

Paris, 16th October, 1978

C(78)127(Final)

Scale 1

COUNCIL

DECISION OF THE COUNCIL

CONCERNING A SPECIAL PROGRAMME ON THE CONTROL OF CHEMICALS

(Adopted by the Council at its 470th Meeting
on 21st September, 1978)

The Council,

Having regard to the Convention on the Organisation for Economic Co-operation and Development of 14th December, 1960, and, in particular, Articles 2(a) and (b), 3, 5(a) and 20 thereof;

Having regard to the Rules of Procedure of the Organisation;

Having regard to the Financial Regulations of the Organisation and, in particular, Articles 5 and 10 thereof;

Having regard to the Resolution of the Council of 25th March, 1975, amending the Mandate of the Environment Committee [C(75)17(Final)];

Having regard to the Recommendation of the Council of 7th July, 1977, establishing guidelines in respect of procedure and requirements for anticipating the effects of chemicals on man and in the environment [C(77)97(Final)];

Considering that at its meeting on 24th-26th April, 1978, the Environment Committee agreed to certain working arrangements for its Programme on Chemicals in the Environment and endorsed the suggestion that within the framework of the Chemicals Group's programme, Member countries wishing jointly to carry out supplementary work which is urgently needed by them should agree to form a Special Programme on the Control of Chemicals financed within the framework of Part II of the Budget;

Considering that Australia, Austria, Belgium, Canada, Denmark, France, Germany, the Netherlands, Norway, Sweden, Switzerland, the United Kingdom, the United States and the Commission of the European Communities (hereinafter referred to as "the Participants") have stated their intention to participate in a Special Programme on the Control of Chemicals (hereinafter called the "Programme").

DECIDES:

*Env.
Sp. Prog. on
Control of chemicals*

PART IRESPONSIBILITIES OF THE ENVIRONMENT COMMITTEE
CONCERNING THE CONTROL OF CHEMICAL SUBSTANCES

(a) The Chemicals Group of the Environment Committee shall be responsible for the work in the field of control of chemical substances to protect the environment and man's health while avoiding negative effects for the economy and trade.

(b) The Chemicals Group should from time to time hold special meetings, as required, in order to give general orientation to the work on chemicals. On such occasions, it should be composed of high level representatives responsible for the administration of national chemical regulation. Conclusions then reached as well as specific directives indicated in respect of priority tasks will be reported to the Environment Committee.

PART IIPROGRAMMEArticle 1PURPOSE

Within the framework of the chemicals' activities of the Organisation, a Programme with a view to providing a forum for co-operation between those Member countries wishing jointly to carry out supplementary work which is urgently needed by them to develop and harmonize practices in order to improve the control of chemicals, is hereby established. The results of the work are intended to contribute to the protection of man and his environment from chemicals' hazards, and to prevent the creation of non-tariff barriers to trade. The Definition of the Programme is set out in the Appendix to this Decision of which it is an integral part. It may be adapted as necessary on subsequent proposals of the Management Committee referred to in Article 2 below.

Article 2MANAGEMENT COMMITTEE OF THE PROGRAMME

(a) A Management Committee of the Programme (hereinafter referred to as the "Management Committee") shall be established and shall be composed of one representative appointed by each Participant.

- (b) Each Participant may appoint an alternate to its representative on the Management Committee.
- (c) The Management Committee shall designate each year among its members a Chairman and Vice-Chairman.
- (d) Taking due account of the overall activities of the Organisation in the field of chemicals, the Management Committee shall submit each year to the Council proposals with respect to the annual programme of work and budget.

Article 3

FUNCTIONS OF THE MANAGEMENT COMMITTEE

- (a) The Management Committee shall be responsible for ensuring the carrying out of the Programme and may consider all questions related thereto. It shall exercise the functions defined in this Decision in accordance with the Decisions and Resolutions of the Council.
- (b) The Management Committee may set up working groups as required to carry out specific tasks.
- (c) The Management Committee shall submit each year to the Council a report on the work under the Programme which might include proposals for appropriate action resulting from this work. Such reports and proposals shall be reported to the Environment Committee in order to ensure co-ordination between activities financed under Part I and those financed under Part II of the Budget.
- (d) The Management Committee shall receive regular reports on the implementation of the Programme.

