

COUNCIL REGULATION (EEC) No 2455/92

of 23 July 1992

concerning the export and import of certain dangerous chemicals

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 ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Regulation (EEC) No 1734/88 ⁽⁴⁾ concerns exports and imports 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 to be replaced by this Regulation;

Whereas certain provisions of Community legislation, and in particular Directives 76/769/EEC ⁽⁵⁾ and 79/117/EEC ⁽⁶⁾ 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; whereas these provisions do not apply to such products when intended for export to third countries;

Whereas Directive 67/548/EEC ⁽⁷⁾ specifies the requirements for packaging and labelling of dangerous chemicals when they are intended for export to third countries; whereas it is necessary to ensure that the rules applicable within the Community for the packaging and labelling of dangerous chemicals should apply to such chemicals when intended for export;

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

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

Whereas schemes for notification, information and PIC 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 exports 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 inform all the Member States of notifications received from third countries with regard to imports of substances banned or severely restricted under the legislation of those countries;

⁽¹⁾ OJ No C 17, 25. 1. 1991, p. 16.

⁽²⁾ OJ No C 305, 25. 11. 1991, p. 112.

⁽³⁾ OJ No C 191, 22. 7. 1991, p. 17.

⁽⁴⁾ OJ No L 155, 22. 6. 1988, p. 2.

⁽⁵⁾ OJ No L 262, 27. 9. 1976, p. 201. Directive as last amended by Directive 91/339/EEC (OJ No L 186, 12. 7. 1991, p. 64).

⁽⁶⁾ OJ No L 33, 8. 2. 1979, p. 36. Directive as last amended by Directive 91/188/EEC (OJ No L 92, 13. 4. 1991, p. 42).

⁽⁷⁾ OJ No L 196, 16. 8. 1967, p. 1. Directive as last amended by Directive 79/831/EEC (OJ No L 259, 15. 10. 1979, p. 10).

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 European Parliament and the Council and at regular intervals, in particular on any possible reaction from the country of destination;

Whereas Resolution 88/C 170/1⁽¹⁾ invited the Commission to submit proposals for adapting Regulation No 1734/88 with a view to introducing a PIC scheme similar to that established by the UNEP and the FAO;

Whereas it is right that citizens of the Member States should 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 it is desirable to establish common conditions for the import and export of substances covered by the PIC scheme;

Whereas Annex 1 lists the chemicals banned or severely restricted in the Community and 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,

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 apply 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⁾.

2. The purpose of this Regulation is also to ensure that the provisions of Directive 67/548/EEC on the classification, packaging and labelling of substances dangerous to man or the environment when they are placed on the market in the Member States shall also apply to such substances when they are exported from the Member States to third countries.

3. This Regulation does not apply to substances or preparations imported or exported for the purposes of analysis or scientific research and development as defined in Article 2, where the quantities involved are sufficiently small that they are unlikely to affect human health or the environment adversely.

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 preparations containing any of these chemicals if the preparation has a labelling obligation under Community legislation as a result of the presence of the Annex I chemical;

2. 'chemical subject to the PIC procedure'

means each chemical listed in Annex II, whether by itself or in preparations, whether manufactured or obtained from nature, unless its concentration in a preparation is insufficient for a labelling requirement under Community legislation.

3. 'banned chemical'

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

4. 'severely restricted chemical'

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

⁽¹⁾ OJ No C 170, 29. 6. 1988, p. 1.

⁽²⁾ 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 in May 1989; FAO International Code of Conduct on the Distribution and Use of Pesticides, Rome 1986, as amended in November 1989.

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 referred to in (a) which are placed under a customs procedure other than transit procedure;

6. 'import'

means the physical introduction into the customs territory of the Community of products which are placed under a customs procedure other than transit procedure;

7. 'prior informed consent' (PIC)

means the principle that international shipment of a chemical which 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;

9. 'labelling'

means the provision on a label of information related to the potential hazard to health, safety or the environment from use of the chemical. It does not refer to labelling requirements for the transport of dangerous goods.

10. 'scientific research and development'

means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic properties, performance and efficacy as well as scientific investigation related to product development.

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 PIC 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 in accordance with the provisions of Article 5.

Article 4

Exports to third countries

1. When a chemical subject to notification is due to be exported from the Community to a third country for the first time following the date as of which it becomes subject to the provisions of this Regulation, the exporter shall provide the designated authority of the Member State in which he is established, no later than 30 days before the export is due to take place, with the information contained in Annex III necessary to enable the designated authority to effect a notification. The designated authority shall take the necessary measures to ensure that the appropriate authorities of the country of destination receive notification of the intended export. Such notification, which shall as far as possible be made at least 15 days before export, must comply with the requirements set out in Annex III.

Where the export of a chemical relates to an emergency situation in which any delay may endanger public health or the environment in the importing country, the provisions referred to above may be waived wholly or partly at the discretion of the designated authority of the exporting Member State.

