



Recommendation of the Council concerning the Exchange of Confidential Data on Chemicals

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Date(s)

Adopted on 26/07/1983

Background Information

The Recommendation concerning the Exchange of Confidential Data on Chemicals was adopted by the OECD Council on 26 July 1983 on the proposal of the Second High-Level Meeting of the Chemicals Group (today under the responsibility of the Chemicals Committee), endorsed by the Environment Committee. Considering the need to avoid necessary duplication of effort in developing data on chemicals and to make better use of existing data, this instrument recommends that Adherents take steps towards creating conditions which will allow the exchange of confidential data among Adherents. Principles by which to do so are provided in the Appendix to the Recommendation.

THE COUNCIL,

HAVING REGARD to Articles 2 a), 2 b), 2 d), 3, and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 14 November 1974 on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215];

HAVING REGARD to the Recommendation of the Council of 7 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)];

HAVING REGARD to the Decision of the Council of 21 September 1978 concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein and the extension of the duration of the Programme by the Council of 12th May 1981 [C(78)127(Final) and C/M(81)7(Final), Item 86];

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)];

HAVING REGARD to the conclusions of the First High-Level Meeting of the Chemicals Group of May 1980, concerning the confidentiality of data [ENV/CHEM/HLM/80.M/1];

HAVING REGARD to the conclusions of the Second High-Level Meeting of the Chemicals Group of November 1982, on the transfer of confidential data [ENV/CHEM/HLM/M/82.1];

CONSIDERING the need to avoid necessary duplication of effort in developing data on chemicals and to make better use of existing data;

CONSIDERING the economic value of certain data and the possible effects of the disclosure of such data on the competitive position of the person or company who develops the data;

CONSIDERING that Member countries differ widely in their assessment of the confidentiality of data under national legislative or administrative provisions and that confidentiality of data is the factor most often limiting the exchange of data on chemicals between countries;

CONSIDERING that the exchange of health, safety, and environmental data on chemicals between Member countries is necessary for purposes of assessment and for other uses relating to the protection of man and the environment;

On the proposal of the Second High-Level Meeting of the Chemicals Group, endorsed by the Environment Committee;

I. RECOMMENDS that Member countries take steps towards creating conditions which will allow the exchange of confidential data.

II. INVITES Member countries to explore the use of the principles set out in the Appendix which is an integral part of this Recommendation, and any other relevant principles in bilateral or multilateral arrangements for the transmission of confidential data.

III. INVITES Member countries to report to the Organisation as the above-mentioned arrangements evolve.

IV. INSTRUCTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in pursuance of this Recommendation and to report thereon to the Council.

APPENDIX

SUGGESTED PRINCIPLES TO GOVERN THE EXCHANGE OF CONFIDENTIAL DATA AND INFORMATION ON CHEMICALS BETWEEN MEMBER COUNTRIES

Preamble

1. The Chemicals Group at its High-Level Meeting in May 1980 stated that the exchange of health, safety and environmental data between Member countries was necessary for the purpose of assessing chemicals with the object of protecting man and the environment. It instructed the Group of Experts on the Confidentiality of Data to work out the principles applicable to the exchange of confidential data.

2. The Group of Experts, in its discussions, defined the scope of such exchange; it was agreed that the exchange of information between the authorities in Member countries responsible for the control of chemicals should complement the company submissions to these authorities and secondly should allow for exchange on request when companies are not involved. Given the worldwide scarcity of material and intellectual resources for conducting tests, exchange, avoiding duplication of tests as far as possible, should enable better use to be made of existing data. Exchangeable data should be both for new chemicals and for existing chemicals.

3. Member countries differ very widely in their assessment of the confidentiality of data submitted in response to regulations or administrative practice for chemicals control. While it is generally recognised that the notifier is entitled to claim confidentiality for some of the data he makes available to a competent authority, the final decision lies with the authority. As a result certain data, which cannot be disclosed in some countries, may be disclosable in others. The extent to which confidential data are circulated within government departments may also vary from one country to another. The exchange of data between countries therefore raises a problem of widening the access to confidential data.

