



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on persistent organic pollutants and amending Directives 79/117/EEC and 96/59/EC

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. BACKGROUND

Persistent organic pollutants (POPs) are chemical substances that persist in the environment, bioaccumulate through the food web, and pose a risk of causing adverse effects to human health and the environment. These pollutants are transported across international boundaries far from their sources, even to regions where they have never been used or produced. The ecosystems and indigenous people of the Arctic are particularly at risk because of the long-range environmental transportation and biomagnification of these substances. Consequently, persistent organic pollutants pose a threat to the environment and to human health all over the globe. The international community has called for actions to reduce and eliminate production, use and releases of these substances.

The European Community and its Member States signed the Protocol to the regional UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP) on POPs in June 1998 and the global Stockholm Convention on POPs in May 2001. Most of the acceding and candidate States have also signed the Protocol and the Convention. Appropriate implementing legislation must now be put in place, at Community level, in order to conclude these international agreements. The proposals should be presented as a matter of urgency since:

- The Stockholm Convention will enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification. As of January 2003, 26 countries have already ratified the Convention.
- The UNECE Protocol on POPs will enter into force on the ninetieth day following the date on which the sixteenth instrument of ratification has been deposited. As of January 2003, 14 Parties to the CLRTAP have already ratified the Protocol.
- The commitment to ratify the global Convention without delay has been reinforced *inter alia* in the Sixth Environment Action Programme (Decision No 1600/2002/EC¹) and more recently in the political declaration made at Johannesburg World Summit on Sustainable Development.

The purpose of the proposed Regulation is to give effect to the main provisions of the Convention and the Protocol which are not yet sufficiently covered by Community legislation. Separate proposals for Council Decisions concerning the Community's conclusions on these two international agreements are being submitted in parallel to the present proposal.

¹ OJ L 242, 10.9.2002, p. 1.

2. THE UNECE PROTOCOL

The Executive Body to the CLRTAP adopted the Protocol on Persistent Organic Pollutants on 24 June 1998 in Aarhus (Denmark). It focuses on a list of 16 substances comprising eleven pesticides, two industrial chemicals and three unintentional by-products. The ultimate objective is to eliminate any discharges, emissions and losses of POPs. The Protocol bans the production and use of some products outright (aldrin, chlordane, chlordecone, dieldrin, endrin, hexabromobiphenyl, mirex and toxaphene). Others are scheduled for elimination at a later stage (DDT, heptachlor, hexachlorobenzene and polychlorinated biphenyls (PCBs)). Finally, the Protocol severely restricts the use of DDT, HCH (including lindane) and PCBs. The Protocol includes provisions for dealing with the wastes of products that will be banned. It also obliges Parties to reduce their emissions of dioxins, furans, PAHs and HCB below their levels in 1990 (or an alternative year between 1985 and 1995). For the incineration of municipal, hazardous and medical waste, it lays down specific limit values.

The UNECE Protocol on POPs was signed by 36 of 48 Parties to the CLRTAP, including all present Member States and all but three candidate countries (Estonia, Malta and Turkey). By March 2003, 14 Parties, including 7 Member States and 2 Candidate Countries had ratified the Protocol. Before the Protocol can enter into force, 16 ratifications are required.

3. THE STOCKHOLM CONVENTION

The Stockholm Convention on Persistent Organic Pollutants (POPs) was formally adopted by 127 governments and signed by 91 countries and by the European Community on 22-23 May 2001 in Stockholm, upon completion of three years of negotiations conducted in the framework of the United Nations Environment Programme (UNEP). The negotiations succeeded in establishing a strong international regime for promoting global action on an initial cluster of twelve POPs, which are all included in the UNECE Protocol, too. The overall objective of the Convention is to protect human health and the environment from POPs. Specific reference is made to a precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development. Most importantly, this principle is made operational in Article 8, which lays down the rules for including additional chemicals in the Convention. The nine intentionally produced chemicals currently listed in Annex A of the Convention (aldrin, chlordane, dieldrin, endrin, hexachlorobenzene, heptachlor, mirex, toxaphene and PCBs) are subject to a ban on production and use except where there are generic or specific exemptions. In addition, the production and use of DDT, a pesticide still used in many developing countries for malaria and other disease vector control, is severely restricted, as set out in Annex B of the Convention.

The generic exemptions allow laboratory-scale research, use as a reference standard and unintentional trace contaminants in products and articles. Articles in use containing POPs are also subject to an exemption provided that Parties submit information on the uses and the national plan for waste management for such articles to the Secretariat of the Convention.

Import and export of the ten intentionally produced POPs is severely restricted by the Convention. After all substance specific-exemptions have ceased, import and export is allowed only for the purpose of environmentally sound disposal under restricted conditions.

Special provisions are included in the Convention for those Parties with regulatory assessment schemes to review existing chemicals for POPs characteristics and to take regulatory measures with the aim of preventing the development, production and marketing of new substances with POP characteristics.

Releases of unintentionally produced by-products listed in Annex C (dioxins, furans, PCBs and HCB) are subject to continuous minimisation with, as objective, the ultimate elimination where feasible. The main tool for this are the National Action Plans, which should cover the source inventories and release estimates as well as plans for release reductions. The most stringent control provision with regard to by-products is that Parties shall promote and, in accordance with their action plans, require the use of best available techniques for new sources within their major source categories.

The Convention also foresees identification and safe management of stockpiles containing or consisting of POPs. Waste containing, consisting of or contaminated with POPs should be disposed of in such a way that the POP content is destroyed or irreversibly transformed so that it does not exhibit POPs characteristics. Where this does not represent the environmentally preferable option or where the POP content is low, waste shall be otherwise disposed of in an environmentally sound manner. Disposal operations that may lead to recovery or re-use of POPs are explicitly forbidden. With regard to shipment of wastes, relevant international rules, standards and guidelines, such as the Basel Convention on the Control of Transfrontier Movements of Hazardous Waste and their Disposal, are to be taken into account.

In addition to the control measures, the Convention includes several general obligations. Each Party is obliged to develop and endeavour to implement a National Implementation Plan, facilitate or undertake the exchange of information and promote and facilitate awareness and public access to information on POPs. The Parties shall also encourage or undertake appropriate research, development, monitoring and co-operation pertaining to POPs, and where relevant, to their alternatives and to candidate POPs. They shall also regularly report to the Conference of the Parties on the measures taken to implement the provisions of the Convention.

The Convention recognises the particular needs of developing countries and countries with economies in transition and therefore specific provisions on technical assistance and on financial resources and mechanisms are included in the general obligations.