The designated authority shall send a copy of the 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 he can obtain from the designated authority of the Member State in which he is established 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 reference to the number of the notification either published in the *Official Journal of the European Communities* or obtained by it from the designated authority of the Member State in which he is established pursuant to the fourth subparagraph of paragraph 1.

4. New notification according to paragraph 1 must be given for exports which take place subsequent to major changes to Community legislation concerning the marketing and use or labelling of the substances in question or whenever the composition of the preparation in question changes to such an extent that the labelling of such preparation is altered. The new notification must comply with the requirements set out in Annex III and must indicate that it is a revision of a previous notification. Information to the effect that a new notification is needed shall be published in the *Official Journal of the European Communities*.

The Commission shall send new notifications to the designated national authorities of countries which have received notification of the export from the Community of the substance or preparation in question in the six months prior to the relevant changes to Community legislation.

5. As regards the transmission of information within the meaning of paragraph 1, the Member States and the Commission shall take account of the need to protect the confidentiality of data and ownership in both the Member States and the countries of destination.

The following shall not be regarded as confidential:

- the names of the substance;
- the names of the preparation;
- the names of substances in Annex I contained in the preparation and their percentage in the preparation;
- the names of the main impurities in the substances in Annex I;
- the name of the manufacturer or exporter;
- information on the precautions to be taken, including the category of danger, the nature of the risk and the relevant warnings;
- physico-chemical data concerning the substances;

- the summary results of the toxicological and ecotoxicological tests;
- the possible ways of rendering the substance harmless;
- the information contained in the safety data sheet;
- the country of destination.

Article 5

Participation in the international notification and 'prior informed consent' (PIC) 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.

2. The Commission shall forward forthwith to the Member States information which 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. The Commission shall take its decision, including interim decisions, in accordance with the procedure laid down in Article 21 of Directive 67/548/EEC. It shall then inform the IRPTC whether import into the Community of each of the chemicals is allowed, prohibited or restricted.

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

- (a) in the case of a substance or preparation banned by Community legislation: import consent for the banned use shall be refused;
- (b) 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;
- (c) 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, interim

import conditions, set on a case by case basis, may be imposed until the Council has taken a decision on the proposed severe restriction or permanent ban.

In the case of a substance or preparation banned or severely restricted by legislation of one or more Member State, the Commission shall, at the written request of the Member State concerned, prepare its decision on the reply to be made to the IRPTC, taking into consideration that Member State's bans or severe restrictions.

The Commission shall, whenever practicable, make use of existing Community procedures and shall ensure that the response does not conflict with existing Community legislation.

3. Annex II shall comprise the following:

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

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

4. The exporter shall be required to comply with the decision of the country of destination participating in the PIC procedure.

5. If a participating importing country does not make a response or responds with an interim decision which does not address importation, the status quo with respect to imports of the chemical should continue. This means that the chemical should not be exported without the explicit consent of the importing country, unless it is a pesticide which is registered in the importing country or is a chemical the use or importation of which has been allowed by other action of the importing country.

Article 6

Infringements

Member States shall take appropriate legal or administrative action in the event of infringement of the provisions of this Regulation.

Article 7

Packaging and labelling

1. Dangerous chemicals which are intended for export shall be subject to the measures on packaging and labelling established pursuant to Directive 67/548/EEC or, as appropriate, of other Directives covering dangerous preparations ⁽¹⁾ 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 the requirements of the importing third country only if such requirements ensure that the label has all the health, safety and environment-related information which Community 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 8

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 the manufacture, use, handling, consumption, transport and/or sale of which 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 9

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.

⁽¹⁾ Directive 78/631/EEC (OJ No L 206, 29. 7. 1978, p. 13), as last amended by Directive 84/299/EEC (OJ No L 144, 30. 5. 1984, p. 1).
Directive 88/379/EEC (OJ No L 187, 16. 7. 1988, p. 14), as last amended by Directive 90/492/EEC (OJ No L 275, 5. 10. 1990, p. 35).

2. The Commission shall regularly compile a report on the basis of the information provided by the Member States and forward it to the European Parliament and the Council. This report shall consist of, *inter alia*, 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 10

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 to those laid down in this Regulation, it shall inform the Commission thereof, specifying the substances concerned.

The Commission shall forward this information to the Member States.

Article 11

Updating of Annexes

1. The list of chemicals in Annex I shall be reviewed by the Commission at regular intervals, particularly in the light of experience gained in implementing this Regulation, with special regard to information received pursuant to Article 10, 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.

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

Done at Brussels, 23 July 1992

In determining whether regulatory action qualifies as a ban or severe restriction, the effect of the action on any one of three major use categories must be considered. These categories are:

- (a) plant protection products;
- (b) industrial chemicals;
- (c) consumer product chemicals

If, for health or environmental reasons, the control action bans or severely restricts the use of a chemical in any one of these categories of use, it will be included in Annex I.

