

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(91) 468 final

Brussels, 6 December 1991

Amended proposal for a

COUNCIL REGULATION (EEC)

concerning Export from and import into the Community
of certain dangerous chemicals

(presented by the Commission pursuant to Article 149(3)
of the EEC-Treaty)

Explanatory Memorandum

In December 1990 the Commission put forward a proposal for a Council Regulation to replace regulation (EEC) number 1734/88. The new Regulation would maintain the current requirements for the notification of the import and export of certain dangerous chemicals and would also introduce a "Prior Informed Consent" (PIC) scheme whereby the export of certain chemicals could take place only in accordance with the announced decision of the importing country.

At its 287th Plenary Session on 29 and 30 May 1991, the Economic and Social Committee unanimously adopted the Opinion of its Section for Protection of the Environment, Public Health and Consumer Affairs approving the aims and principles of the Commission's proposal.

At its Plenary Session on 24 October 1991, the European Parliament approved the proposal with a total of 17 amendments. Eight of the amendments have been accepted by the Commission but the others are considered to be detrimental to the Commission's proposal.

The acceptable amendments help ensure the proposal is compatible with the international PIC scheme set up by the UNEP and FAO. They also define the frequency of Commission reports on the operation of the proposed Regulation, and require Member States to provide some additional information to the Commission concerning dangerous chemicals imported or exported for use in research and development.

The majority of the unacceptable amendments would, in effect, require a fundamental change in the nature of the proposed Regulation and would make it incompatible with the international PIC scheme. This scheme is based on the principle that exports of banned and severely restricted chemicals are permissible under specific conditions, namely that the importing country has decided to permit the import of such a chemical after being fully informed of its potential hazards. The proposed amendments would require that the Community institutions decide what can be exported or not; this could be attacked as an attempt to erode the discretion of third countries.

Another amendment would require that the addition to Annex III of every new chemical that becomes subject to the international PIC procedure would require a Council decision. The Commission's proposal, on the other hand, would enable such modifications to be made following discussion by the Commission and Member States in a Committee set up to review technical progress.

The complete text of the proposed Regulation follows, with amendments accepted by the Commission shown alongside the original text.

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130s thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas Council Regulation (EEC) No 1734/88 (*) concerns the export from and import into the Community of certain dangerous chemicals;

Whereas an amendment to Regulation (EEC) No 1734/88 is necessary to implement the 'prior informed consent' (PIC) procedure;

Whereas, on the occasion of this amendment, Regulation (EEC) No 1734/88 is also to be replaced by this Regulation;

Whereas certain provisions of Community legislation, and in particular Council Directives 76/769/EEC (*), as last amended by Directive 89/678/EEC(*) and 79/117/EEC (*), as last amended by Directive 89/365/EEC (*), restrict the marketing and use of

certain dangerous substances and preparations and prohibit the placing on the market and use of plant protection products containing certain active substances in the Member States of the Community; whereas these provisions do not apply to those products when they are intended for export to third countries;

Whereas international trade in certain chemicals which are banned or severely restricted in countries of export has caused international concern on grounds of protection of man and the environment;

Whereas measures are necessary for the protection of man and the environment, both in the Community and third countries

(*) OJ No L 155, 22. 6. 1988, p. 2.

(*) OJ No L 262, 27. 9. 1976, p. 201.

Whereas schemes for notification, information and prior informed consent concerning international trade in such substances have been set up within the framework of international organizations, namely the Organization for Economic Cooperation and Development (OECD), the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization (FAO);

Whereas the Community and its Member States have actively participated in the work of these and of other international organizations relating to banned and severely restricted substances; whereas it is appropriate that the Community acts upon the results of this work through uniform Community procedures;

Whereas the export of chemicals to which this Regulation applies should be made subject to a common notification procedure which would permit the Community to notify third countries with regard to such exports;

Whereas it is necessary to ensure that the rules applicable within the Community for the packaging and labelling of banned or severely restricted chemicals should apply to such chemicals when destined for export;