Altogether 150 countries and the Community have signed the Stockholm Convention in the time limit set for signatories. By March 2003, 30 countries had already ratified it. After the fiftieth ratification the Convention will enter into force. All EU Member States and all but two candidate countries to the EU (Cyprus and Estonia) have signed the Convention, and so far six Member States and two Candidate Countries have already ratified the Convention.

4. EXISTING COMMUNITY RULES

Current Community legislation includes restrictions on marketing and use of most of the intentionally produced substances listed in the Convention and in the Protocol. However, there is no Community legislation on mirex, chlordecone or hexabromobiphenyl. The existing restrictions are given mainly in the framework of Council Directive 79/117/EEC² prohibiting the placing on the market and use of plant protection products containing certain active substances. The use restrictions of PCBs are laid down in Council Directive 76/769/EEC³ 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.

The main deficiency in the present Community legislation is that there is no legislation on prohibition of the production of any of the currently listed chemicals nor is there any framework to prohibit the production of new POPs added in the agreements in future. Another significant deficiency is that most of the existing Community prohibitions on the marketing and use of specific POP chemicals are not complete, as Directive 79/117/EEC only covers use of substances as plant protection products, not e.g. biocidal or industrial uses. Furthermore, placing on the market and use of chemicals occurring as constituents of articles are not in all cases banned, either, and exemptions given in the two limitations Directives are wider than those set in the Convention.

Most of the listed POP substances have already been included in Council Regulation (EEC) No 2455/92 concerning the export and import of certain dangerous chemicals⁴ and thus export and import of these substances is already subject to prior informed consent procedure. This Regulation has recently been replaced by Regulation (EC) No 304/2003 of the European Parliament and of the Council⁵, which implements the obligations of the Rotterdam Convention for the application of the Prior Informed Consent (PIC) procedure for certain hazardous chemicals and pesticides in international trade. Moreover, Regulation (EC) No 304/2003 prohibits export of the 10 POP substances currently listed in the Stockholm Convention according to the provisions therein.

The obligation to prevent marketing and use of new POP-like chemicals can already be implemented in the assessment schemes set for new substances (in the framework of Council Directive 67/548/EEC⁶), plant protection products (Council Directive 91/414/EEC⁷ and for biocides (Directive 98/8/EC of the European Parliament

² OJ L 33, 8.2.1979, p. 36. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

³ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2003/11/EC (OJ L 42, 15.2.2003, p. 45).

⁴ OJ L 251, 29.8.1992, p. 13. Regulation as last amended by Commission Regulation (EC) No 2247/98 (OJ L 282, 20.10.1998, p. 12).

⁵ OJ L 63, 6.3.2003, p. 1.

⁶ OJ P 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).

⁷ OJ L 242, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2003/5/EC (OJ L 8, 14.1.2003, p. 7).

and of the Council)⁸. However, production of new substances with POP characteristics cannot be prevented by any of these Directives. This should be covered by the future REACH system proposed in the White Paper on Strategy for a future Chemicals Policy (Communication of the Commission COM(2001) 88 final).

With regard to unintentionally produced POPs, there are several instruments in Community legislation that will have an impact on the reduction of releases of these substances. The main release control measures are set out in Directive 96/61/EC (the IPPC Directive)⁹, which covers the major stationary sources (industrial sources, energy industry and waste management) of by-product POPs. The European pollutant emission register (EPER), a Community-wide inventory of the principal emissions and responsible sources, was established by Commission Decision 2000/479/EC¹⁰ and it covers already all unintentionally produced POPs, except PCBs. The list of pollutants to be registered will be expanded due to other international obligations and also PCBs will be included.

The Waste Incineration Directive (Directive 2000/76/EC¹¹), which covers all waste incineration facilities, deals with a very important source of by-product POPs. In addition, the Directive on Large Combustion Plants (Directive 2001/80/EC¹²) is relevant from the POPs emissions point of view. Directive 2000/53/EC¹³ on end-of life vehicles imposes the segregation of hazardous components from the vehicle before any shredding of the carcass and an adequate disposal of the shredder residues. This would help decrease the releases of POPs from shredder plants, which are considered to be a source of POPs. The recently adopted Directives of the Council and the European Parliament on waste electrical and electronic equipment (WEEE) (Directive 2002/96/EC¹⁴) and on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2002/95/EC¹⁵) establish the mandatory segregation of PCB-containing components to ensure their adequate disposal and the restriction of use of some dangerous substances in electric and electronic equipment. All these directives will contribute to reduce the releases of POPs in the environment.

With regard to the prevention of accidental releases of dangerous substances, Council Directive 96/82/EC¹⁶ on the control of major-accident hazards, the so-called Seveso II Directive, is an important piece of Community legislation.

Regarding the releases of POPs to waters, Council Directive 76/464/EEC¹⁷ on pollution caused by discharges of certain dangerous substances has some relevance.

⁸ OJ L 123, 24.4.1998, p. 1.

⁹ OJ L 257, 10.10.1996, p. 26.

¹⁰ OJ L 192, 28.7.2000, p. 36.

¹¹ OJ L 332, 28.12.2000, p. 91.

¹² OJ L 309, 27.11.2001, p. 1.

¹³ OJ L 269, 21.10.2000, p. 34. Directive as amended by Commission Decision 2002/525/EC (OJ L 170, 29.6.2002, p. 81).

¹⁴ OJ L 37, 13.2.2003, p. 24.

¹⁵ OJ L 37, 13.2.2003, p. 19.

¹⁶ OJ L 10, 14.1.1997, p. 13. Directive as last amended by Commission Decision 98/433/EC (OJ L 192, 8.7.1998, p. 19).

However, concrete Emission Limit Values (ELVs) have not been set for other POPs than HCB (Council Directive 88/347/EEC¹⁸). Directive 76/464/EEC is now integrated in the Water Framework Directive (Directive 2000/60/EC¹⁹) and some of the listed POPs are included in the list of priority substances.

The overall conclusion with regard to release control measures is that the Community legislation is well in accordance with the requirements set in the two international agreements. However, no emission reduction targets as such have been set at Community level and the current release inventories do not cover all sources of POPs. The present Community legislation on PAHs is very limited, but the Commission is in the process of preparing a proposal on a daughter directive under the Ambient Air Quality Framework Directive 96/62/EC which would lay down an air quality target value for benzo[a]pyrene as a marker for PAHs.