Confidentiality of data is certainly the factor most often limiting exchange of information on chemicals between countries. The Group therefore considered it opportune to recommend that certain types of data should not be designated as confidential and that their exchange should not be limited by principles.

4. It would seem to be premature, at the present stage, to try to solve these problems by proposals aiming at international harmonization of the relevant laws. Even if greater harmonization of chemicals control regulations can be achieved, the purpose underlying the work of the OECD chemicals programme, the fact remains that concepts of administrative secrecy, and of industrial and commercial secrecy, in different countries derive from fundamental principles associated with national law, which must act as a curb on harmonization. The Group has pointed out that the OECD work towards harmonization should, in particular, encourage those Member countries which have not yet adopted legislation on chemicals control to do so in the years ahead.

5. The exchange of confidential data between countries should be governed by principles taking account of the differences between legislation and administrative practice in different countries, and enable countries to participate in such exchange without infringing the law or practice prevailing in their own territories. Clearly, a list of principles extensively respecting the traditions of countries strictly applying the rule of administrative secrecy to any information imparted to the government imposes restrictions on the possibilities for exchange. A competent authority will only transmit confidential information if it can be certain that the requesting authority will treat it at least with the same degree of confidentiality as is practised in the transmitting country. Countries whose laws or administrative practices favour disclosure could agree to follow less restrictive principles in transmitting data which originated in these countries.

6. The principles were defined by the Group on the following basis:

- The exchange system must respect the sovereignty of the country transmitting information in its decision on the confidential nature of the information;

- A competent authority must make every reasonable effort to obtain the information available in its country before requesting confidential information from the competent authority in another country;
- Exchanges of confidential data between competent authorities in different countries should not distort competition and in particular, should not have the effect:
 - of subjecting nationals in the solicited country to a more severe testing or reporting requirement than would apply to a national of the soliciting country in the same situation;
 - or exempting nationals of the soliciting country from conforming to the notification procedures prevailing in their country;
- All data made available to a competent authority must remain the property of the submitter, even after exchange with competent authorities elsewhere, to the extent recognised in the original country.

The text of the principles drawn up by the Group is presented below, accompanied by explanatory comments reflecting the various opinions expressed during the work of the Group.

Principle No. 1

The exchange of confidential information on chemicals between the competent authorities of countries is intended solely to facilitate the hazard assessment of chemicals and the protection of man and the environment.

Comments

7. The Group distinguished three categories of confidential information that might be available to a competent authority and might be exchangeable between Member countries: data reported under chemical control legislation or regulation, or in the normal course of chemical control administration, data supplied by companies voluntarily or upon request, and data produced under the sponsorship of government departments and other public services. The Group was mainly interested in the exchange of data in the first category, pointing out that such exchange should not be an alternative to ordinary submissions by companies to competent authorities.

8. It seemed difficult if not impossible to establish principles which could govern the exchange in the two other categories. The discretionary power exercised by the competent authority in deciding or declining to transmit its own data, or data provided voluntarily by companies, lends itself to no general rule and will be different from case to case. However, there should be nothing to prevent such data from being exchanged when appropriate.

9. From the standpoint of protecting man and the environment, the Group considered that it should not define the term "chemicals". The Group also made no distinction between existing chemicals and new chemicals. This distinction becomes very difficult in an instance where data are exchanged between countries whose systems of notification of new chemicals are different in scope. For similar reasons, it did not appear desirable to distinguish chemicals in terms of the particular use made of them, and to exclude some categories from eligibility for exchange.

10. Exchange is intended to transmit data already available to the competent authority, and not to have the transmitting authority gather and develop new data for this purpose.

Principle No. 2

A country having received information in response to a request must in no circumstances use such information for any purpose other than the assessment of hazards of chemicals and the protection of man and the environment.

Comments

11. This limitation of the uses that can be made of information transmitted accurately reflects the need recognised by the Chemicals Group at its May 1980 High-Level Meeting. Any extension of the use of information received would prejudice the smooth running of the exchange and the maintenance of the commitment entered into by the countries participating in it.

