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In accordance with Council Regulation (EEC, Euratom) No 354/83 of 1 February 1983 concerning the opening to the public of the historical archives of the European Economic Community and the European Atomic Energy Community (OJ L 43, 15.2.1983, p. 1), as amended by Regulation (EC, Euratom) No 1700/2003 of 22 September 2003 (OJ L 243, 27.9.2003, p. 1), this file is open to the public. Where necessary, classified documents in this file have been declassified in conformity with Article 5 of the aforementioned regulation.

In Übereinstimmung mit der Verordnung (EWG, Euratom) Nr. 354/83 des Rates vom 1. Februar 1983 über die Freigabe der historischen Archive der Europäischen Wirtschaftsgemeinschaft und der Europäischen Atomgemeinschaft (ABl. L 43 vom 15.2.1983, S. 1), geändert durch die Verordnung (EG, Euratom) Nr. 1700/2003 vom 22. September 2003 (ABl. L 243 vom 27.9.2003, S. 1), ist diese Datei der Öffentlichkeit zugänglich. Soweit erforderlich, wurden die Verschlussachen in dieser Datei in Übereinstimmung mit Artikel 5 der genannten Verordnung freigegeben.

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(74) 1189 final

Brussels, 25 July 1974

Proposal for a

COUNCIL DIRECTIVE

on the approximation of the laws of the
Member States restricting the marketing
and use of certain dangerous substances
and preparations

(submitted to the Council by the Commission)

EXPLANATORY MEMORANDUM

I. GENERAL OBSERVATIONS

1. There are a large number of dangerous substances and preparations which are toxic, noxious, corrosive, irritant, explosive or readily inflammable and which may cause damage to man or to the environment. In order to protect the general public, and especially those who use them, from the risks attaching to dangerous substances and preparations, the Council, acting on a proposal from the Commission, adopted on 27 June 1967 a Directive on the classification, packaging and labelling of dangerous substances¹, most recently amended by the Council Directive of 21 May 1973². To provide even more effective protection against the risks attaching to the use of dangerous substances and preparations, the Council adopted on 4 June 1973 a Directive on dangerous preparations used as solvents³. It subsequently transpired that for some dangerous substances and preparations, regulations governing classification, packaging and labelling were not sufficient; it was also necessary to prohibit or restrict marketing and use under certain conditions. Consequently a Directive to supplement Community provisions already existing in this field was necessary.

Some Member States have adopted provisions governing various sectors of this field. These provisions show disparities and thus hinder the free movement of goods. In order to eliminate these barriers, it is necessary to harmonize the existing provisions laid down by law in the Member States.

2. At Community level, there are already Directives guaranteeing the free movement of goods and ensuring protection to human health and the environment. They do not, however, form an adequate basis for the introduction of general restrictions on the marketing or use of dangerous substances and preparations. Therefore it is necessary to adopt a Directive containing general restrictive provisions applying to fields which are not covered by other Directives, such as those on

¹OJ No 196, 16 August, 1967, p.1.

²OJ No L 167, 25 June 1973, p.1.

³OJ No L 189, 11 July 1973, p.7.

the composition of petrol (lead content), the sulphur levels of fuels, lead and cadmium in ceramics and dangerous substances in paints and varnishes.

3. The Directive will also have the advantage of allowing more rapid and effective implementation in the European Community of restrictions recommended or adopted by other international organizations, such as the decision by the Council of the Organization for Economic Cooperation and Development (OECD) to restrict production and sale of chemical products known as polychlorinated biphenyls (PCBs) the use of which may contaminate human health and the environment.

4. The toxicity and persistence of PCBs was noticed for the first time in 1966, when traces of these products were found in poisoned fish and wild birds. Accidents which occurred included the contamination of chickens by PCBs present in plastic packaging materials, the discovery of PCBs in wrappings of food products, as a result of the use of carbonless copying paper in the manufacture of paper pulp, and the presence of PCB in cow's milk due to absorption by these animals from feedingstuffs of PCBs arising from herbicide treatment or storage silos. In the most serious accident human beings were poisoned as a result of the leakage of heat transfer liquid in a rice oil pasteurization factory in Japan.

For these reasons, a restriction on the marketing and use of PCBs is necessary. Thus the only uses to remain authorized will be those contained in a certain limitative list, consisting mainly of cases where the non-inflammable nature of PCBs is an indispensable characteristic.

5. The main purpose of the following proposal for a Directive is to attain the following objectives of the Treaty establishing the Community:

- improved protection of the life and health of the general public, and in particular of persons obliged by their occupation to be in contact with dangerous substances and preparations;

- guaranteeing of the free movement of goods in the European Community.

A further purpose of the proposed Directive is to help to protect the environment and to restore, maintain and improve the quality of life.

6. For these reasons provision is made for this Directive in both the Council Resolution of 17 December 1973 on industrial policy, and the Declaration of the Council and of the representatives of the Governments of the Member States meeting in the Council of 22 November 1973 on the programme of action of the European Communities on the environment.

7. To leave open the possibility of extending the scope of the Directive to other dangerous substances and preparations or of determining or amending the details of the restrictions, a simple and rapid procedure was necessary. To this end, the Committee on Dangerous Substances, established by the Council Directive of 21 May 1973, will be consulted whenever the question of extending or amending the Directive arises.

8. The proposal for a Directive has been drawn up with a view to complete harmonization, which means that Community provisions will replace national provisions existing in Member States.

The complete harmonization solution has been adopted in this case having regard to the fact that these substances and preparations are dangerous to human beings and may pollute the environment.

