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Report

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the protection of the European Consumer against imports into the Community of products declared unfit for consumption by US legislation
(Doc. 1-781/80/rev.)

Rapporteur : Mrs V. SQUARCIALUPI

PE 82.200/fin.

English Edition

At its sitting of 12 January 1981, the European Parliament decided, pursuant to Rule 47 of the Rules of Procedure, to refer the motion for a resolution tabled by Mr Glinne and others on the protection of the European consumer against imports of products declared unfit for consumption by US legislation (Doc. 1-781/80/rev.) to the Committee on the Environment, Public Health and Consumer Protection.

At its meeting of 2 October 1981, the committee decided to draw up a report and appointed Mrs SQUARCIALUPI rapporteur.

It considered the draft report at its meetings of 17 May 1982, 23 June 1982, 24 November 1982, 26 January 1983 and 16 March 1983 and, at the latter meeting, adopted the motion for a resolution by 11 votes to 9 with 1 abstention.

The following took part in the vote :

Mr Collins, chairman; Mr Ryan and Mrs Weber, vice-chairmen; Mrs Squarcialupi, rapporteur; Mr Alber, Mr Bombard, Mr Ceravolo (deputizing for Mr Spinelli), Mr Del Duca, Mr Eisma (deputizing for Mrs Spaak), Mrs Ewing (deputizing for Mr Remilly), Mr Geurtsen (deputizing for Mr Berkhouwer), Mr Ghergo, Mrs Van Hemeldonck, Mrs Krouwel-Vlam, Mrs Lentz-Cornette, Mr Nordmann, Mr Pantazi, Mrs Schleicher, Mrs Seibel-Emmerling, Mr Sherlock and Mr Vanneck (deputizing for Mr Forth).

The report was tabled on 23 March 1983.

C o n t e n t s

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The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following motion for a resolution together with explanatory statement :

MOTION FOR A RESOLUTION

on the protection of the European Consumer against imports into the Community of products declared unfit for consumption by US. legislation

The European Parliament;

- having regard to the motion for a resolution tabled by Mr Glinne and others (Doc. 1-781/80/rev.),

- having regard to the motion for a resolution tabled by Mrs Van Hemeldonck and others on the export of hazardous products from the United States (Doc. 1-919 /82),

- having regard to the report by the Committee on the Environment, Public Health and Consumer Protection (Doc. 1-91/83),

A. Stressing the right of European consumers to the protection of their health and safety,

B. convinced of the need to prevent trade relations between the European Community and the United States from being disrupted by trade in products which are unfit for consumption,

C. considering that an approximation of the laws of the European Community and the United States can prevent cases of unfair competition,

D. noting with dismay and concern that US legislation on harmful products is not as stringent as it used to be and, indeed, is tending progressively to reduce or even abolish altogether the seller's responsibilities to foreign purchasers of dangerous substances,

E. noting that, in addition to the various specific directives, Article 23 of Directive 79/831 of 18 September 1979 (safeguard clause) constitutes a legislative means of preventing the circulation in a Member State of

products originating in third countries and therefore also in the United States which are unfit for consumption.

1. Urges the Commission of the European Communities to request the United States Government to speed up the current negotiations on the possibility of concluding an agreement on detailed rules for the application of the Toxic Substances Control Act (TSCA) to products originating in the USA and of Community legislation to products originating in Community countries;

2. Also calls on the Commission to submit as soon as possible to the Council a proposal amending Directive 76/769 of 27 July 1976 so that the annexes can be quickly amplified and modified by the Technical Adaptation Committee;

3. Requests the US Government not to implement its plans to allow the free sale abroad of dangerous products produced in that country.

4. Instructs its President to forward this resolution to the Commission and the Council and to the Government and the Congress of the United States.

EXPLANATORY STATEMENT

1. Content of the motion for a resolution
tabled by Mr GLINNE and others

1.1 The motion for a resolution calls for better protection of consumers in the European Community against products declared unfit for consumption by United States legislation.