Article 4

EXPENDITURE

- (a) The expenditure arising from the implementation of the Programme shall be defrayed from the appropriations authorised for it under Part II of the Budget of the Organisation.
- (b) The Programme may include activities to be financed in whole or in part from grants by public or private institutions.
- (c) Notwithstanding the provisions of Article 14(b) of the Financial Regulations, the Secretary-General may accept grants not exceeding Frs. 200,000 each in respect of activities which have been included in the annual programme as adopted by the Council.

(d) Notwithstanding the provisions of Article 16(b) of the Financial Regulations, appropriations in respect of the Programme for which no commitment has been entered into before 31st December, 1978, shall be automatically carried forward to the Financial year 1979.

Article 5

PARTICIPANTS

(a) The Participants shall be the Member countries as listed in the Preamble and the Commission of the European Communities.

(b) Any other Member country of the Organisation may participate at a later stage in the Programme.

Article 6

DURATION

(a) The Programme is established for the period 1st October, 1978, to 31st December, 1981.

(b) The Council shall review the provisions of this Decision before the end of this period, taking into account the experience acquired in carrying out the Programme.

APPENDIX
to the Decision of the Council
concerning a Special Programme on The
Control of Chemicals

Within the Special Programme on the Control of Chemicals the following topics are to be studied: Good Laboratory Practices; Development of Information Exchange Procedures regarding Chemicals; Confidentiality of Data; an International Glossary of Key Terms. The aims of the studies are described in this Appendix.

GOOD LABORATORY PRACTICES

1. Agreement between countries on basic standards to govern the acquisition of data respecting potential hazards to human health and the environment is an important step towards mutual acceptance of the data. It is proposed, therefore that consideration be given to developing acceptable laboratory standards for the generation of laboratory data for regulatory purposes in OECD Member countries. In particular, attention should be given to:

- (a) specifying minimal acceptable laboratory practices governing tests to be specified by the current OECD Chemicals Testing Programme;
- (b) record-keeping procedures, storage and accessibility for national control purposes of records and minimum time-period during which records and specimens must be retained after completion of a study;
- (c) qualifications and experience required of personnel (professional and technical).

2. It should be recognised that the objective is to establish basic standards although emphasizing the desirability of encouraging the development and universal application of the highest possible standards of laboratory investigations.

3. In elaborating the basic laboratory practices, due cognizance should be given to existing authoritative documents on this subject. In particular, the forthcoming report from WHO on the principles for evaluating the toxicity of chemicals, and documents such as the US Good Laboratory Practices Regulations and the compliance Programme pertaining to these Regulations, should be referred to.

4. It is also proposed that mutually acceptable means be developed to ensure that data in respect of hazards to human health and the environment is obtained in accordance with these basic standards. Bearing in mind the technical feasibility and practicality of implementing procedures that may be recommended, it is proposed to examine:

- (a) systems of accreditation and/or inspection of laboratories existing or proposed in each country and by international organisations;
- b) means of harmonizing such systems;

- (c) certification (validation) procedures to ensure that acceptable laboratory practices have been employed in connection with any particular investigation;
- (d) the need to establish exchange of information on national accreditation schemes (bearing in mind confidentiality aspects, appropriate time for exchange, etc.);
- (e) the need to make provision for appropriate action against laboratories failing to meet acceptable standards.

DEVELOPMENT OF INFORMATION EXCHANGE
PROCEDURES REGARDING CHEMICALS

1. Three different aspects of information exchange can be identified and OECD is considered as an appropriate forum to undertake further work in this field. The three aspects are:

- (a) substance-related information aimed mainly at the early identification of potential problems;
- (b) information on regulatory action, particularly where such action may affect countries other than those initiating the regulations;
- (c) information which should accompany chemicals when they are marketed, especially when traded internationally.

