

COMMISSION OF THE EUROPEAN COMMUNITIES

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RECOMMENDATION OF THE COMMISSION TO THE COUNCIL

concerning the opening of negotiations with the United States of America
on problems raised by the United States Toxic Substances Control Act
(T.S.C.A.)

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Recommendation of the Commission to the Council concerning the opening of negotiations with the United States of America on problems raised by the United States Toxic Substances Control Act (T.S.C.A.)

1. Review of current legislations

- a) For some years now there has been a tendency for industrialised nations to draw up and implement preventative regulations with a view to obliging manufacturers of chemical substances to notify the public authorities, before or at the time of marketing, of the likely impact of such substances on man and the environment.

In 1977 France passed a law on the control of chemical products (1). This law is designed to protect man and his environment against the risks arising from new chemicals or old chemical substances manufactured or used in novel ways.

It introduces a system whereby a declaration and a technical dossier must be submitted prior to marketing.

The United Kingdom is contemplating the introduction of a system of notification of the toxic properties of certain substances.

The most significant piece of legislation, however, both in scope and in its effects on international trade, is without doubt the American Toxic Substances Control Act (TSCA) adopted on 11 October 1976.

The aim of TSCA is to protect man and the environment against "unreasonable" risks from chemical compounds and to ensure that all the competent authorities are fully informed about this type

of hazard. The requirement to submit a technical data file is a further means of keeping a watch on these substances. This monitoring is carried out by the Environmental Protection Agency (EPA) which has powers to :

- ask manufacturers of chemical substances (new and existing) to carry out the requisite tests to show the possible effects of these substances on man and the environment;
- regulate substances (new and existing) which constitute or are likely to constitute an "unreasonable" risk for man and the environment;
- promote research in order to improve methods for evaluation of the effects of such substances on man and the environment;

b) The Community has also paid attention to this problem. The first Programme of Action on the Environment (1) provides, in the chapter on products, that the Commission will investigate the measures still required to harmonize and strengthen control by the public authorities over certain substances or new products before they are marketed, particularly :

- the improvement and harmonization of quantitative analysis techniques,
- investigations into the long-term toxicity of these substances and the standardization of toxic tests,
- compulsory submission of samples, accompanied by a description of the methods of quantitative analyses.

In addition, the general programme for the removal of technical barriers to trade provides for the harmonization of the laws of the Member States concerning the classification, packaging and labelling of certain dangerous preparations.

In implementation of these two programmes the Commission placed a proposal for a directive before the Council on 21 September 1976 (2) forming the sixth amendment to the Directive of 27 June 1967 concerning the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

(1) O.J. C 112, 20 December 1973

(2) O.J. C 260, 5 November 1976

The principal points of this proposal are as follows :

- The manufacturer or importer of any new substance is required to effect a preliminary study in order to evaluate the risks presented by the new substance to man and the environment, and to present to the competent national authorities, not later than the time of marketing, a document comprising :
 - . a technical report containing, in particular, results of the various tests listed in Annex VII;
 - . a declaration concerning the risks;
 - . proposals concerning the conditions of use for limiting the risks.
- The competent national authority then examines the information and proposals of the document, and may demand further information, and can also take appropriate measures relative to the conditions of use, until Community measures are available.
- The Commission receives a copy of the document and forwards it to the other Member States. The Commission will moreover establish a list of all notified substances.
- A Committee of representatives of the Member States, presided by the Commission, has to advise on Community measures which have to be applied to the substance in question.

The proposal for the directive also determines the criteria applicable to the separation of the substances into the different categories provided for in the directive.

The second Action Programme on the Environment (1) reasserts the need to carry out scrupulous checks on a Community basis on the environment.

Within the framework of its research programmes (2), the Community has also started work on the development of methods of evaluating the effects on toxic substances on man and the environment.

The foregoing comments indicate that the monitoring and control of chemical substances is proceeding along the same lines on both sides of the Atlantic and explain the keen interest in, and reaction to, the Toxic Substances Control Act in view of its environmental protection objective, and also of its likely impact on trade.

(1) O.J. C 139, 13 June 1977

(2) O.J. L 74, 20 March 1976

2. Background to the dialogue with the American authorities.

a) Details of this law were first given by representatives of the Environmental Protection Agency at the 14th meeting of the OECD Working Party on Chemical Products held between 14 and 16 June 1977 in Paris.

At the instance of the Commission representatives, the representatives of the Member States present stated during the preliminary meeting prior to the OECD meeting itself that they intended to adopt a common position in respect of the problems raised by this law.

This position was confirmed on the first day of the meeting and has been the subject of a written note attached to the summary record of the 14th meeting of the Working Party on Chemical Products on the position of the European Community in respect of the United States Law controlling toxic substances.