In particular, it:

- deplores the attitude of the United States who have still not banned the export of such products to the Community;

- expresses concern for the health of European consumers in face of the threats posed by the commercial availability of dangerous substances;

- stresses the need for more stringent criteria in authorizing the use of certain substances.

2. Examples of trade in US products regarded as harmful

2.1 In 1977 the US government banned the sale of children's nightclothes treated with TRIS (to make them non-inflammable) because the substance was shown to be carcinogenic. The 2,400,000 items already in stock were sold on European and Asian markets'.[1,2]

2.2 The Canadian government forbade the importation of a large number of lamps for children's bedrooms, the sale of which was stopped in the USA because they did not conform to safety standards.[1]

2.3 The governments of Taiwan and South Korea forbade (in 1980) the importation from the USA of animal fats contaminated with PCB[1].

[1] Philadelphia Inquirer, 9 August 1980

[2] Draft Report of Interagency Working Group on Hazardous Substances Export Policy (45 Fed.reg. 53754, 12 August 1980)

2.4 In 1979 the Consumer Product Safety Commission forbade the sale of certain dummies on which babies could choke. In 1979, 120,000 dummies not meeting US standards were exported to Australia.[1]

2.5 The President of Sierra Leone refused (in 1980) an offer of 25 million dollars from a Colorado manufacturing industry which wanted to export to that country toxic waste from its factories.[1]

2.6 In 1977 the US government banned the use of DDT as a pesticide, but 20,000 tonnes of that product are still produced yearly for export abroad.[2]

2.7 Kepone, a substance harmful to the nervous system is produced in Virginia exclusively for export, however, in Guatemala the product is used on bananas which are subsequently exported to the USA. Similarly, Dieldrin, Aldrin, Heptochlor and Clordane produced for export in the United States return to that country from Equador (in cocoa), Costa Rica (in coffee) and India (in sugar).[1]

2.8 Leptophos (or Phosvel) has caused a number of deaths in Egypt and partial paralysis among some American workers. Traces of this pesticide were found on tomatoes arriving from Mexico.[1,3]

2.9 Even pesticides, the use of which is permitted but subject to restrictions can be dangerous. In Pakistan five people died and 2,900 became ill as a result of using the pesticide Malathion without observing the necessary precautions, for instance by mixing it with their bare hands.[1]

2.10 In March 1978 the FDA forbade inessential uses of chlorofluoro-hydrocarbons (as spray propellants) because they had been shown to endanger the atmosphere, causing climatic changes, and also to promote certain forms of skin cancer. Following representations from the manufacturers, the FDA allowed the exportation of these products provided they were not banned in the importing country.[3]

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[1] Washington Post, 25 February 1980

[2] Philadelphia Inquirer, 9 August 1980

[3] Draft Report of Interagency Working Group on Hazardous Substances Export Policy (45 Fed. reg. 53754, 12 August 1980)

2.11 The Upjohn Company, which had been forbidden to sell Depo-Prover, a medicament used in the form of injections as a means of birth control, is now exporting the product through a Belgian company.[1,2]

2.12 Winstrol, a synthetic male harmone, banned because of its deleterious side effects on the growth of children has been sold in Brazil as an appetite stimulant.[1]

2.13 Chloramphenicol, a powerful antibiotic, is used in the United States only for the treatment of typhoid, because of possible side effects, such as aplastic aenemia. But it appears that this antibiotic has been exported to Spanish-speaking countries for the treatment of common diseases without any warnings as to the possible consequences.[2]

3. Current state of US legislation on protection of the consumer against harmful substances

3.1 Up to now American legislation on harmful substances has been characterized by strict domestic control and various obligations towards the foreign buyer, determined by the following three considerations :

(a) ethics,

(b) the possible deleterious effect on products subsequently imported into the USA, and

(c) the need to maintain good external relations.