In 2001 the Commission adopted a Communication on a Community Strategy for Dioxins, Furans and Polychlorinated Biphenyls (COM(2001) 593 final). This strategy aims to assess the current state of the environment and the ecosystem, to reduce human exposure to dioxins and PCBs in the short-term, to maintain human exposure at safe levels in the medium to long term and to reduce environmental effects from dioxins and PCBs. No legislative changes are proposed in the strategy, but several other measures, including proper enforcement of the current Community legislation (in particular the PCB disposal Directive and the IPPC Directive), are proposed. As such the strategy could form a Community-wide action plan to reduce and eliminate releases of these POPs.

The management of stockpiles, before they become waste, is subject to existing chemicals legislation and, in terms of plant safety and when it comes to larger storage, Seveso II Directive requirements. Several of the provisions related to waste management in the UNECE Protocol and the Convention have already been included in Community legislation, in particular in Directive 75/442/EEC²⁰ on waste, which constitutes the legal framework for Community policy on waste management. Directive 91/689/EEC²¹ contains additional management and monitoring obligations for hazardous waste and Council Directive 96/59/EC lays down special provisions for the disposal of PCBs. However, except for PCBs, there are currently no restrictions in the Community legislation on the recovery of POPs-containing waste as required in the Convention.

Transboundary shipments of waste are covered by Council Regulation (EEC) No 259/93 on the supervision and control of shipments of waste within, into and out of the Community²². This Regulation is the main instrument to transpose

¹⁷ OJ L 129, 18.5.1976, p. 23. Directive as last amended by Directive 2000/60/EC of the European Parliament and of the Council (OJ L 327, 22.12.2000, p. 1).

¹⁸ OJ L 158, 25.6.1988, p. 35.

¹⁹ OJ L 327, 22.12.2000, p. 1.

²⁰ OJ L 194, 25.7.1975, p. 39. Directive as last amended by Commission Decision 96/350/EC (OJ L 135, 6.6.1996, p. 32).

²¹ OJ L 377, 31.12.1991, p. 20. Directive as last amended by Council Directive 94/31/EC (OJ L 168, 2.7.1994, p. 28).

²² OJ L 30, 6.2.1993, p. 1. Regulation as last amended by Commission Regulation (EC) No 2557/2001 (OJ L 349, 31.12.2001, p. 1).

the Basel Convention into Community legislation. Waste consisting of, containing or contaminated with POP substances is also covered by that Regulation. Currently shipments of such waste within the Community are subject to a procedure based on prior written notification and written consent. As regards exports out of the Community, the Regulation establishes that exports for disposal are totally banned whereas exports for recovery are only allowed if destined for recovery in OECD countries²³. Imports into the Community are allowed if they come from EFTA countries or countries that are Parties to the Basel Convention or, when the waste is destined for recovery, also from other OECD countries. This Regulation is currently under revision. The Commission proposal establishes that shipments of waste consisting, containing or contaminated with the substances listed in the Stockholm Convention are subject to the same provisions as shipments of waste destined for disposal. This means in effect that all shipments within the Community will continue to be subject to the requirement of written notification and written consent and that all exports out of the Community will be banned. As regards imports into the Community, these will only be allowed if they come from EFTA countries or countries that are Parties to the Basel Convention.

5. IMPLEMENTATION STRATEGY

The Community and the Member States are strongly committed to a rapid ratification and effective implementation of both international agreements on POPs. The present status of ratifications lays down a stringent timetable for the Community if it wishes to be sure of becoming a Party before the first Conference of the Parties, which is likely to be held in 2004.

Most of the acceding and candidate States have also signed the international agreements on POPs. In a recent survey, all 10 acceding States confirmed their intentions to implement the international obligations on POPs. The situation with regard to practical implementation of the proposed provisions in the acceding and candidate States is expected to be largely similar to the present Member States, but in the absence of exact detailed information, it has not been possible for the Commission to analyse this in a full and comprehensive manner before the adoption of this proposal. Therefore, the Commission will, during the early stages of the decision-making procedure, gather further scientific information about the situation in these countries, including through consultations with the acceding and candidate States, to find out whether there will be impacts on these countries going beyond those on the current Member States. Following this survey, the Commission will, if appropriate, take relevant action in the framework of the Treaties of Accession, including a possibility to make modifications to the enclosed proposal.

The POP agreements are very wide in scope in the sense that the control measures cover the whole life cycle of POPs, from production to disposal. Secondary Community legislation does not yet fully cover all these measures.

²³

The terminology used is: Countries to which the OECD Decision applies. The OECD Decision refers to the Decision of the OECD Council of 30 March 1992 on the control of transfrontier movements of wastes destined for recovery operations, as amended.

Although most of the listed POPs are no longer produced or used in the Community, the present chemicals legislation does not include actual provisions to prevent and eliminate intentionally produced POPs from being placed on the market. In addition, Community legislation on waste does not include all the measures set forth in the Stockholm Convention.

At the same time as the current proposal, the Commission is preparing a comprehensive reform of the chemicals legislation as a follow-up to the White Paper on Strategy for a future Chemicals Policy affecting all the main current chemicals legislation. This new legislation would be the best instrument to implement the necessary control measures on production, marketing and use of intentionally produced POPs. However, given the scale and complexity of the proposal on the new chemicals legislation, the final adoption of the new rules may take some time. Therefore, and in order to facilitate early ratification of the two international POP agreements, the implementation measures related to production, marketing and use of the currently listed POPs are included in the present proposal as a temporary measure. In the medium term, it is intended that these measures will be subsequently incorporated in the new chemicals legislation. The proposal for the new chemicals legislation will therefore include measures to transfer these provisions from the POP Regulation.

Some control provisions in the two POP agreements are aspirational rather than legally binding obligations. In addition, while some of the provisions clearly fall under Community competence, others belong to competence shared with or left to the Member States. Therefore, not all provisions of the agreements require new provisions at Community level. In general, the Community has exercised its competence in the field of all control measures and, in addition, in the fields of *inter alia* research and monitoring. However, while control measures on intentionally produced chemicals would continue to have to be fully harmonised in order to prevent any distortion of the internal market, the implementation of additional release control measures on by-products, provisions on soil contamination as well as certain general obligations of the Convention could be addressed in accordance with the subsidiarity principle.

Against this background, it appears that the most appropriate way to implement the main control provisions of the Convention and the UNECE Protocol within a reasonable timeframe is via a single, horizontal legal instrument. Later on, the provisions on production, marketing and use of the listed POPs and on the prevention of production and use of substances exhibiting POP characteristics are to be introduced as a part of the new chemicals legislation. In future, as Community legislation and the international agreements on POPs develop, other provisions may also need to be introduced in Community legislation.