9. Finally, the proposed Directive is intended to encourage manufacturers of dangerous substances and preparations to replace these by equivalent products which are less dangerous to human health and the environment.

II. COMMENTS ON THE ARTICLES

Article 1

This governs the scope of the Directive and contains definitions. The scope is restricted as little as possible in order that, in the future

restrictions may be laid down for all the dangerous substances and preparations meriting consideration, providing that these restrictions are prompted by a desire to safeguard health or the environment.

Article 2

This provision compels Member States to control the marketing and use of the substances and preparations listed in the Annex in accordance with the conditions laid down.

Article 3

This Article provides for a procedure for amending the Annex to the Directive in the light of technical progress. Amendments must be adopted in accordance with the procedure laid down in the Council Directive of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Some of the experts consulted were against this procedure since unanimous agreement would not be required to supplement or amend the Annex.

Articles 4 and 5

These Articles are common to all Directives.

Annex

1. The Annex contains at present only polychlorinated biphenyls (PCB) for which the restrictive conditions are the same as those laid down by the Council of the Organization for Economic Cooperation and Development (OECD) on 13 February 1973.

The number of substances in the Annex has been reduced compared with the initial draft, for two reasons. Firstly, the substances removed from the Annex will be covered by particular Directives in which the ways and means of restricting them will be given and secondly, the Commission departments were not in possession of sufficient scientific information to decide upon immediate restrictions on a Community-wide scale.

2. The polychlorinated biphenyls (PCB) are a group of stable substances, consisting theoretically of more than 200 compounds, many of which are widely used, particularly on account of their dielectric properties and their non-inflammable nature. They are at present obtained by chlorination of biphenyl, which gives rise to mixtures which are characterized by their mean chlorine contents. Because of the persistence and toxicity of some of these compounds, effects upon the environment have been observed and accidents which have been reported during the last few years have caused serious misgivings in various countries. That is why priority has been given to studying the need for, and possibility of, concerted action to control the use of PCBs.

3. According to Article 2, the marketing and use of PCBs is prohibited except for a small number of categories listed in the Annex to the Directive, that is, "closed systems".

The use of PCBs in closed systems may be defined as applications where the PCBs are recoverable. PCBs used in transformers, large capacitors, heat transfer systems, hydraulic equipment and vacuum pumps are in theory recoverable because, while they are being used, they are not generally dispersed into the environment.

III. CONSULTATION OF THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE

It is essential that these two institutions give their opinion in accordance with Article 100(2).

PROPOSAL FOR A COUNCIL DIRECTIVE
on the approximation of the laws of the Member States
restricting the marketing and use of certain dangerous
substances and preparations

THE COUNCIL OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 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 any rules concerning the placing on the market of dangerous substances and preparations must aim at protecting the public, and in particular workers using such substances and preparations;
Whereas they should also contribute to the restoration, preservation and improvement of human life and to the protection against risks to health caused by environmental pollution;
Whereas dangerous substances and preparations are governed by rules in the Member States, and whereas these rules differ as to the conditions of their marketing and use; whereas these differences constitute an obstacle to trade and directly affect the establishment and functioning of the Common Market;
Whereas this obstacle should therefore be removed and whereas this entails approximating the existing relevant laws in the Member States;
Whereas the provisions relating to certain dangerous substances and preparations have already been provided for in Community directives; whereas it is still necessary to lay down rules for other products, in particular for those for which international organizations have established restrictions, for example, the Council of the OECD

.../...

decided on 13 February 1973 the restriction of the production and use of the polychlorinated biphenyls (PCB). This provision was necessary to prevent the absorption of the PCB in the human body and the resultant danger to human health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Without prejudice to the implementation of other relevant Community provisions, this Directive is concerned with restricting the marketing and use of certain dangerous substances and preparations in the Member States of the Community, and in particular those which present characteristic of ecotoxicity.
2. This Directive does not apply to:
 - (a) the carriage of dangerous substances and preparations by rail, road, inland waterway, sea or air;
 - (b) dangerous substances and preparations exported to non-member countries;
 - (c) substances and preparations in transit and subject to customs inspection, provided that they undergo no processing.
3. For the purposes of this Directive:
 - (a) "substances" means
Chemical elements and their compounds as they occur in the natural state or as produced by industry;
 - (b) "preparations" means
Mixtures or solutions composed of two or more substances.

.../...

Article 2

Member States shall take all necessary measures to ensure that the dangerous substances and preparations listed in the annex and subject to the conditions specified therein cannot be placed on the market or used, except for purposes of research or analysis.

Article 3

The amendments required to adapt the annex in the light of technical progress shall be adopted in accordance with the procedure laid down in Article 8 c of the Directive of 27 June 1967 (7/548/EEC) concerning the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as last amended by the Directive of 21 May 1973 (73/145/EEC).

Article 4

1. Member States shall adopt and publish the measures needed in order to comply with this Directive by 1 January 1976 and shall forthwith inform the Commission thereof. They shall apply these provisions from 1 October 1976.
2. On notification of this Directive, Member States shall inform the Commission, in time to enable it to put forward its comments, of all draft laws, regulations or administrative provisions which they contemplate adopting in the field covered by this Directive.

Article 5

This Directive is addressed to the Member States.

ANNEX

Designation of the substance or
preparation or groups of substances

Conditions of restriction

1. Polychlorinated Biphenyls (PCB) . May not be used except for the following:
- Dielectric fluids for transformers or large power factor correction capacitors (\geq 1 kg);
 - Heat transfer fluids (other than in installations for processing of foods, drugs, feeds and veterinary products);
 - Hydraulic fluids in mining equipment;
 - Small capacitors ($<$ 1 kg and \leq 42% Cl).