3.2 The Interagency Working Group on Hazardous Substances Export Policy, which was active in 1980, during the Carter Presidency, indicated in its report that the regulations governing the exportation from the United States of banned or rigorously restricted products currently provide for five types of measure depending on the goods involved. They concern :

I. goods, the exportation of which is unrestricted or limited solely by the laws of the importing country;

II. goods, for the exportation of which prior notification is required by the importing country;

III. goods for which prior approval by the importing country is required;

IV. goods, the exportation of which may be prohibited by one of the Federal Agencies as posing a threat to health or the environment within the USA;

V. goods subject to a total ban : medicaments not approved for human or animal use, biological products (serums, vaccines, meat and poultry not meeting Federal quality standards).

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[1] Washington Post, 25 February 1980

[2] Draft Report of Interagency Working Group on Hazardous Substances Export Policy (45 Fed. reg. 53754, 12 August 1980)

3.3 On 11 October 1976 the Toxic Substances Control Act (TSCA) was passed in the USA with the aim of protecting man and the environment from what was defined as 'unacceptable' risks from chemical substances regarded as dangerous.

3.4 About the same time proposals were put forward in the Community for directives to harmonize the laws of the Member States in respect of the classification, packaging and labelling of dangerous substances.

3.5 In addition to the TSCA there is other legislation in the United States, such as the CPSA (Consumer Product Safety Act), governing the manufacture and exportation of dangerous substances. However, the FHSA (Federal Hazardous Substances Act), passed by the Carter Administration in January 1981, was repealed in February of the same year when the Reagan Administration took office because it was considered 'inconvenient and costly for the public and private sectors'.

3.6 Further evidence of an attempt to weaken US controls over materials intended for export is to be found in a report by the United States Secretary for Trade, Mr Balbridge, which maintains that it would be desirabled to end the ban on the exportation of medicaments which are not authorized for use within the United States.

4. The negotiations between the European Community and the United States

4.1 The USA-EEC dialogue initiated in 1977 does not promise an early conclusion, although in the circles concerned an optimistic outlook has prevailed throughout the negotiations.

4.2 Following the preliminary information meetings between experts, the Council entrusted the Commission with the task of starting negotiations with the USA with the aim of examining the prospects for the conculsion of an agreement on the way the TSCA can be applied to products originating in the EEC, on the one hand, and Community legislation to products originating in the USA, on the other.

4.3 The Community based its negotiating position on the following points:

(a) harmonization of classifications and of methods of assessing toxicity, ecotoxicity and environmental impact of chemical substances;

(b) mutual recognition of basic data required for the establishment of notification dossiers;

(c) mutual recognition of laboratories designated to carry out the testing or to check its results;

(d) definition of the procedure for assessing the risks carried by chemical substances for man and the environment;

(e) procedures to ensure mutual respect of the confidential nature of specific data;

(f) clarification of the position of State legislation vis-à-vis Federal legislation in respect of controls over the substances concerned;

(g) the method of sharing the costs resulting from the application of the TSCA, on the one hand, and of Community legislation, on the other;

(h) the compilation of priority lists for chemical substances likely to require special surveillance and control provisions. On this subject pressure from the various lobbies might neutralize one another; they might also cause the negotiations to stall. It is therefore necessary that the Community urgently adopt a set of priority criteria, based, for example, on the risk exposure of the population;

(i) harmonization of the inventories of chemical substances;

(j) examination of scope for possible cooperation in the research field.

4.4 According to the Commission's report to the Council of 3 November 1980, the negotiations were progressing satisfactorily but some sensitive problems, such as the confidentiality of data, the priority list for substances requiring special surveillance and control provisions, and the differences in the inventories, still remained to be solved.

4.5 The Commission stated in the report that the US authorities are seeking to put in motion a machinery of unfair competition which the European Community should not accept. This probably refers to the predominance of investigations on substances produced by industries in Europe.

4.6 It would therefore be well to go over the US legislation point by point to put the negotiations on a wider and more up-to-date basis.