Whereas it is necessary to inform all the Member States of notifications received from third countries with regard to import into the Community of substances banned or severely restricted under the legislation of those countries;

Whereas the common notification procedures should also provide a basis for an appropriate exchange of information within the Community, including information on the implementation of the international notification scheme;

Whereas to this end the Commission will report to the Council and to the European Parliament, at regular intervals, in particular on any possible reaction from the country of destination;

Whereas the Council resolution of 16 June 1988 (*) invited the Commission to submit proposals with a view to the possible adjustment of the Regulation so as to introduce a PIC scheme similar to that established by the UNEP and the FAO;

Whereas it is proper that the citizens of the Community receive no less protection than that afforded to the citizens of other importing countries participating in the international PIC scheme;

Whereas a single contact point for Community interaction with the international PIC scheme is desirable in order to coordinate and disseminate information; whereas, in light of the single European market of 1993, it is necessary to establish common conditions for the import and export of substances covered by the PIC scheme;

Whereas Annex I lists the chemicals banned or severely restricted in the Community; whereas this list should be subject to review at intervals and amendment as necessary; whereas any such amendment to Annex I should be made on the basis of proposals from the Commission and should be the subject of a decision by the Council by a qualified majority;

Whereas Annex II comprises a list of chemicals subject to the PIC procedure, the list of countries participating in the PIC procedure and the decisions of these countries regarding the import of the listed chemicals; whereas these lists and decisions will be amended at intervals jointly by the UNEP and the FAO; whereas the amendments should be adopted into Annex II to this Regulation following their publication by the Commission in the *Official Journal of the European Communities*;

Whereas Annex III identifies the information which should be included in the notification of the export to a third country of a chemical listed in Annex I; whereas to facilitate the amendment of Annex III, a system should be set up providing for close collaboration between the Member States and the Commission by means of a committee for the adaptation of that Annex to technical progress;

Whereas the Regulation excludes chemicals intended for analytical or research and development purposes;

Whereas the Commission, in the light of the operation of this Regulation, may propose to the Council appropriate amendments thereto,

HAS ADOPTED THIS REGULATION:

Article 1

Objectives

1. The purpose of this Regulation is to establish a common system of notification and information for imports from and exports to third countries of certain chemicals which are banned or severely restricted on account of their effects on human health and the environment and to participate in the international notification and 'prior informed consent' (PIC) procedure established by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization (FAO) (*).

2. This Regulation does not apply to substances or preparations imported or exported for the purposes of analysis or research and development where the quantities involved are sufficiently small that they are not likely to adversely affect human health or the environment.

2. This Regulation does not apply to substances or preparations imported or exported for the purposes of analysis or research and development where the quantities involved are sufficiently small that they are not likely to adversely affect human health or the environment. These quantities and the relevant justification shall in any case be notified to the Commission.

Article 2

Definitions

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

1. 'chemical subject to notification' means any of the chemical substances listed in Annex I and to preparations for which there is a labelling obligation due to the presence of a substance listed in Annex I;

2. 'chemical subject to the PIC-procedure' means each chemical listed in Annex II, whether by itself or in a mixture or preparation, whether manufactured or obtained from nature, unless its concentration in the mixture or preparation is insufficient for a labelling requirement;

3. 'banned chemical' means a chemical which has, for health or environmental reasons, been prohibited for all uses by final governmental regulatory action;

(* London Guidelines for the Exchange of Information on Chemicals in International Trade, Decision 14/27 of the Governing Council of UNEP of 17 June 1987 as amended

4. 'severely restricted chemical' means a chemical for which, for health or environmental reasons, virtually all uses have been prohibited nationally by final governmental regulatory action, but for which certain specific uses remain authorized;

5. 'export' means:
 - (a) the permanent or temporary export of products meeting the conditions of Article 9 (2) of the Treaty;

 - (b) the re-export of products not meeting the conditions of Article 9 (2) of the Treaty;

6. 'import' means any physical introduction of products into the customs territory of the Community meeting the conditions of Article 10 (1) of the Treaty;

7. 'prior informed consent' or 'PIC' means the principle that international shipment of a chemical that is banned or severely restricted in order to protect human health or the environment should not proceed without the agreement, where such agreement exists, or contrary to the decision of the designated national authority of the importing country;

8. 'reference number' means the number assigned by the Commission to each chemical subject to notification when it is exported for the first time to a third country. This number remains unchanged for every subsequent export of the same chemical from the Community to the same third country.