This first expression of common purpose on the part of the Member States and the Commission has shown the need to maintain a close and on-going dialogue between the Community and the authorities of the United States and of other countries in order to, on one hand, increase the effectiveness of the protection of man and the environment and, on the other hand, to avoid the establishment of incompatible evaluation methods which would create barriers to trade.

This memorandum focusses on three main problem and topic areas, namely :

- the scope and application of TSCA
- procedure for assessing and interpreting the findings
- the timetable for implementation.

b) These problems were again raised at a bilateral meeting held in Washington as part of the regular exchange of information between the American Government authorities (primarily the EPA) and the Commission which had been organized by an exchange of letters approved by the Commission on 1 July 1974. The EPA gave a written reply to the questions on TSCA raised by the Community; it was then decided to hold an initial broader-based information meeting between the EPA and the Commission, with the participation of representatives of the Member States and of the European Industry.

This meeting was duly organized on 3, 4 and 5 October 1977 in Brussels by the Environment and Consumer Protection Service. Prior to this a consultation meeting was held between the Council Working Parties on the Environment and on Economic Affairs, representatives of the Member States and of the Commission. The preparatory meeting confirmed the general interest of the Member States in Community-level discussions with the United States and an initial consensus was obtained on the minimum requirements for the technical data report to be submitted.

Over one hundred experts from the nine Member States the Commission, the European Industry and the European Environment Bureau took part in the meeting with the representatives of the Environmental Protection Agency.

The very lively and frank discussions have, in particular, produced a greater degree of understanding of the objectives envisaged by TSCA, of the interpretation given to certain of these measures, and of the methods which the American authorities intend to develop in order to apply them.

This meeting also showed the importance of generating new ideas on certain other aspects of the application of TSCA such as the definition of tests for the chemical substances, the definition of criteria by which the laboratories for testing and controlling the results may be chosen, the procedures to be followed in order to respect industrial confidentiality, the ways of dividing costs, etc...

It is for this reason that a second information meeting was organized by common agreement in Brussels on 18, 19 and 20 January 1978 between the EPA and the Commission at which representatives of the Member States and European Industry also participated. As in the first encounter, a prior consultation meeting between the Member States was organized between the "Economic Affairs" and "Environment" groups of the Council, which allowed the definition of a Community position on the evolution of the meeting with the EPA.

This three-day meeting stressed the following points :

- In the field of toxicity testing, a very detailed and complete exchange of information was given to the problems posed by acute toxicity and by delayed toxicity. Mutagenic tests, and the effects on reproduction, will be the object of another meeting towards the end of 1978. Problems concerning the control of toxicological data will also become the object of a future discussion.
- In the field of ecotoxicity testing, there was large agreement on the tests required for the basic document : physico-chemical measures, tests on degradation, bioaccumulation, tests for daphnia, a lethal dose 50 for fish, as well as a test for algae.

It is useful to tackle the problems of the methodology and quality control of data with a view to harmonising the results.

- In the field of administrative, regulatory and economic problems the exchange of opinions has made it possible to tackle all the problem actually raised. The attitude of each of the delegates was clearly defined concerning, in the main, mutual agreement on the basic document, procedures for risk evaluation, the choice of laboratories, confidentiality, division of costs, inventory of substances and lists of priority substances.

To sum up, one can consider the information exchange between the American delegation and the European Community to be virtually completed at least as far as the meeting of experts are concerned.

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These two information meetings have allowed not only a better knowledge and, in certain cases, a deepening of the scope of TSCA, but have also shown a large agreement on the necessity of beginning, as quickly as possible, official negotiations with the United States on the modalities of application of this law to Community products.

It is important to stress that the opening of these negotiations is urgent, chiefly owing to the peremptory and imminent dates for application of the American law.

3. CONCLUSIONS

For these reasons the Commission recommends that the Council:

- authorize it to open negotiations with the United States of America with a view to concluding an agreement on the procedures for applying to Community products the American law on the control of toxic chemical substances (Toxic Substances Control Act : TSCA) and concerning particularly the subjects referred to in the Annex;
- provide for the Commission to prepare and conduct the negotiations in consultation with experts nominated by the Member States.

ANNEX I

The Commission is endeavouring to obtain an agreement on the following topics in particular :

- the harmonisation of categories and methods for the necessary tests for the evaluation of toxicity, ecotoxicity and the impact on the environment of toxic chemical products;
- the mutual recognition of the basic data required to produce the documents of notification;
- the accreditation of laboratories charged with realising the tests and the control of results;
- the establishment of procedures for the evaluation of risks, caused by chemical products, to man and the environment;
- the procedures likely to ensure the mutual respect of confidentiality of certain data;
- means of dividing the costs incurred by the application of the Toxic Substances Control Act;
establishment of priority lists of existing toxic substances suitable to be the object of special measures for surveillance and control;
- the harmonization of inventories of toxic substances;
- the study of eventual possibilities for cooperation in the field of research.