4.7 Finally, the Commission reported that it had informally offered to the US authorities its own ideas on the labelling of products with a view to a regulation on the subject being issued in the USA, but that in this area too the problems remain because responsibility has passed to another body.

4.8 It would thus appear that the entire negotiations, which had had a successful start, have no run aground on a number of highly sensitive questions which go beyond the problem of harmonizing the respective legislations in scientific and technical terms and are, instead, concerned with economic relations and international law. In any event it is in the interest of the Community that a solution be found rapidly because, given the legislation currently in force in the USA, most of the disadvantages of the present situation rebound on the Community.

5. Council Directive 79/831/EEC of 18 September 1979 on the classification, packaging and labelling of dangerous substances

5.1 The purpose of this directive is to protect man and the environment against potential risks from the placing on the market of new chemical substances and, as the Glinne resolution points out, it provides a platform for the negotiations with the USA.

5.2 Manufacturers and/or importers are required to submit data on tests for toxicity, potential risks for man and the environment, conditions of use and a whole number of recommendations and precautions relating to the safe use of the substance.

5.3 By requiring the submission of a technical dossier, the European Community has adopted a system of control which - in principle at least - could be used to prevent the use and even the production within the Community of substances which do not meet the safety standards laid down.

5.4 The Community could thus make use of all the provisions for the protection of human health and of the environment against substances imported from the United States which are regarded as unsuitable.

5.5 Of equal importance is the responsibility placed on the manufacturer or any other person placing on the market a dangerous substance, whether it has already been notified or is newly produced.

5.6 Indeed, the competent authorities must be informed (Article 6) of any changes in the quantitites of the substance placed on the market, of any new knowledge of the effects of the substance on man and/or the environment, and of any new uses envisaged for this substance.

5.7 A list of new substances and an inventory of those already available on the Community market shall be established and their classification shall be updated, with recommendations on safer packaging.

5.8 Regulation in this field gives rise to the problem of the confidentiality of the information supplied to the authorities by the notifier. The Directive guarantees such confidentiality (Article 7), thus protecting industrial secrets, because it provides that information such as the identity of the substances concerned and the method of identifying them, as well as the quantities placed on the market need not be published, but only information required for assessing their potential danger, the precautions for their use and general safety rules.

5.9 A whole series of groups or classes of products which are already subject to controls under other specific legislation do not fall within the ambit of the directive. Excluded, notably, are medicinal products, narcotics, radioactive substances, foodstuffs, feedingstuffs and agricultural chemicals.

5.10 In addition to the requirement of complying with Community legislation, it has been left open (Article 23) to individual Member States to provisionally prohibit or subject to special conditions, in their territory, the sale of substances considered dangerous. Article 23 reads as follows :

> '1. Where a Member State has detailed evidence that a substance, although satisfying the requirements of this Directive, constitutes a hazard for man or the environment by reason of its classification, packaging or labelling, it may provisionally prohibit the sale of that substance or subject it to special conditions in its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.
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> 2. The Commission shall consult the Member States concerned within six weeks, then give its view without delay and take the appropriate measures.
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> 3. If the Commission considers that technical adaptations to this Directive are necessary, such adaptations shall be adopted, either by the Commission or by the Council, in accordance with the procedure laid down in Article 21; in such case, the Member State which has adopted safeguard measures may maintain them until the adaptations enter into force.'

6. Directive 76/769/EEC of 27 July 1976 on restrictions on the marketing and use of certain dangerous substances and preparations

6.1 Directive 76/769/EEC of 17 July 1976 is the legal instrument for preventing the access of dangerous substances, preparations or manufactures to the Community market.

6.2 If it proved necessary to add some item to the annexes or to modify them to bring them into line with new requirements, the customary administrative procedure could be followed : consultation of the European Parliament and of the Economic and Social Committee, followed by a decision of the Council of Ministers. However, such a procedure would take at least 18 to 24 months to complete, which is rather a long time for decisions which ought to be taken rapidly.