Article 3

Designation of authorities

1. Each Member State shall designate the authority or authorities, hereinafter referred to as the 'designated authority' or 'designated authorities', competent for the notification and information procedures laid down by this Regulation. It shall inform the Commission of such designation.

2. As far as the participation of the Community in the international 'prior informed consent' procedure is concerned, the Commission shall act as common designated authority with regard to receiving information from the competent bodies dealing with the international PIC procedure, and for providing information to these bodies on common decisions which have been taken in close cooperation and consultation with the Member States. The Commission shall advise the relevant competent bodies of its role relating to the PIC procedure.

Article 4

Exports to third countries

1. When a chemical subject to notification is exported for the first time following the date of the entry into force of Regulation (EEC) No 1734/88 (22 June 1989) from the Community to a third country, the designated authority of the State from which it is exported shall take the necessary measures to ensure that the appropriate authorities of the country of destination receive notification of the fact. Such notification, which shall take place prior to export must comply with the requirements set out in Annex III.

The designated authority shall send a copy of such notification to the Commission, which shall forward it to the designated authorities of the other Member States and to the International Register of Potentially Toxic Chemicals (IRPTC).

The Commission shall assign a reference number to each notification received and communicate it immediately to the designated authorities of the Member States. It shall periodically publish a list of these reference numbers in the *Official Journal of the European Communities*, stating the chemical concerned, and the third country of destination. Until a relevant reference number is published in the *Official Journal of the European Communities*, the exporter shall assume that such an export has not previously taken place unless it can obtain from the designated authority of its Member State the relevant reference number previously assigned by the Commission.

2. The designated authority of the relevant Member State shall inform the Commission as soon as possible of any significant reaction from the country of destination. The Commission shall ensure that the other Member States are informed as soon as possible of that country's reaction.

3. For every subsequent export of the chemical concerned from the Community to the same third country the exporter shall ensure that the export is accompanied by a reference to the number of the notification published in the *Official Journal of the European Communities* pursuant to the provisions of the third subparagraph of paragraph 1.

4. Notification must be given afresh whenever major changes are made to the Community legislation concerning the marketing and use of the substances in question or whenever the labelling of the preparation in question changes.

5. As regards the transmission of information within the meaning of paragraph 1, the Member States and the

5a. Member States shall take the necessary legal measures to enable severe sanctions to be imposed on persons exporting chemicals which are banned or severely restricted in the Community (according to the list in Annex I) without complying with the notification requirements contained in this Regulation. Such sanctions should, as far as possible, be the same in all Member States.

Article 5

Participation in the international notification and 'prior informed consent' procedure

1. The Commission shall notify the competent bodies dealing with the international PIC procedure of the chemicals which are banned or severely restricted in the Community (Annex I). It shall provide all relevant information especially on the identity of the chemicals, their dangerous properties, Community labelling requirements and necessary precautionary measures. It shall also identify the relevant control actions and the reasons for them.

1. The Commission shall notify the competent bodies dealing with the international PIC procedure of the chemicals which are banned or severely restricted in the Community (Annex I). It shall provide all relevant information especially on the identity of the chemicals, their dangerous properties, Community labelling requirements and necessary precautionary measures. It shall also identify the relevant control actions and the reasons for them. If a control action bans some uses but continues authorization for other uses, these shall be clearly identified.

2. The Commission shall forward forthwith to the Member States information it receives regarding chemicals subject to the PIC procedure and the decisions of third countries regarding the imposition of bans or import conditions on these chemicals. The Commission shall evaluate in close cooperation with the Member States the risks posed by the chemicals. It shall then inform the International Register of Potentially Toxic Chemicals whether import into the Community of each of the chemicals shall be allowed, prohibited or restricted. Before taking its decision the Commission shall consult the committee established under Article 20 of Council Directive 67/548/EEC (*).

