

GENERAL AGREEMENT ON TARIFFS AND TRADE

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Committee on Technical Barriers
to Trade

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COMMUNICATION FROM THE CHAIRMAN OF THE COMMITTEE

The following letter, addressed to the Chairman of the Committee by the Environment Directorate of the Organization for Economic Cooperation and Development in connexion with Article 13.3 of the Agreement, is being circulated for the information of the members of the Committee at the request of the Chairman.

One of the underlying objectives of the programme on chemicals of the Organisation for Economic Cooperation and Development (OECD) is the elimination of non-tariff barriers to trade. It is mainly from this perspective that I have been reviewing the Agreement on Technical Barriers to Trade ("Agreement") to determine how and in what manner the OECD programme on chemicals interrelates with work carried out under the Agreement. As you know, the major part of the present OECD programme on chemicals is directed toward reaching international agreements in such areas as test methods, good laboratory practices, minimum data requirements for new chemicals and principles governing confidentiality of data. These are the types of activities which, it seems to me, help to further the objectives of the Agreement and would, therefore, be of interest to the Parties to the Agreement.

Because of this interrelationship of our respective activities, I am taking the liberty of writing to you as Chairman of the Committee on Technical Barriers to Trade. I note that the Committee is composed of representatives from each of the Parties to the Agreement and that the Committee has broad responsibilities under Article 13 of the Agreement. I note with particular interest Section 13.3. which states that unnecessary duplication should be avoided between the work under the Agreement and that of governments in other bodies and that the Committee should "examine this problem with a view toward minimizing such duplication".

Therefore, I would like to inform the Committee through you, Mr. Chairman, of the activities of the OECD chemicals programme which I believe to have direct relevance to the work of the Committee.

Background

Although chemicals activities in OECD go back to 1972, any discussion of the present OECD chemicals programme probably should start by reference to an international meeting on the control of toxic substances held in Stockholm in April, 1978. This meeting was attended by high-level officials from sixteen OECD countries and six international organisations. The meeting agreed that there is an urgent need to harmonize national chemical regulatory programmes in order to utilize available resources effectively and to avoid unnecessary barriers to international trade. The meeting identified six priority areas "where work needs to be completed as soon as possible"; namely

1. The development of consistent data requirements and testing methods (a "first essential task").
2. The development of consistent standards for good laboratory practices.
3. The resolving of problems with respect to confidentiality of data.
4. The development of consistent methodologies for analyzing the economic and trade impact of actions in regulating toxic chemicals.
5. The development of mechanisms to facilitate information exchange.
6. The development of an international glossary of key terms.

The present OECD chemicals programme consists of major activities in each of these areas. While work had clearly been started by the OECD Chemicals Group in two of these areas, it was this April 1978 meeting of high-level administrators which focused attention on the need for international action in these areas and provided the real impetus for an expanded international programme.

The OECD Chemicals Programme

As indicated above, there are six major components of the present OECD Chemicals Programme:

1. Test Methods and Data Requirements

Six expert groups were convened under this part of the programme. Five of these expert groups were mandated to work on test methods in the fields of (a) physical-chemical properties, (b) eco-toxicology, (c) degradation-accumulation, (d) long-term health effects of chemical substances, and (e) short-term health effects of chemical substances. Except for follow-up work in a

couple of areas, the work of these groups has been completed and their reports have been submitted. These reports cover, among other things, some 100 Test Guidelines (testing methods) which have been designed and agreed upon by the expert groups. These Test Guidelines are now undergoing a final review process under the guidance of a panel established by the OECD Chemicals Group. The next step in the programme will be to determine if international agreements can be reached on the Test Guidelines elaborated by the expert groups.

A sixth expert group has been established under this part of the programme to consider the concept of step-sequence testing systems. This expert group has completed the first phase of its work and has agreed upon a preliminary report. The report covers, mainly, the minimum pre-marketing set of data (base set) which should be generated for all new chemicals in Member countries. Agreement by Member countries upon such a pre-marketing set of data could be the first major step toward eliminating trade barriers which might exist because of differing data requirements in different countries.

2. Good Laboratory Practice

Good Laboratory Practice (GLP) is concerned with conditions under which laboratory studies are conducted, monitored, recorded and reported. The term "Good Laboratory Practice" embraces all factors that contribute to the validity of scientific studies in the laboratory.

The development of principles of GLP is a key part of the OECD programme because the development of such principles is a prerequisite for mutual acceptance of data between countries. And, as you know, the refusal by one country to accept data generated in another can be an effective barrier to trade.

An Expert Group on Good Laboratory Practice has completed the first phase of its work and has developed and reported on general principles of GLP.

3. Confidentiality of Data

The submission of data to national regulatory authorities by manufacturers and importers, and the exchange of information between countries, raise important questions relating to the confidentiality of data. For example, what principles should govern the balancing by national regulatory authorities of industry's legitimate need to maintain trade secrets with the public's need to be informed?

An Expert Group on Confidentiality of Data was established in 1979. This expert group has made a review of national laws relating to confidentiality of data and has undertaken to identify the data in a minimum base set which might give rise to problems of confidentiality when exchanged internationally. This group, upon the basis of its preliminary work, is preparing a report which will identify the major issues which must be resolved in this field. These issues, together with solutions proposed by the expert group, will be put before a high-level meeting of the OECD Chemicals Group in May, 1980.

4. Economic and Trade Effects

Chemical control laws have the potential to affect international trade adversely. Therefore, it is important that we have consistent methodologies for analyzing the economic and trade impacts of such laws.

New work is under way in the OECD programme which (a) analyzes in depth the economic and trade impact of chemicals control and (b) seeks the development of appropriate methodology for further study in this area.

5. Expanded Information Exchange/Consultation Procedure

In June, 1977, the Chemicals Group established a new Information Exchange/Consultation Procedure. This new procedure functions through a system of national contact points. Such contact points have been appointed by almost all OECD countries and several international organizations.

The main purpose of this new Procedure is to give countries fast notice of proposed or final regulatory actions which have international implications. The emphasis is upon proposed actions, it being the view that one way to harmonize standards is to give countries a chance to react to proposals before they become a fixed part of a regulatory scheme.

I note the similarities between these OECD procedures and those set forth in Sec. 2.5 of the Agreement. It seems to me that our objectives are entirely consistent. Because of the importance of this type of information exchange procedure, work has recently begun to strengthen and expand this procedure.

6. International Glossary of Key Terms

Work is under way on 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 work will include an examination of definitions already developed by other international organizations. In this connection, I note the provisions of Sections 1.1 and 1.2 of the Agreement.

The May 1980 High-Level Meeting

In May 1980, there will be a meeting of the OECD Chemicals Group at high administrative level. This type of meeting is provided for in the OECD Council Decision setting up the expanded chemicals programme. The meeting will bring together the high-level government officials responsible for the administration of national chemical regulation.

This meeting will have before it the results thus far from the OECD chemicals programme. These results will include the testing guidelines, the principles of good laboratory practice and the minimum set of pre-marketing data which have been developed by the expert groups, together with resolutions for the mutual acceptance of data and the continuation of work on test guidelines. The meeting will be asked to determine whether these matters should be recommended to the OECD Council for formal agreement. The meeting will also consider major issues which have arisen in connection with the work and proposals for future activities.

I will keep you informed of relevant developments within the OECD chemicals programme. Please let me know if there is any specific information which you or your Committee might wish to have.

I would appreciate being informed of any actions of your Committee which are relevant to our chemicals programme.

Signed: Mr. Peter J. Crawford,
Environment Directorate,
Organization for Economic
Cooperation and Development.