6.3 Provision should therefore be made for shortening the decision-making procedure by incorporating into the Directive the 'Technical Progress Committee' procedures included in the other directives on dangerous substances and preparations. This would save a great deal of time and allow any urgent situation arising from the importation of dangerous substances and preparations to be dealt with swiftly.

ANNEX I

MOTION FOR A RESOLUTION (Doc. 1-781/80/rev.)
tabled by Mr GLINNE, Mrs FUILLET, Mrs SEIBEL-EMMERLING, Mrs ROUDY, Mrs KROUWEL-VLAM, Mr ADAM, Mr COLLINS, Mr MUNTINGH and Mrs WEBER

pursuant to Rule 25 of the Rules of Procedure on the protection of the European consumer against imports into the Community of products declared unfit for consumption by US legislation

The European Parliament,

- having regard to Community legislation for the protection of the health and safety of consumers,
- having regard more particularly to the Council directive of 27 June 1967 on the classification, packaging and labelling of dangerous substances and the sixth amendment thereto due to enter into force in 1981, and also to the Council directive of 27 July 1976 on the approximation of the statutory and administrative provisions of the Member States on the restriction on placing on the market and utilizing certain dangerous substances and preparations,
- whereas thousands of tonnes of products (insecticides, pharmaceuticals, chemical products) are exported to the Community although they are held to be unfit for consumption under American legislation,
- having regard to the work done in the United States by the Interagency Working Group on a Hazardous Substances Export Policy and the Consumers Product Safety Commission,
- having regard to recent cases of imports into the EEC of toxic products such as children's pyjamas treated with TRIS which is recognised to be carcinogenic and the insecticide LEPTOHOS which is prohibited in the USA but has been sold for a long time in other countries,
- having regard to the TSCA negotiations between the EEC and the USA,

1. Regrets that the US executive authorities have so far refused to pass an executive order prohibiting the exportation, in particular to the Community market, of substances which are deemed to be unfit for consumption under the provisions of US legislation;
2. Is disturbed by such trade practices which are a threat to the health and safety of the European consumer;
3. Points to the need to ensure that the use of permitted substances is made more directly dependent on their toxicity;
4. Instructs its committee responsible to prepare a report on this subject.

ANNEX II

MOTION FOR A RESOLUTION (Doc. 1-919/82)

tabled by Mrs VAN HEMELDONCK, Mr GLINNE, Mr COLLINS, Mr MUNTINGH, Mrs KROUWEL-VLAM, Mrs PANTAZI, Mrs DUPORT, Mrs DURY, Mr KEY, Mr ENRIGHT, Mr ADAM, Mr VAN MINNEN on behalf of the Socialist Group

pursuant to Rule 47 of the Rules of Procedure on the export of hazardous products from the United States

The European Parliament,

- having regard to Directive 75/319/EEC (1) and Directive 76/769/EEC (2) and its subsequent amendments,

A. alarmed at the fact that under a policy recently proposed by the U.S. State and Commerce Department, unsafe and ineffective drugs, medical devices, and biological medical products such as plasma and vaccines made in the United States could be freely sold abroad,

B. disturbed by the fact that under this policy, U.S. exporters of toxic chemicals and banned pesticides would no longer be required to inform foreign governments of impending shipments,

1. Declares that a reversal of the existing U.S. export restrictions or limitations on hazardous products will be harmful to many people in the industrialised as well as in the developing countries;
2. Declares that the proposal could undercut a pending agreement for stricter export controls within the Organisation for Economic Cooperation and Development;
3. Calls on the U.S. Administration not to put these plans into effect;
4. Calls on the U.S. Congress not to grant its approval to changes in the existing controls on hazardous products;
5. Instructs its President to forward this resolution to the U.S. authorities, the U.S. Congress, the Council, the Commission, the Governments and the Parliaments of the Member States.

(1) OJ No L 147,9.6.1975, p. 13
(2) OJ No L 262,27.9.1976, p. 201.