When taking such a decision, the following principles shall be observed:

- (i) in the case of a substance or preparation banned by Community legislation: import consent shall be refused;
- (ii) in the case of a substance or preparation severely restricted by Community legislation: import consent shall be subject to conditions. The appropriate conditions shall be decided on a case by case basis;
- (iii) in the case of a substance or preparation not banned or severely restricted by Community legislation: import consent shall not normally be refused. However, if the Commission, in consultation with Member States, considers that a proposal should be made to the Council to ban or severely restrict

a substance or preparation not produced in the Community, then interim import conditions, set on a case by case basis, may be imposed until the Council has taken a decision on the proposed permanent ban or severe restriction.

The Commission shall pay particular attention to ensuring that its response does not conflict with existing Community legislation.

3. Annex II shall comprise the following:

- (i) the international list of banned and severely restricted chemicals subject to the PIC procedure established by the UNEP and FAO;
- (ii) a list of the countries participating in the PIC scheme; and
- (iii) the decisions of these countries (including the Community) regarding the import of the listed chemicals.

The Commission shall immediately notify the Member States of information it receives regarding changes to the above. It shall periodically publish these changes in the *Official Journal of the European Communities*.

The Commission shall, immediately upon receipt, forward to Member States decisions of third countries regarding the imposition of bans or import conditions on chemicals subject to the PIC procedure. Such a ban or imposition of conditions must be applied by the third country to all sources of the chemical, including local manufacture. An

ORIGINAL TEXT

AMENDED TEXT

4. The exporter is required to comply with the decision of the country of destination participating in the PIC procedure. Member States shall take appropriate legal measures to enable severe or dissuasive sanctions to be imposed on persons exporting chemicals subject to the international PIC procedure (Annex II) contrary to the PIC decision of the country of destination. The sanctions should, as far as possible, be the same in all Member States.

4. The exporter is required to comply with the decision of the country of destination participating in the PIC procedure. Member States shall take appropriate legal measures to enable severe or dissuasive sanctions to be imposed on persons exporting chemicals subject to the international PIC procedure (Annex II) contrary to the PIC decision of the country of destination. The sanctions should, as far as possible, be the same in all Member States. To this end, Member States shall, within one year of the date of entry into force of the regulation, notify the Commission of the sanctions adopted to comply with this provision.

Article 6

Packaging and labelling

1. Any of the chemicals listed in Annexes I and II which are intended for export shall be subject to such measures on packaging and labelling established in pursuance of Council Directive 67/548/EEC or, as appropriate, of other Directives covering dangerous preparations (*) as are applicable in the Member State from which the goods are to be exported or in which they have been produced. This obligation shall be without prejudice to any specific requirements of the importing third country. The label need comply with only the requirements of the importing third country

if such requirements ensure the label has all the health, safety and environment related information which EEC use would require.

2. The information on the label shall as far as practicable be given in the language(s), or in one or more of the principal languages, of the country of destination or of the area of intended use.

Article 7

Notification from third countries

1. Where the designated authority of a Member State receives a notification from the competent authority of a third country concerning the export to the Community of a chemical whose manufacture, use, handling, consumption, transport and/or sale is subject to prohibition or substantial legal restriction under that country's legislation, it shall send forthwith to the Commission a copy of that notification together with all relevant information.

2. The Commission shall forward forthwith to the Member States any notification received either directly or indirectly, together with all available information.

3. The Commission shall periodically evaluate the information received via the Member States or directly from third countries and, if necessary, submit appropriate proposals to the Council.

Article 8

Exchange of information and monitoring

1. Member States shall regularly forward to the Commission information on the operation of the notification system provided for in this Regulation.