The proposal takes the form of a Regulation, as it would allow for more rapid and straightforward implementation throughout the Community, including the new Member States. It will also avoid legislative gaps and inconsistencies between different Community and national texts and allow for more consistent practical application.

The principal aim of the Regulation is the protection of human health and the environment and therefore the legal basis is Article 175(1) of the Treaty. However, prohibitions and restrictions of production, placing on the market and use of POPs

are relevant to the functioning of the internal market and their legal basis is therefore Article 95(1) of the Treaty.

6. PROPOSED NEW RULES

The proposed Regulation of the European Parliament and the Council would implement the main provisions of the Stockholm Convention and the UNECE Protocol on intentionally produced POPs by prohibiting the production, use and placing on the market of the listed substances. To ensure a high level of protection of health and the environment, the proposed new Regulation would not make use of the possibility offered by the international agreements to continue the production, placing on the market and use of some of the listed substances for limited uses.

The proposed Regulation would also contain certain provisions on stockpiles and waste, which to some extent would go beyond those set in the Convention. As the necessary legislation on the listed by-products is to a great extent in place, it is proposed to include only provisions on release inventories and on the development and implementation of the national action plans in the Regulation.

In addition to provisions on control measures, the Regulation would contain certain general obligations based on the provisions of the Convention and the Protocol.

Adding new POP substances is a crucial element of the proposed Regulation, and new chemicals will most likely be added relatively soon both in the Convention and in the UNECE Protocol. After a decision on listing of a substance is made under either of the two international legally binding instruments on POPs, the Regulation would be amended, as appropriate, by using a regulatory committee procedure. This is sufficient because all Member States and the Council would have already dealt with the listing of a new POP during international negotiations. This procedure provides a possibility also for the European Parliament to react on the Commission proposals and decisions taken. The regulatory committee procedure would enable the Community to decide on the inclusion of a substance in the given one year timeframe.

For the sake of legal clarity, it is proposed to repeal the obsolete marketing and use restrictions on eight POP pesticides set out in Council Directive 79/117/EEC. In addition, it is proposed to make a slight amendment in the PCB Disposal Directive (96/59/EC). However, the present restrictions on PCBs would remain intact.

7. CONTENT OF THE REGULATION

Article 1

This article outlines the subject matter and scope of the Regulation by emphasising the type of control measures to be taken. It also emphasises the subordination of the Regulation to the international legally binding instruments. In addition, the second paragraph clarifies that the control measures concerning the production, marketing and use specified in Article 3 and 4 do not apply to waste.

Article 2

Only few definitions are deemed to be necessary for the purposes of the Regulation. These definitions are based either on the Convention or on the existing Community legislation, except the definition of ‘articles’. For definitions of ‘substance’, ‘waste’ and ‘recovery’ the text refers to definitions of relevant existing Community legislation.

Article 3

Article 3 lays down the prohibitions and restrictions on production, placing on the market and use of the intentionally produced POPs. In the first paragraph reference is made to Annex I, which contains both the ten intentionally produced POPs currently listed in the Convention and two of the additional three substances listed in the UNECE Protocol. There is no known production or uses of these substances in the current Member States (with the exception of use of existing PCB equipment) and no specific exemptions have been asked for by the Community or by the Member States under the Convention. According to available information, most of the Candidate Countries have banned the import and use of the listed substances, and these substances are not produced, either. Two of the Candidate Countries have, however, provisionally requested a country-specific exemption on use of HCB as an intermediate. In line with the aim of elimination, it is proposed nonetheless to prohibit the production and use of these substances completely, even though the international agreements would allow production and use of some of them.

In the second paragraph reference is made to Annex II, which contains a list of substances that would be subject to restrictions of production, placing on the market and use. At the moment only HCH (lindane) is included in this Annex. The production and use of HCH is restricted under the Protocol but several main uses are still allowed. In the Community, the marketing and use of lindane for plant protection purposes ceased in July 2002, as set out in Commission Decision 2000/801/EC. However, according to available information, some minor biocidal and pharmaceutical uses seem still to exist in some Member States and possibly also in some Candidate Countries. Therefore a total ban of production, marketing and use is not yet regarded possible and consequently lindane has been listed under Annex II with specification of the allowed uses. These remaining uses are all in accordance with the current international obligations.

In the Convention, the term ‘use of substance’ includes not only the use of a substance as such and in chemical preparations but also as constituents of manufactured articles (e.g. wood preserved with chemicals). This is emphasised in Article 3 of the Regulation.

Article 4

This Article defines certain general exemptions from the provisions concerning production, placing on the market and use. These exemptions follow closely the very limited general exemptions given in Article 3(5) and Annexes A and B of the Convention. For the sake of clarity and consistency, the same limited exemptions would apply to the three additional substances listed in the Protocol, although the Protocol would in principle allow much wider exemptions (e.g. for public health emergencies and so called minor applications).

General exemptions would apply to quantities of substances to be used for laboratory-scale research or as reference standards or occurring as unintentional trace contaminants in products and articles. Substances used as constituents of articles manufactured or already in use before the entry into force of the prohibition in question would be allowed in cases where the Community has notified the Secretariat of the remaining use of such articles. However, this notification obligation applies only to substances listed in the Convention, and therefore reference is made to Part A of Annexes I and II. As this exemption might involve not only use but also placing on the market of articles (e.g. in case where articles have been manufactured or imported but not sold before the entry into force of the prohibition), it should be applied throughout the Community and thus the Commission should notify the Secretariat. An initiative for the notification should usually come from the Member State wishing to apply the exemption. It should be noted that this procedure would not apply to the existing PCB equipment as the Convention and Annex I of the Regulation contain a special exemption on them. Concerning the other substances currently listed in the Convention, no treated articles are known to be on the market or in use in the Community. The situation in the acceding and candidate States may be different, but by notifying such possibly remaining articles, their use could still continue.

The Convention allows the use of DDT and HCB as closed-system site-limited intermediates with certain conditions. In line with the aim of elimination, these substance-specific exemptions are not transposed in the Regulation. However, the concept as such is introduced in the third paragraph to be applied for possible future substances. With regard to the substances listed in the Convention and consequently in Part A of Annex I or II of this Regulation, the intermediate use has to be notified to the Secretariat. As by definition no placing on the market can take place, this notification obligation would be left for the Member States. However, the Commission and other Member States should be informed about such notifications.