2. The recently established supplementary information exchange procedure in OECD has provided a valuable new tool which is relevant to all three aspects and one area for further work is the development of this procedure. In order to maximise its value, there is a need to study and categorise the information needs of those using the information that passes through the procedure. This might be facilitated by a more **harmonized** system for identifying substances and categorising the information exchanged. The users include the major supplying nations as well as the nations which are essentially importers, the different sectors of national governments (e.g. environmental protection, health protection, transportation, trade, etc) and the different sectors of industry. It is recognised that additional national resources are required to meet this need, particularly in countries where the information to be submitted as well as the information received must be translated.

3. At the moment, information is principally generated by the major producing countries and particular attention should be paid to defining the needs of importing countries so that the information generated takes account of such needs. This is specially important in the context of (c) above, as is the outcome of the work of the existing six expert groups of the OECD Chemicals Testing Programme. Better labelling and transportation documentation could result. There is also a need to co-ordinate better the work going on internationally on labelling, and OECD should consider whether it has a role to play in this field.

4. OECD has shown itself well suited to meet the administrative needs for information but should not become too deeply concerned in the exchange of detailed technical/scientific information. This is more properly a function for planned data systems such as IRPTC.

5. In addition to its Information Exchange Procedure, OECD has the ability to call "Consultation" meetings on subjects of particular concern. This has been done for PCBs (twice) and for the US Toxic Substances Control Act. There might be a need to develop something in between the mere exchange of information and formal consultations which would allow those concerned with the control of specific problems to come together quickly to pool experience and to discuss any international aspects which might arise.

6. Finally, the economic implications in all of these areas should be carefully considered in order to ensure maximum return on the resources allocated.

CONFIDENTIALITY OF DATA

1. Firstly, a survey should be compiled of the provisions made in existing (or proposed) national and international schemes for the registration and the regulation of toxic chemicals, or other relevant legislation. This will indicate how national governments and international groupings (e.g. EEC) deal with problems of confidentiality at the present time, or in proposed schemes.

2. There should be clear identification of the different types of data which are under discussion, e.g. the basic dossier of tests provided by chemical manufacturers, health and safety data, risk assessments, etc.

3. An attempt should be made to identify the weight which each country assigns to the public interest on the one hand and to commercial secrecy on the other hand, in reaching decisions on confidentiality. Suggestions could be presented on how potential conflicts might be resolved.

4. Having identified or resolved the differences of opinion regarding the balance between data which should remain secret and that which can be released, those studying the problems could consider how the dissemination of information could be managed.

5. Within each country there may be a need to pass information on toxic chemicals to other government departments, to regional or local authorities etc. This problem should be considered together with its implications for confidentiality. Is there a danger to confidentiality if more than one national register is maintained?

6. Consideration should also be given to the type of information to be passed on to other countries. Should this include risk assessments and if so, what effect could this have on commercial interests?

7. Although not a first priority, those dealing with the questions of confidentiality of information should be aware of the implications for testing costs and their reimbursement, if data are released.

8. Finally, consideration should be given to how industry could participate in specific decisions on disclosure of information, so that the implications for commercial interests are taken into account.

INTERNATIONAL GLOSSARY

1. Work should be directed towards the development of a consistent international glossary of key terms which would provide uniform definitions for use in the development of control actions on chemicals that have international implications, e.g. in trade. This includes the adoption of a common nomenclature for chemical substances in commerce.
2. The tasks envisaged include:
 - (a) The elaboration and submission within six months by each Member country of key terms which they perceive to be of major international significance. Submissions should include legal and regulatory documentation and existing interpretations. The principal focus should be on definitions which affect the control of chemicals.
 - (b) The compilation of national submissions.
 - (c) The development of a list of terms with special emphasis given to those terms requiring definition and clarification with a suggested time-table for resolution, based on the urgency of the recognised needs. Cognizance would be given to examinations of definitions already developed by other International Organisations.
 - (d) The development of recommendations for resolution and **harmonization** of terminology.
3. It is recognised that this is a dynamic activity and consequently the glossary will be open to future development and amendment.