2. The Commission shall regularly compile a report on the basis of the information provided by the Member States and forward it to the Council and the European Parliament. This report shall consist, inter alia, of information on participation in international notification and PIC systems, on the cover provided by such systems and on how they are complied with by third countries.

2. The Commission shall, each year after the entry into force of this Regulation, compile a report on the basis of the information provided by the Member States and forward it to the Council and the European Parliament. This report shall consist, inter alia, of information on participation in international notification and PIC systems, on the cover provided by such systems and on how they are complied with by third countries.

3. As regards the information supplied pursuant to paragraphs 1 and 2, the Member States and the Commission shall take account of the need to protect the confidentiality of data and ownership.

Article 9

If a Member State applies, with respect to substances other than those in Annex I, a national system using similar information procedures in respect of third countries of those laid down in this Regulation, it shall inform the Commission, specifying the substances concerned. The Commission shall forward this information to the Member States.

Article 10

Updating of Annexes

1. The list of chemicals in Annex I shall be reviewed by the Commission at intervals particularly in the light of experience gained in implementing this Regulation, with special regard to information received pursuant to Article 9, and on the basis of developments in Community legislation concerning marketing and use and of developments within the framework of the OECD, the UNEP and the FAO. The list shall be amended as necessary by decisions taken by the Council by qualified majority on a proposal from the Commission.

1. The list of chemicals in Annex I shall be reviewed by the Commission at intervals particularly in the light of experience gained in implementing this Regulation, with special regard to information received pursuant to Article 9, and on the basis of developments in Community legislation concerning marketing and use and of developments within the framework of the OECD, the UNEP and the FAO if and when further chemicals are banned or severely restricted in the Community. The list shall be amended as necessary by decisions taken by the Council by qualified majority on a proposal from the Commission.

1a. Within five years of the date of adoption of this Regulation the Commission will re-order the list of substances appearing at Annex I to conform with the categories of use to be decided by the UNEP and FAO.

2. Amendments initiated by the UNEP and the FAO to the list of chemicals subject to the international PIC procedure and to the PIC decisions of importing countries (Annex II) shall be adopted in accordance with the procedure laid down in Article 21 of Directive 67/548/EEC.

3. The amendments required for adapting Annex III to scientific and technical progress shall be adopted in accordance with the procedure laid down in Article 21 of Directive 67/548/EEC.

Article 11

1. Regulation (EEC) No 1734/88 is hereby repealed.

2. References to the Regulation repealed under paragraph 1 shall be construed as references to this Regulation.

Article 12

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

ANNEX I

List of chemicals banned or severely restricted to certain uses owing to their effects on human health and the environment

Chemical	CAS No (*)	Einecs No (*)
1. Mercuric oxide	21908-53-2	2446547
2. Mercurous chloride (calomel)	10112-91-1	2333075
3. Other inorganic mercury compounds		
4. Alkyl mercury compounds		
5. Alkoxyalkyl and aryl mercury compounds		
6. Aldrin	309-00-2	2062158
7. Chlordane	57-74-9	2003490
8. Dieldrin	60-57-1	2004845
9. DDT	50-29-3	2000243
10. Endrin	72-20-8	2007757
11. HCH containing less than 99,0 % of the gamma isomer	608-73-1	2101689
12. Heptachlor	76-44-8	2009623
13. Hexachlorobenzene	118-74-1	2042739
14. Camphechlor (toxaphene)	8001-35-2	2322833
15. Polychlorinated biphenyls (PCB), except mono- and dichlorinated biphenyls	1336-36-3	2156481
16. Polychlorinated terphenyls (PCT)	61788-33-8	2629682
17. Preparations with a PCB or PCT content higher than 0,01 % by weight		
18. Tris(2,3 dibromopropyl) phosphate	126-72-7	2047999
19. Tris-aziridinyl-phosphinoxide	545-55-1	2088925
20. Polybrominated biphenyls (PBB)		
21. Crocidolite	12001-28-4	
22. Chrysotile	12001-29-5	
23. Amosite	12172-73-5	
24. Anthophyllite	77536-67-5	
25. Actinolite	77536-66-5	
26. Tremolite	77536-68-6	
27. Nitrofen	1836-75-5	217-406-0
28. 1,2-Dibromoethane	106-93-4	203-444-5
29. 1,2-Dichloroethene	540-59-0	208-750-2

(*) CAS: Chemical Abstracts Service.