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 12

1. Regulation (EEC) No 1734/88 is hereby repealed.
2. References to Regulation (EEC) No 1734/88 shall be construed as references to this Regulation.

Article 13

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

For the Council

The President

J. COPE

ANNEX I

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

Chemical	CAS No (a)	EINECS No (b)	Use (c) category	Use (d) limitation
1. Mercuric oxide	21908-53-2	244-654-7	p	sr
2. Mercurous chloride (calomel)	10112-91-1	233-307-5	p	sr
3. Other inorganic mercury compounds			p	b
4. Alkyl mercury compounds			p	sr
5. Alkoxyalkyl and aryl mercury compounds			p	b
6. Aldrin	309-00-2	206-215-8	p	sr
7. Chlordane	57-74-9	200-349-0	p	b
8. Dieldrin	60-57-1	200-484-5	p	b
9. DDT	50-29-3	200-024-3	p	b
10. Endrin	72-20-8	200-775-7	p	sr
11. HCH containing less than 99,0 % of the gamma isomer	608-73-1	210-168-9	p	b
12. Heptachlor	76-44-8	200-962-3	p	b
13. Hexachlorobenzene	118-74-1	204-273-9	p	b
14. Camphechlor (toxaphene)	8001-35-2	232-283-3	p	b
15. Polychlorinated biphenyls (PCB), except mono- and dichlorinated biphenyls	1336-36-3	215-648-1	i	b
16. Polychlorinated terphenyls (PCT)	61788-33-8	262-968-2	i	b
17. Preparations with a PCB or PCT content higher than 0,01% by weight			i	b
18. Tris (2,3-dibromopropyl) phosphate	126-72-7	204-799-9	i	sr
19. Tris-aziridinyl-phosphin oxide	545-55-1	208-892-5	i	sr
20. Polybrominated biphenyls (PBB)			i	sr
21. Crocidolite	12001-28-4		i	sr
22. Nitrofen	1836-75-5	217-406-0	p	b
23. 1,2 Dibromoethane	106-93-4	203-444-5	p	b
24. 1,2 Dichloroethane	107-06-2	203-458-1	p	b

(a) CAS = Chemical Abstracts Service.

(b) EINECS = European Inventory of Existing Commercial Chemical Substances.

(c) Use category:

p: plant-protection product

i: industrial chemical

(d) Use limitation:

sr: severe restriction

b: ban

ANNEX II

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

[Article 5(3), (a), (b) and (c)]

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),
 - EINECS-number and CAS-number, 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 or fax numbers of the designated authority from which further information may be obtained.
4. Summary of regulatory restrictions and reasons for them.
5. Expected date of first export.
6. Reference number.
7. Country of destination.
8. Use category.
9. Estimated amount of the chemical to be exported to the destination country in the next year if possible.

The above information should be provided on an expert notification form as shown hereafter.

COMMISSION OF THE EUROPEAN COMMUNITIES

REGULATION (EEC) No. 2455/92

EXPORT NOTIFICATION FORM FOR BANNED AND SEVERELY RESTRICTED CHEMICALS

1. EXPORT NOTIFICATION REFERENCE NUMBER:

2. EXPORT CONSISTS OF A BANNED OR SEVERELY RESTRICTED CHEMICAL (1):
Name(s) of chemical:
EINECS No: CAS No:

3. EXPORT CONSISTS OF A PREPARATION CONTAINING ONE OR MORE BANNED OR SEVERELY RESTRICTED CHEMICAL(S) (1):
Name(s) of preparation:
Labelling code for preparation:
Name(s) of constituent chemical(s) banned or severely restricted:
i) % in preparation EINECS No: CAS No:
ii) % in preparation: EINECS No: CAS No:

4. COUNTRY OF DESTINATION:
Expected date of first export:
Estimated amount of the chemical to be exported to the destination country in the next year (if possible):

5. DESIGNATED NATIONAL AUTHORITIES:
in the EC:
in the importing country:
Representative of exporting country Official stamp
Signature
Date

(1) Box 2 or box 3 to be completed.
Note: Chemical and legal data overleaf.

DATA SHEET FOR A BANNED OR SEVERELY RESTRICTED CHEMICAL

CHEMICAL NAME(S):

EINECS No: CAS No: Use category(ies):

LABELLING REQUIREMENTS FOR CHEMICAL

Classification: Code:

Risk phrases:

Safety phrases:

SUMMARY OF CONTROL ACTION AND USE(S) CONTROLLED:

REFERENCE TO COMMUNITY OR NATIONAL LEGISLATION:

REASONS SUPPORTING THE CONTROL ACTION.

ADDITIONAL INFORMATION:

Note: If a preparation contains more than one chemical which is banned or severely restricted in the Community, data sheets on the additional chemicals must be attached hereto.
