, defined by the six-digit code as classified in Commission Decision 2000/532/EC (²)

▼M3

Pre-treatment operations prior to permanent storage pursuant to this part of this Annex may be performed, provided that a substance listed in Annex IV that is isolated from the waste during the pre-treatment is subsequently disposed of in accordance with Part 1 of this Annex. In addition, repackaging and temporary storage operations may be performed prior to such pre-treatment or prior to permanent storage pursuant to this part of this Annex.

⁽¹⁾ OJ L 332, 28.12.2000, p. 91.

⁽²⁾ Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3). Decision as last amended by Council Decision 2001/573/EC (OJ L 203, 28.7.2001, p. 18).

and an analysis of	in Commission Decision 2000/532/EC	Maximum concentration limits of substances listed in Annex IV (1)	Operation	
10	WASTES FROM THERMAL PROCESSES	Chlordane: 5 000 mg/kg;	Permanent storage only in — safe, deep, underground	
10 01	Wastes from power stations and other combustion plants (except 19)	Dieldrin: 5 000 mg/kg; Endrin: 5 000 mg/kg; Heptachlor: 5 000 mg/kg; Hexachlorobenzene: 5 000 mg/kg; Mirex: 5 000 mg/kg; Toxaphene: 5 000 mg/kg; Polychlorinated Biphenyls (PCB) (3): 50 mg/kg; DDT (1,1,1-trichloro-2,2-	hard rock formations, — salt mines or — a landfill site for hazardous waste (provided that the waste is solidified or partly stabilised where technically feasible as required for classification of the waste ir subchapter 1903 or Decision 2000/532/EC)	
10 01 14 * (²)	Bottom ash, slag and boiler dust from co-incineration containing dangerous substances			
10 01 16 *	Fly ash from co-incineration containing dangerous substances			
10 02	Wastes from the iron and steel industry	Polychlorinated dibenzo-p-	whereby the provisions Council Directive 1999/	
10 02 07 *	Solid wastes from gas treatment containing dangerous substances	the sum of alpha-, beta- and gamma-HCH: 5 000 mg/kg;	EC (4) and Council Decision 2003/33/EC (5) have to adhered to and whereby has been demonstrated the	
10 03	Wastes from aluminium thermal metallurgy	Hexabromobiphenyl: 5 000 mg/kg	the selected operation environmentally preferable	
10 03 04 *	Primary production slags			
10 03 08 *	Salt slags from secondary production			
10 03 09 *	Black drosses from secondary production			
10 03 19 *	Flue-gas dust containing dangerous substances			
10 03 21 *	Other particulates and dust (including ball mill dust) containing dangerous substances			
10 03 29 *	Wastes from treatment of salt slags and black drosses containing dangerous substances			
10 04	Wastes from lead thermal metallurgy			
10 04 01 *	Slags from primary and secondary production			
10 04 02 *	Dross and skimmings from primary and secondary production			
10 04 04 *	Flue-gas dust			
10 04 05 *	Other particulates and dust			
10 04 06 *	Solid wastes from gas treatment			
10 05	Wastes from zinc thermal metallurgy			
10 05 03 *	Flue-gas dust			
10 05 05 *	Solid waste from gas treatment			
10 06	Wastes from copper thermal metallurgy			
10 06 03 *	Flue-gas dust			
10 06 06 *	Solid wastes from gas treatment			
	1		1	

▼<u>M2</u>

Wastes as classifie	d in Commission Decision 2000/532/EC	Maximum concentration limits of substances listed in Annex IV (1)	Operation
10 08 08 *	Salt slag from primary and secondary production		
10 08 15 *	Flue-gas dust containing dangerous substances		
10 09	Wastes from casting of ferrous pieces		
10 09 09 *	Flue-gas dust containing dangerous substances		
16	WASTES NOT OTHERWISE SPECIFIED IN THE LIST		
16 11	Waste linings and refractories		
16 11 01 *	Carbon-based linings and refractories from metallurgical processes containing dangerous substances		
16 11 03 *	Other linings and refractories from metallurgical processes containing dangerous substances		
17	CONSTRUCTION AND DEMOLITION WASTES (INCLUDING EXCAVATED SOIL FROM CONTAMINATED SITES)		
17 01	Concrete, bricks, tiles and ceramics		
17 01 06 *	Mixtures of, or separate fractions of concrete, bricks, tiles and ceramics containing dangerous substances		
17 05	Soil including excavated soil from contaminated sites, stones and dredging spoil		
17 05 03 *	Inorganic fraction of soil and stones containing dangerous substances		
17 09	Other construction and demo- lition wastes		
17 09 02 *	Construction and demolition wastes containing PCB, excluding PCB containing equipment		
17 09 03 *	Other construction and demo- lition wastes containing dangerous substances		
19	WASTES FROM WASTE MANAGEMENT FACILITIES, OFF-SITE WASTE WATER TREATMENT PLANTS AND THE PREPARATION OF WATER INTENDED FOR HUMAN CONSUMPTION AND WATER FROM INDUSTRIAL USE		
19 01	Wastes from incineration or pyrolysis of waste		

▼<u>M2</u>

Wastes as classified in 0	Commission Decision 2000/532/EC	Maximum concentration limits of substances listed in Annex IV (¹)	Operation
19 01 07 *	Solid wastes from gas treatment		
19 01 11 *	Bottom ash and slag containing dangerous substances		
19 01 13 *	Fly ash containing dangerous substances		
19 01 15 *	Boiler dust containing dangerous substances		
19 04	Vitrified waste and waste from vitrification		
19 04 02 *	Fly ash and other flue-gas treatment wastes		
19 04 03 *	Non-vitrified solid phase		

- (1) These limits exclusively apply to a landfill site for hazardous waste and do not apply to permanent underground storage facilities
- for hazardous wastes, including salt mines.

 (2) Any waste marked with an asterisk * is considered as hazardous waste pursuant to Directive 91/689/EEC and is subject to the provisions of that Directive.

 (3) Where applicable, the calculation method laid down in European standards EN 12766-1 and EN 12766-2 shall be applied.

 (4) Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182, 16.7.1999, p. 1). Directive as amended by
- Regulation (EC) No 1882/2003.
- Council Decision 2003/33/EC of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC (OJ L 11, 16.1.2003, p. 27).
- (6) M5 The limit is calculated as PCDD and PCDF according to the following toxic equivalency factors (TEFs):

PCDD	TEF
2,3,7,8-TeCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0,1
1,2,3,6,7,8-HxCDD	0,1
1,2,3,7,8,9-HxCDD	0,1
1,2,3,4,6,7,8-HpCDD	0,01
OCDD	0,0003
PCDF	TEF
2,3,7,8-TeCDF	0,1
1,2,3,7,8-PeCDF	0,03
2,3,4,7,8-PeCDF	0,3
1,2,3,4,7,8-HxCDF	0,1
1,2,3,6,7,8-HxCDF	0,1
1,2,3,7,8,9-HxCDF	0,1
2,3,4,6,7,8-HxCDF	0,1
1,2,3,4,6,7,8-HpCDF	0,01
1,2,3,4,7,8,9-HpCDF	0,01
OCDF	0,0003 ◀