Article 5

Article 5 follows the provisions laid down in Article 6 of the Convention and contains provisions to identify stockpiles of intentionally produced POPs and manage them in an environmentally sound manner. However, the provisions in the Regulation are more specific than those in the Convention. This is deemed necessary as obsolete or carelessly stored POP stockpiles have caused severe risks to human health and the environment.

The first paragraph stipulates that the possibly remaining stockpiles consisting of or containing POPs which are totally prohibited should be treated as waste. This waste will be subject to Community waste legislation and Article 7 of this Regulation. It is assumed that no such stockpiles of the chemicals currently listed in Annex I are left in the Member States. The situation is different in some of the acceding and candidate States, which have large amounts of obsolete pesticides. To provide a status of stockpiles in the 10 acceding States, the Commission has recently had made

a study²⁴ on the issue. The results indicate that there are large stockpiles of obsolete pesticides in Poland and in the Baltic states and that these stockpiles could contain up to 27 000 tons of POP pesticides. To dispose of these stockpiles safely, EU financial and technical assistance through existing financial instruments may be necessary for e.g. to support capacity building for waste management planning or for the building of safe disposal facilities.

The second paragraph defines provisions applied to stockpiles of POP substances, which are only subject to restrictions. The holders of stockpiles over 100 kg should notify the competent authority of the Member State about the nature and quantity of these stockpiles within 12 months of entry into force of the restriction in question and yearly thereafter until the end of the time warranted for restriction. The Member States would be obliged to monitor that the stockpiles are stored, handled and managed appropriately.

In addition, Article 12 of the Regulation requests Member States every three years to submit a summary report to the Commission on any stockpiles they have been informed about. This would allow the Commission to monitor and evaluate the need for additional Community measures to ensure that the objectives of the Regulation are met.

Article 6

In order to capture all the main control provisions and the listed substances of the Convention and the Protocol, certain general provisions related to release reduction are included in the Regulation. Article 8 obliges Member States to develop and maintain release inventories for dioxins, furans and other by-product POPs listed in the two international agreements and specified in Annex III to the Regulation. Moreover, Member States are obliged to develop and implement National Action Plans designed to identify, characterise and reduce the releases of these substances, as laid down in the Convention. Both the release inventories and the National Action Plans are regarded as essential tools for cost-effective and continuing release reduction of by-product POPs.

Article 7

Community legislation on waste applies already now to all waste containing POPs. However, as article 6(1)(d) of the Convention lays down certain detailed provisions not yet covered by Community legislation, an Article on these specific waste management provisions is included in the Regulation.

Article 7 lays down the general rules on waste containing substances listed either in the Convention or in the Protocol. However, polycyclic aromatic hydrocarbons (PAHs) are not listed in the Convention. As it would be very difficult to apply these specific rules to waste containing PAHs, this group of substances is left out of the scope of this Article. For the sake of legal clarity, a separate Annex IV is established for the purposes of the waste provisions.

²⁴ Obsolete Pesticides Status in Candidate Countries. Final Report, September 2002. European Commission, Directorate General for Environment.

As a general rule, waste containing any of the listed POPs should be disposed of without undue delay in such a way that the POP content is destroyed or irreversibly transformed. However, the Convention recognises that it is not always advisable or feasible to eliminate the POP content totally. Therefore, the second paragraph stipulates that waste may be otherwise disposed of in accordance with Article 4 of Directive 75/442/EEC when the content of the listed substances in waste is below the concentration limits given in Annex IV of the Regulation. In the current Annex IV there are no limit values but these are currently under development and will be introduced later by the regulatory committee procedure.

The Convention would also allow exemption from the basic obligation in cases where destruction does not represent the environmentally preferable option. It is not proposed to transpose this exemption in the Community legislation as the destruction of POPs is regarded as the only environmentally sustainable way to deal with waste with high POP concentration. Based on this view, the provision in Directive 96/59/EC on PCB/PCT disposal allowing permanent underground storage in salt mines as a disposal method regardless of the POP concentration would become obsolete. To prevent this disposal possibility and for the sake of legal clarity, it is proposed to amend Directive 96/59/EC accordingly in Article 18.

In accordance with the Convention, paragraphs 3 and 4 stipulate that re-use or recovery of waste containing POPs is not allowed unless the POP content can be destroyed in the recovery process or isolated from the waste carrier and subsequently disposed of in an environmentally safe manner. PCB waste, however, is already covered by a complete recovery ban laid down in Directive 96/59/EC. This stricter provision is meant to take precedence and therefore a specific reference to that Directive is made in paragraph 4.

Article 8

This Article sets out the obligation to develop an implementation plan, as requested in Article 7 of the Convention. As a Party to the Convention, also the Community has to develop a plan of implementation. However, as the competence with regard to matters under the Convention is shared between the Community and the Member States, this share of duties should also be reflected in the implementation plans.

The plans should subsequently be implemented and, as appropriate, updated and renewed. In order to facilitate co-operation and information exchange within the Community, the Implementation Plans are to be submitted to the Commission and other Member States.

Article 9

Article 9 lays down an obligation for the Commission and the Member States to establish, in close co-operation, appropriate programmes and mechanisms for the environmental monitoring of three of the listed substances, namely dioxins, furans and PCBs. This obligation goes beyond the provisions of the international agreements but it is based on the Communication from the Commission on the Strategy for Dioxins, Furans and PCBs. Taking into account the current lack of data on the environmental levels and trends of dioxins, furans and PCBs and the need to evaluate the effectiveness of the control measures, a specific provision on monitoring

is considered necessary. However, it is necessary that measurement and monitoring tools are available that allow appropriate conditions for such activities. It can be expected that such tools will be fully available within a time scale of 10 to 15 years.

Similar obligations with regard to other POPs is not deemed necessary but the general encouragement on monitoring laid down in the Convention is regarded sufficient at the moment.

Article 10

The provisions on information exchange laid down in Article 9 of the Convention are transposed by Article 10 of the Regulation. Transposition is considered necessary as the exchange of information between the countries, public awareness and access to information play a vital role in the elimination of pollution caused by POPs. In line with the Convention, Article 10 also lays down the provisions on confidential information.

Article 11

This Article is based on Article 12 of the Convention and sets out the general obligations of the Commission and the Member States in providing technical assistance to developing countries and countries with economies in transition. Technical assistance should be designed to strengthen the capacities of these countries and to find solutions for such issues as the remaining use of DDT in some developing countries. The Convention still allows the production and use of DDT for disease vector control in countries where safe, effective and affordable alternatives are not available. In order to gradually eliminate the use of DDT and in line with the Communication from the Commission (COM(2003) 93 final)²⁵, research, development and introduction of alternatives to DDT should be promoted.