(*) Einecs: European Inventory of Existing Commercial Chemical Substances.

ANNEX II

Chemicals subject to the international PIC procedure and the PIC decisions of importing countries

ANNEX III

Information required pursuant to Article 4

1. Identity of the substance or preparation to be exported:
 - 1.1. Substances:
 - name in nomenclature of the International Union of Pure and Applied Chemistry,
 - other names (usual name, trade name, abbreviation),
 - Eines No and CAS No (if available),
 - main impurities of the substance, when particularly relevant.
 - 1.2. Preparations:
 - trade name or designation of the preparation,
 - for each substance listed in Annex I, percentage and details as specified under 1.1.
2. Information on precautions to be taken, including category of danger and risk, and safety advice.
3. The name, address, telephone and telex numbers of the designated authority from whom further information may be obtained.

4. Summary of regulatory restrictions and reasons for them.

4. Summary of regulatory restrictions, reasons for them and indication of potential impact on human beings and their environment.

5. Expected date of export.
6. Reference number.
7. Country of destination.

The above information should be provided on an export notification form as shown overleaf.

ORIGINAL TEXT

AMENDED TEXT

COMMISSION
OF THE
EUROPEAN COMMUNITIES

REGULATION (EEC) No 1734/88

EXPORT NOTIFICATION FORM FOR BANNED AND SEVERELY RESTRICTED CHEMICALS

1. EXPORT NOTIFICATION REFERENCE NUMBER:

2. EXPORT CONSISTS OF A BANNED OR SEVERELY RESTRICTED CHEMICAL (*)
 Name(s) of chemical:
 Eines No: CAS No:

3. EXPORT CONSISTS OF A PREPARATION CONTAINING ONE OR MORE BANNED OR SEVERELY RESTRICTED CHEMICAL(S) (*)
 Name(s) of preparation:
 Labelling code for preparation:
 Name(s) of constituent chemical(s) banned or severely restricted

i) % in preparation: Eines No: CAS No:

ii) % in preparation: Eines No: CAS No:

iii) % in preparation: Eines No: CAS No:

4. COUNTRY OF DESTINATION:
 Expected date of first export:

DESIGNATED NATIONAL AUTHORITIES

in the EC:	in the importing country:
.....
.....
.....
.....
.....
.....
.....

Representative of exporting country: Signature: Date:	Official stamp
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(*) Box 2 or box 3 to be completed.
 Note: Chemical and label data overleaf

ORIGINAL TEXT

AMENDED TEXT

DATA SHEET FOR A BANNED OR SEVERELY RESTRICTED CHEMICAL

CHEMICAL NAME(S):	
Einecs No:	CAS No:

LABELLING REQUIREMENTS FOR CHEMICAL	
Classification:	Code:
Risk phrases:	
Safety phrases:	

SUMMARY OF CONTROL ACTION AND USE(S) CONTROLLED:
REFERENCE TO EEC OR NATIONAL LEGISLATION:
REASONS SUPPORTING THE CONTROL ACTION:

ADDITIONAL INFORMATION:

LEGISLATIVE RESOLUTION

embodying the opinion of the European Parliament on the proposal from the Commission to the Council for a regulation concerning export and import of certain dangerous chemicals

The European Parliament,

- having regard to the Commission proposal to the Council (COM(90) 0591)¹,
 - having been consulted by the Council pursuant to Article 130b of the EEC Treaty (C3-0051/91),
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Protection (A3-0256/91),
1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;
 2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;
 3. Calls on the Council to notify Parliament should it intend to depart from the text approved by Parliament;
 4. Asks to be consulted again should Council intend to make substantial modifications to the Commission proposal;
 5. Instructs its President to forward this opinion to the Council and Commission.

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