Principle No. 3

A country, whenever requesting information about a chemical, must substantiate the need for the information, on the grounds that:

- a) The chemical is present or is shortly to be marketed in its territory; and
- b) The information is necessary for the assessment of its hazards and the protection of man and the environment.

Comments

12. Automatic exchange of the available data among all Member countries would be an administrative burden and is not considered worthwhile. Such an exchange would also increase the risk of disclosure of confidential data. Therefore, data would be exchanged only in response to a substantiated request.

13. Linking the acceptability of a request to the information needs as defined in the principle helps to avoid excessively frequent requests, making exchange impractical, and to avoid undue latitude in the reasons a country can give for declining it.

14. The expression "present ... in its territory" has been chosen to include not only the presence of a chemical on a country's market but also its presence in the country's territory due to transfrontier pollution. The expression "shortly to be marketed" was chosen to include chemicals for which the marketing process has been launched even though the chemical is not yet physically present in the territory.

15. Several experts considered that the principle above would be too restrictive and reduce the value of the exchange of information in respect to hazard assessment. They suggested supplementing the principle by:

"or demonstrate the usefulness of the information because of a similarity in structure to a chemical present or shortly to be marketed in its territory".

However, other experts were of the opinion that the present state of scientific knowledge does not allow the establishment of a direct relationship between chemical structure and effect upon man and the environment which can be generally applied. Those experts also thought that the concept could harm the proprietary rights of a manufacturer of a chemical showing "similarity in structure" without its chemical being directly concerned or relevant to the case under consideration.

The Group agreed that Member countries could include a provision on structural similarity in bilateral exchange agreements.

Principle No. 4

A country requesting information:

- a) Must abide by the decision made by the transmitting country with respect to the confidential nature of the information;
- b) Must treat the transmitted information with at least the same degree of confidentiality as is practised in the country from which the information has been requested;
- c) May make the information available to national, regional or local authorities only when necessary for purposes of hazard assessment of chemicals or protection of man and the

environment and only when such authorities are able to guarantee the same level of confidential treatment;

- d) Shall not transmit the information received to any other country.

Comments

16. The national authority having recognised the confidentiality of information submitted to it has the first responsibility for ensuring that it is effectively safeguarded. The authority can only transmit such information if it is certain that the requesting country will respect the confidentiality of such information.

17. "Treat the transmitted information with at least the same degree of confidentiality as is practised in the country from which the information has been requested" means that the requesting country must treat the information in a manner that is the practical equivalent of the treatment of that information in the originating country. The Group understands that receiving countries will not have legislation identical to that in originating countries.

18. The Group recognised that different authorities within a country's government may need access to information, and that to make it accessible only to one competent authority would remove much of the value of an exchange of confidential information.

19. Each country should designate an authority to be responsible for transmitting confidential data to another country. The receiving country shall not transmit them elsewhere.

Principle No. 5

The requesting country shall not ask for the transmission of confidential information which it does not have the authority to collect and use under its legislation or in the normal course of its administration.

Comments

20. Exchangeable information would essentially be limited to data submitted under laws, regulations and practice of control of chemicals. It is therefore necessary to avoid a situation in which countries with stricter notification requirements than others find themselves constantly being asked to provide data.

21. OECD work under the chemicals programme, and especially work on exchanging confidential data, should be part of a broader effort to harmonize chemicals control procedures, and not be allowed to act as a substitute for harmonization. In particular, it should encourage Member countries which have not yet adopted legislation on the matter to do so over the coming years.

Principle No. 6

The solicited country should consult with the person who submitted the requested confidential data before transmitting them.

Comments

22. Since any exchange involves a further risk of disclosure, whose consequences cannot always be fully assessed by the government, it would seem normal to consult the submitter.

23. However, it should be clearly understood that this is a consultation and that the final decision must be taken by the government, and that consultation is without prejudice to specific agreements already in force between some Member countries and in accordance with national or international provisions.

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