Within the context of technical assistance, the Commission and the Member States should also consider giving support to non-governmental organisations, the role of which can be very important.

Article 12

The first paragraph of Article 12 deals with reporting within the Community. On the basis of the information provided by Member States and its own monitoring, the Commission can assess the overall functioning of the Regulation.

The second paragraph sets out a specific reporting obligation on the production and placing on the market of substances listed in Annex I or II, as laid down in Article 15 of the Convention. Given that issues concerning internal market belong to Community competence, the Commission would compile a joint report on the basis of the information provided by the Member States and provide it to the Secretariat. This is laid down in the fourth paragraph.

²⁵ Communication from the Commission to the Council and the European Parliament. "Update on the EC Programme of Action - Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction". 26.2.2003.

The third paragraph lays down two specific reporting obligations for the Member States. Every three years they would have to submit summary reports on stockpiles and release inventories. This would allow the Commission to assess the functioning of the control measures at the Community level and, if necessary, propose appropriate amendments.

Apart from these particular reporting obligations, provisions on general reporting as foreseen in the Convention and the Protocol are not included in the Regulation but the issue is left for the Member States.

Article 13

This Article is a standard provision for penalties in the event of infringements.

Article 14

This Article, together with Article 16 lays down the procedures to be followed for amending and updating the Annexes of the Regulation. When a decision has been taken at the international level on the inclusion of a substance in the Convention or in the UNECE Protocol, the Commission would prepare a proposal on amendment of relevant Annexes. The decision would be taken using the regulatory committee procedure. According to Article 22 of the Convention, amendments to Annex A, B or C will enter into force on the expiry of one year from the date of communication on the amendment decision, unless the Party notifies that it is unable to accept the amendment or unless the Party has made a specific declaration together with its ratification instrument, in accordance with Article 25(4) of the Convention.

The detailed conditions and possible exemptions for prohibitions and restrictions of substances listed in the Annexes should be reviewed by the Commission at regular intervals. In particular, the Commission should, before 31 December 2007, review the entry in Part B of Annex II concerning hexachlorocyclohexane HCH, including lindane, in the light of the results of risk assessments and of the development of knowledge and techniques in respect of substitutes for HCH. Appropriate modifications should be made on the basis of the developments in the Community and under the Convention and the Protocol.

Article 15

The Convention or the Protocol does not require Parties to designate competent authorities. However, as the Regulation lays down several duties for the Member States, it is deemed appropriate that specific authorities are designated to act for the performance of the administrative functions required by the Regulation.

Article 16

This Article outlines the committee procedures to be followed. It is not proposed to establish a new committee but the Committee established by Directive 67/548/EEC should assist the Commission.

Articles 17 and 18

These Articles would repeal certain existing provisions. Restrictions adopted under Directive 79/117/EEC on eight POP pesticides become obsolete and good legislative practice would require these to be repealed. In addition, it is proposed to amend the provision of Council Directive 96/59/EC on the disposal of PCBs/PCTs allowing permanent storage of PCB waste in accordance with the rules of the Convention and the proposed Regulation. It should be noted that the other specific restrictions of PCBs under that Directive would remain valid.

Article 19

This standard Article is relating to entry into force and application of the proposed new Regulation. As the Regulation implements provisions of two self-standing international agreements, it is not appropriate to link the application date to the entry into force of these agreements. Instead a fixed date is proposed.

Annexes

The Annexes contain the lists of persistent organic pollutants subject to the various provisions under the two international agreements and, consequently, under this Regulation. Once agreed in the framework of either of the international agreements, new substances will be added to one or more of the Annexes. In addition, Annexes may be modified, in accordance with Article 14. Due to the differences in the lists of POPs and in the provisions of the two agreements, several Annexes are needed in the Regulation in order to clearly specify the scope of each control measure.

Annex I sets out the list of 10 intentionally produced substances listed both in the Convention and the Protocol (Part A) and the list of 2 additional substances listed only in the Protocol. These substances are subject to total prohibitions pursuant to Article 4(1). There is only one substance specific exemption in that Annex, concerning existing equipment containing PCBs. However, for substances added later, certain uses (e.g. as an intermediate) could be allowed, if in accordance with the international agreements.

Annex II lists the substances subject to restrictions on production, placing on the market and use pursuant to Article 3(2). As Annex I, also this Annex is divided in two parts, in accordance with the status of the substances under the two international agreements. Currently it contains only one substance in Part B, namely HCH (lindane), which for the time being is still allowed for certain limited uses. Two of these uses are time limited, while others remain open-ended. However, the Commission should review the remaining uses by the end of 2007 and a specific provision to that effect is laid down in Article 14(2).

Annex III lists the unintentionally produced substances, which are all subject to release inventories and release reduction measures pursuant to Article 6.

Annex IV lists the substances, which are subject to specific waste management provisions laid down in Article 7. In addition, this Annex contains the concentration limits referred to in paragraph 2 of that Article. As these limits are still under development in the framework of the Basel and Stockholm Conventions and as the

Commission is launching its own studies on this issue, no limit values are yet included in Annex IV.

8. COSTS

Economic impact of the present proposal is deemed negligible in the present Member States. In some acceding and candidate States there are considerable amounts of obsolete stockpiles of POPs and their safe disposal is likely to cause significant financial impacts. However, EU technical and financial assistance through existing financial instruments is available for *inter alia* to support capacity building for the waste management planning and for the building of safe disposal facilities.

In general, the Regulation should not bring additional costs to those already imposed by existing Community legislation. In the Commission, no additional resources other than those already allocated to POPs related tasks are needed. In the Member States, there will be an impact in terms of slightly increased administrative burden due to certain notification and reporting obligations.

The costs have to be weighed against the benefits: The provisions contribute to elimination of the most harmful substances of global concern. Furthermore, the Regulation would transpose international obligations to which the Community, the Member States and most of the acceding and candidate States have already committed themselves.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on persistent organic pollutants and amending Directives 79/117/EEC and 96/59/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95(1) and Article 175(1) thereof,

Having regard to the proposal from the Commission²⁶,

Having regard to the opinion of the European Economic and Social Committee²⁷,

Having regard to the opinion of the Committee of the Regions²⁸,

Acting in accordance with the procedure laid down in Article 251 of the Treaty²⁹,

Whereas:

- (1) This Regulation primarily concerns environmental protection and the legal basis is therefore Article 175(1) of the Treaty. However, in so far as the prohibitions and restrictions as regards the production, placing on the market and use of persistent organic pollutants are relevant to the functioning of the internal market, this Regulation is based also on Article 95(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”.

