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PROGRESS REPORT ON NEGOTIATIONS
BETWEEN THE EUROPEAN COMMUNITY AND THE UNITED STATES
AUTHORITIES ON THE CONTROL OF TOXIC SUBSTANCES
(COUNCIL MANDATE OF 30 MAY 1978)

(Communication of the Commission to the Council)

COMMUNICATION OF THE COMMISSION TO THE COUNCIL

Progress report on negotiations between the European Community and the United States Authorities on the control of toxic substances (Council mandate of 30 May 1978)

On 30 May 1978 the Council authorized the Commission to open negotiations with the United States of America with a view to investigating means of arriving at an agreement on the procedures for applying the Toxic Substances Control Act to Community products, and the corresponding Community legislations to products from the United States.

In particular the negotiations were to cover the following topics:

1. The harmonization of categories and methods for the necessary tests for the evaluation of toxicity, ecotoxicity and the impact on the environment of chemical substances;
2. The mutual recognition of the basic data required to establish the notification dossier;
3. The mutual accreditation of laboratories responsible for carrying out the tests and the verification of results;
4. The establishment of procedures for the evaluation of risks to human beings and the environment caused by chemical substances;
5. The application of the Toxic Substances Control Act and of the corresponding Community legislation to chemical substances contained both in manufactured products and in preparations;
6. The procedures for ensuring the mutual respect of the confidential nature of certain data;
7. The laws of the individual States of the United States of America versus federal law regarding controls of chemicals substances;
8. Methods of apportioning the costs arising from the implementation of the Toxic Substances Control Act and of the relevant Community legislation;
9. The establishment of priority lists of existing chemical substances which could well be the subject of special monitoring and control measures;

10. The harmonization of inventories of chemical substances;
11. The study of the possibilities for cooperation in the field of research.

The present document is a report from the Commission, approved by the group of representatives of Member States at its 11th meeting on 3-4 November 1980.

Over the last two years there have been six meetings between the Commission and the American Authorities responsible for implementing the TSCA. In preparing for these meetings the Commission was assisted by representatives of member States; the outcome of fourteen meetings between the Commission and this group of representatives has been a series of eleven papers setting out the EEC's observations on various rules proposed to implement the TSCA (1).

This work has made it possible to clarify for the American Authorities the Community position on the control of chemical substances, and the process has shown how important it is for the two parties to enter into a dialogue.

The adoption by the Council on 18 September 1979 of the sixth amendment to the 1967 Directive on dangerous substances (2) has, on one hand, given more weight to the Community intervention and on the other hand, led the United States to give more importance to the dialogue with the EEC with a view to harmonizing as far as possible their approaches on the question of controlling chemical substances.

The existence and the results of these bilateral meetings have gradually influenced the work carried out in the framework of the Chemicals Programme in OECD, where marking progress has been achieved. This progress has been put in concrete form at the high level meeting held in Paris on 19-21 May 1980.

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(1) See Annex I

(2) Council Directive of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (Directive T9/83/EEC, OJ L 259 of 15 October 1979).

Harmonization of approaches and practices may be regarded as having been achieved on three of the subjects defined in the terms of reference issued by the Council on 30 May 1978. These concern testing methods, the minimal pre-marketing set data (MPD) and the principles of good laboratory practice (GLP).

- Testing methods: for new chemicals which have to be notified, an agreement has been reached within the OECD. The testing guidelines developed by OECD should be on one hand incorporated into Annex V of the 6th Amendment and on the other hand implemented by the US Environmental Protection Agency.
- Minimal premarketing set of data (MPD): its use will not be difficult at EEC level, as the 6th Amendment already imposes the use of a similar set (in its annex VII).

The United States approved MPD in principle at the high level OECD meeting held in Paris on 19-21 May 1980, in spite of the fact that US law makes no such provision. But for the EEC, it is important that this work be pursued rapidly and efficiently to develop a complete step sequence testing system (Stufenplan).

- Good laboratory practice: the principles of GLP, drawn up by the OECD, have been accepted by the EEC and the United States. Nevertheless the problem of monitoring enforcement of the principles remains and discussions on this point must continue. The EEC should stand firm and insist that internationally acceptable monitoring systems be developed and that the countries be left to decide which systems they are best able to implement.

It therefore seems that on these three topics the EEC will have no difficulty in implementing the decisions taken with a view to harmonizing approaches and practices on the control of chemical substances. The American Authorities on the other hand will have problems as they have approved principles for which there is no provision in their legislations. The EEC will therefore have to continue to press the United States to actually implement these principles.

Moreover, in the United States a problem still remains with regard to section 4 of the TSCA which provides for the promulgation of testing rules. In connection with these testing rules, the EPA wants to impose standardized methods (testing standards), which differ from the OECD guidelines. If the EPA finalizes these testing standards, it will again put international harmonization in question.

On two further topics listed in the Council mandate of 30 May 1978 the harmonization prospects also seem to be favourable. Discussions are currently taking place on risk assessment methods, both bilaterally and in OECD. For the sharing of costs arising out of the testing of new substances, the EPA is coming round to the EEC's point of view, i.e. to leave companies to regulate this type of problem among themselves.

Two questions raised by the EEC may be regarded as provisionally settled.

The American Authorities have decided not to require the systematic notification of new chemicals included in manufactured products; they will decide on a case-by-case basis. They have also rejected the possibility that a State law could take precedence over federal law (TSCA).