²⁶ OJ C
²⁷ OJ C
²⁸ OJ C
²⁹ OJ C

- (4) 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 which to take measures designed in particular to eliminate the production, placing on the market and use of intentionally produced persistent organic pollutants.
- (5) Moreover, having regard to the precautionary principle and in view of the ultimate objective of eliminating 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.
- (6) The best instrument by means of which to implement the necessary control measures on production, placing on the market and use of the listed substances would be the legislation planned to implement the Commission's White Paper on Strategy for a future Chemicals Policy³⁰. However, on account of its scale and complexity, that legislation is expected to take some time to be adopted and, since it is important to ratify the Convention and the Protocol as soon as possible, this Regulation should temporarily implement those measures.
- (7) 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 substances³¹ 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 preparations³². 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.
- (8) The production and use of hexachlorocyclohexane (HCH), including lindane, is subject to restrictions under the Protocol but not totally prohibited. That substance is still used in some Member States and therefore it is not yet appropriate to prohibit all 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.
- (9) Obsolete or carelessly managed stockpiles of persistent organic 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

³⁰ COM(2001) 88 final.

³¹ OJ L 33, 8.2.1979, p. 36. Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

³² OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2003/11/EC (OJ L 42, 15.2.2003, p. 45).

production or use of which is still allowed should be notified to the authorities and properly supervised.

- (10) In line with the Communication from the Commission on the Community Strategy for Dioxins, Furans and Polychlorinated Biphenyls (PCBs)³³, 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 with the aim of their ultimate elimination. 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.
- (11) 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.
- (12) 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. 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 both the high level of protection and the feasibility of the requirements, limit values defining a low content of the substances in waste will be established later.
- (13) The Convention provides that each Party is to draw up a plan for the implementation of its obligations under the Convention. Since the Community and the Member States share competence in that regard, implementation plans should be drawn up both at national and Community level. Co-operation and an exchange of information between the Commission and the authorities of the Member States should be promoted.
- (14) 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.
- (15) In order to achieve the aims of the Convention, it is necessary, where appropriate, to give technical assistance to developing countries and countries with economies in transition. The Commission and the Member States should therefore provide appropriate and timely technical assistance designed especially to strengthen the capacity of those countries to implement the Convention, including such issues as the remaining use of DDT in disease vector control and development and implementation of suitable alternative products, methods and strategies.
- (16) 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.

³³ OJ C 322, 17.11.2001, p. 2.

- (17) 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.
- (18) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission³⁴, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.
- (19) 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.
- (20) 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 acting alone, 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.
- (21) In the light of the above, Directive 79/117/EEC and Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCBs/PCTs)³⁵ should be amended,

HAVE ADOPTED THIS REGULATION:

Article 1
Subject-matter and scope

1. This Regulation concerns the production, placing on the market, use, release and disposal of substances subject to prohibitions or restrictions under 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”.

Those substances are listed in Annexes I to IV to this Regulation.

2. Articles 3 and 4 shall not apply to waste consisting of, containing or contaminated by any substance listed in Annexes I or II.

³⁴ OJ L 184, 17.7.1999, p. 23.

³⁵ OJ L 243, 24.9.1996, p. 31.

Article 2
Definitions

For the purposes of this Regulation:

- (a) ‘*placing on the market*’ means supplying or making available, whether in return for payment or free of charge;
- (b) ‘*article*’ means an object composed of one or more substances and/or preparations which during production is given a specific 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/EEC³⁶;
- (d) ‘*waste*’ is as defined in Article 1(a) of Council Directive 75/442/EEC³⁷;
- (e) ‘*recovery*’ is as defined in Article 1(f) of Directive 75/442/EEC.

For the purposes of this Regulation, imports into the customs territory of the Community shall also be deemed to be placed on the market.

Article 3
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.

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.

³⁶ OJ P 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).

³⁷ OJ L 194, 25.7.1975, p. 39. Directive as last amended by Commission Decision 96/350/EC (OJ L 135, 6.6.1996, p. 32).

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

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

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.

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 shall dispose of that stockpile as waste and in accordance with Article 7.
2. The holder of a stockpile greater than 100 kg and consisting of or containing any substance listed in Annex II 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 the relevant provision of this Regulation and annually thereafter until the deadline specified in Annex 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.

Article 6 *Release reduction*

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.

Within the same period, Member States shall also draw up a national action plan designed to identify, characterise and reduce the total releases derived from anthropogenic sources of each of the substances listed in Annex III.

Each Member State shall implement its national action plan as part of its national implementation plan drawn up pursuant to Article 8.

Article 7 *Waste management*

1. Waste consisting of, containing or contaminated by any substance listed in Annex IV shall be disposed of without undue delay and 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.
2. By way of derogation from paragraph 1, waste consisting of, containing or contaminated by any substance listed in Annex IV may be otherwise disposed of in accordance with Article 4 of Directive 75/442/EEC, provided that the content of the listed substances in the waste is below the concentration limits specified in Annex IV to this Regulation.
3. The re-use or recovery of waste consisting of, containing or contaminated by any substance listed in Annex IV shall be prohibited.
4. By way of derogation from paragraph 3, the recovery of waste consisting of, containing or contaminated by any substance listed in Annex IV shall be allowed, provided that the operator demonstrates that the persistent organic pollutant content is destroyed during the recovery operation, irreversibly transformed during the recovery operation or isolated from the waste carrier and subsequently disposed of in accordance with paragraph 1.

The first subparagraph shall apply without prejudice to Directive 96/59/EC.

Article 8 *Implementation plans*

1. Each Member State shall, within two years of the entry into force of this Regulation, draw up a plan for the implementation of its obligations under the Convention.

As soon as a Member State has adopted its national implementation plan, it shall communicate it both to the Commission and to the other Member States.

Each Member State shall implement its plan and shall review and update it, as appropriate.

2. 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 co-operation, appropriate programmes and mechanisms, consistent with the state of the art, for the continuous provision of comparable monitoring data on the presence of dioxins, furans and PCBs 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 or elimination 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 the Member States shall promote and facilitate awareness and public availability of information on persistent organic pollutants and on the reduction or elimination of their production, use and release.
3. The Commission and the Member States shall protect any confidential information received from a third country, in accordance with any agreement with that third country. Without prejudice to Council Directive 90/313/EEC³⁸, information on human health and safety and on the environment shall not be regarded as confidential.

³⁸ OJ L 158, 23.6.1990, p. 56.

Article 11
Technical assistance

The Commission and the Member States shall co-operate in providing appropriate and timely technical assistance, including training, or support to non-governmental organisations, to developing countries and countries with economies in transition to assist them, taking into account their particular needs, to develop and strengthen their capacity to implement their obligations under the Convention.

Article 12
Reporting

1. Member States shall every three years forward to the Commission information on the application of this Regulation.
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 in the environment, as compiled pursuant to Article 9.
4. 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.
5. The Commission shall regularly compile a report on the application of this Regulation and shall integrate it with the information provided by the Member States under paragraphs 1, 2 and 3 to form a synthesis report. It shall forward a summary of the synthesis report to the European Parliament and to the Council.

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.

Article 14
Amendment of Annexes

1. Whenever a substance is listed in the Convention or the Protocol, the Commission shall, where appropriate, amend the Annexes to this Regulation accordingly, in accordance with the procedure referred to in Article 16(2).
2. Modifications to the existing entries in the Annexes, including their adaptation to scientific and technical progress, shall be adopted by the Commission in accordance with the procedure referred to in Article 16(2).

In particular, the Commission shall, before 31 December 2007, review the entry in Part B of Annex II concerning hexachlorocyclohexane HCH, including lindane, in the light of the results of risk assessments and of the development of knowledge and techniques in respect of substitutes for HCH.

Article 15
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 procedure

1. The Commission shall be assisted by the Committee established by Article 29 of Directive 67/548/EEC.
2. Where reference is made to this paragraph, Article 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 three months.

3. The Committee shall adopt its rules of procedure.

Article 17
Amendments to Directive 79/117/EEC

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

Article 18
Amendments to Directive 96/59/EC

In Article 2 of Directive 96/59/EC, point (f) is replaced by the following:

‘(f) “disposal” means operations D 8, D 9, D 10 and D 15 provided for in Annex II to Directive 75/442/EEC.’

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.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

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 INTERMEDIATE USE OR OTHER SPECIFICATION
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	-

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		-
Hexabromobiphenyl	36355-01-8		-

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
HCH, including lindane	608-73-1, 58-89-9	210-168-9, 200-401-2	<p>Technical HCH is restricted to use as an intermediate in chemical manufacturing.</p> <p>Products in which at least 99% of the HCH isomer is in the gamma form (lindane) are restricted to the use as public health and veterinary topical insecticide.</p> <p>By way of derogation, the following uses are allowed until 1.9.2006:</p> <p>a) Professional remedial and industrial treatment of lumber, timber and logs;</p> <p>b) Indoor industrial and residential applications.</p>

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)

ANNEX IV

**LIST OF SUBSTANCES SUBJECT TO WASTE MANAGEMENT PROVISIONS SET
OUT IN ARTICLE 7**

SUBSTANCE	CAS No	EC No	LIMIT CONCENTRATION REFERRED TO IN ARTICLE 7(2), ppm (parts per million)
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	
DDT (1,1,1-trichloro-2,2- bis(4-chlorophenyl) ethane)	50-29-3	200-024-3	
Chlordecone	143-50-0		
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)			
HCH, including lindane	608-73-1, 58-89-9	210-168-9, 200-401-2	

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES(SMEs)

TITLE OF PROPOSAL

Proposal for a Regulation of the European Parliament and of the Council on persistent organic pollutants and amending Directives 79/117/EEC and 96/59/EC.

DOCUMENT REFERENCE NUMBER

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THE PROPOSAL

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

The Regulation lays down at Community level requirements for the implementation of the Stockholm Convention on Persistent Organic Pollutants and the UNECE Protocol on Persistent Organic Pollutants, in accordance with the shared competence between the Member States and the Community. The ultimate objective of these international agreements is to protect human health and the environment from persistent organic pollutants.

The Regulation aims at facilitating rapid and effective implementation of the two agreements. It also aims to avoid legislative gaps and inconsistencies between different Community and national texts and to allow for more consistent practical application. This approach should also contribute to the effective functioning of the internal market.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

In principle, all sizes of business related to the production, marketing, use, releases and disposal of the listed persistent organic pollutants are affected. It should be noted, however, that there is hardly any production of the listed substances in the Community or in the acceding or candidate States and thus the direct impact is regarded as low.

The proposal would have a similar impact over the entire Community, and in the acceding and candidate States. It is not aimed at any particular region.

3. What will business have to do to comply with the proposal?

As there is no known production or stockpiles of the listed substances in the Community, there are currently no direct obligations to business in the present Member States. In some acceding and candidate States there are considerable amounts of obsolete stockpiles of POPs, but most of these stockpiles are held by the Government, not by companies. When additional substances are listed in the Regulation, and if they are still being produced, used or exported, the companies involved have to ensure that the rules and conditions are respected and to report regularly on the production, import, export and stockpiles.

With regard to release prevention and control of the listed persistent organic pollutants and their monitoring, no additional direct provisions are addressed to business. The industries releasing the highest quantities of these substances are already subjected to prevention, control and monitoring obligations under existing Community legislation.

Waste containing the listed POPs has to be disposed of without undue delay and in accordance with the specific requirements. This may lead to changes in waste management practices in some enterprises.

4. What economic effects is the proposal likely to have?

Precise assessment of the economic impact of the proposal is difficult to make. The proposed Regulation goes beyond the requirements of the international agreements in certain respects. However, in most cases these additional requirements will have no effect as the currently listed substances are no longer being produced or used in the Community. Therefore it is assessed that the proposal will have no significant effects on employment, investment and the creation of new businesses or on the competitiveness of businesses.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

The scope of the proposal is horizontal and its provisions are generic. Therefore, it does not contain measures specifically aimed at or adapted for small and medium-sized firms.

CONSULTATION

6. List the organisations, which have been consulted about the proposal and outline their main views.

No separate external consultation has been launched on the proposal as it is based on the outcome of wide international negotiations which were closely followed by chemical industry associations, environmental and consumer organisations and other stakeholders. The joint positions of the Community and the Member States were prepared in co-ordination meetings and the information gathered in these contexts has been utilised in the preparation of the implementation proposals.

During the negotiation conferences, separate meetings were arranged to exchange views with the acceding and candidate States. After the negotiations were concluded, the Community implementation and the situation and plans in various acceding and candidate States with regard to these international obligations have been discussed with these countries in some bilateral and regional meetings. Moreover, a special study focussing on obsolete POP pesticides in the 10 acceding States has been made in order to *inter alia* gather background information for the preparation of the Commission proposals.