Nevertheless the TSCA text on these two points contradicts the assurance given by the American Authorities. The EEC cannot therefore yet regard these matters as finalized.

Concerning the inventory of existing chemical substances, there is a major difference between the Community and American approaches. The American inventory is dynamic; i.e. new substances are added to the list upon notification to EPA. The Community inventory will only list those substances which will be on the EEC market on 18 September 1981. By definition, these two inventories cannot be harmonized; however the EEC benefits from the American experience in this field.

There are two major problems ahead. They are the question of confidentiality and the drawing up of priority lists of existing chemicals which should be the object of special testing. The problem of ensuring the confidentiality of data remains the most urgent and the one most difficult to resolve. It will be necessary to reconcile two different legal systems as well as the interests of industry and of the general public. The EPA has been applying Section 5 of the TSCA, which requires notification of new chemical substances, since July 1979. From 18 September 1981 notification will be required in the EEC under the 6th Amendment. Consequently every effort will have to be made to harmonize the confidential treatment of data submitted by notifiers.

Concerning the priority list of existing chemical substances which should be the object of specific testing, the Community should investigate with the United States harmonizing the criteria for selecting substances. It will be more difficult to harmonize the contents of the lists as in order to determine whether a substance should be examined urgently several factors, which vary from country to country, have to be taken into account: population density, geography, the cost/benefit ratio, etc.

The consequences for the EEC of the United States drawing up a priority list should not be underestimated since, if a list is established, the EPA could want to have the costs of the tests it imposes shared. In addition the American authorities will certainly consider winning acceptance for their priorities in the relevant international fora.

In addition to the 11 points of negotiation individually stated in the Council mandate of 30 May 1978, there are others, implicitly covered by the same mandate, which have been the object of discussions. One example is the labelling of chemical substances, about which the EEC has informally communicated its points of view to the American authorities, while awaiting the publication of certain details of the American proposed rule.

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Thus, there are favourable developments as regards harmonization of the approaches of the Community and the United States to the control of chemical substances (testing methods, MPD, GLP, sharing of costs, risk assessment). However, to ensure the elimination of all barriers to international trade in chemical products whilst at the same time maintaining the original objectives of providing effective protection for man and his environment, negotiations must continue, particularly on priority substances and the confidential treatment of data. Moreover, it cannot be ignored that certain toxic substances (for example, as in manufactured products) generally covered by TSCA, could be regulated more strictly under other laws such as the Federal Hazardous Substances Act or the Consumer Product Safety Act, with serious consequences for Community imports into the United States.

Therefore, it appears necessary to discuss with the American Authorities the difficulties which could arise from applying laws other than TSCA to toxic substances.

Annex I

List of documents "Aide-mémoire" transmitted by the European Community to the Environmental Protection Agency of the United States with respect to proposed rules for the implementation of the "Toxic Substances Control Act".

- I. ENV/595/78, 22.9.78:
EPA Preliminary draft guidance for premanufacture notification under TSCA.
- II. ENV/672/78, 26.10.78:
Further comments on TSCA guidance for premanufacture notification (draft document of 12 September 1978).
- III. ENV/183/79, 19.3.79:
Comments of the European Community on the proposed rules for TSCA section 5 (Fed. Reg. vol. 44, p. 2242 et seq., 10 January 1979).
- IV. ENV/353/79, 6.6.79:
Comments on toxic substances control: "Discussion of premanufacture policy and technical issues" (Fed. Reg. vol. 44, p. 16240 et seq., 16.3.79).
- V. ENV/430/79, 31.7.79:
Comments on "Proposed Health Effects Standards for TSCA Test Rules" and "Good Laboratory Practice Standards for Health Effects" (Fed. Reg. vol. 44, pp. 27337-27362 and pp. 27362-27375, 9.5.79).
- VI. ENV/621/79, 2.10.79:
Comments of the European Community on "Proposed Health Effects Test Standards for Toxic Substances Control Act Test Rules and Proposed Good Laboratory Practice Standards for Health Effects" (Fed. Reg. vol. 44, pp. 44054-44093, 26.7.79).
- VII. ENV/692/79, 14.11.79:
Comments of the European Community on Data Reimbursement under sections 4 and 5 of the Toxic Substances Control Act (Fed. Reg. vol. 44, pp. 54284-54290, 18.9.79).
- VIII. ENV/732/79, 23.11.79:
Comments of the European Community on the Reproposal of Toxic Substances Control Act Premanufacture Notice Forms and Provisions of Rules (Fed. Reg. vol. 44, pp. 59794-59882, 16.10.79).

Annex I

IX. ENV/I/316/80, 6.5.80:

Comments of the European Community on "Policy Statement under the Toxic Substances Control Act for Import of Chemical Substances" (EPA draft proposal of 12.3.80).

X. ENV/837/80, december 1980:

Comments of the European Community on the Proposed Production Restrictions of Ozone-Depleting Chlorofluorocarbons (Fed. Reg. vol. 45, pp. 66726-66734 of 7 October 1980).

XI. ENV/960/80, 9.1.81:

Comments of the European Community on the Proposed Environmental Test Standards and Proposed Good Laboratory Practice Standards for Physical, Chemical, Persistence and Ecological Effects Testing (Fed. Reg. vol. 45, pp. 77332-77365).

