Recommendation of the Council establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment

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Background Information

The Recommendation establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment was adopted by the OECD Council on 7 July 1977 on the proposal of the Environment Committee. This instrument recommends that Adherents establish new procedures or extend existing procedures for anticipating the effects of chemicals taking into account the guidelines contained in the annexes to the Recommendation.

THE COUNCIL,

HAVING REGARD to Article 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 26 May 1972 on Guiding Principles concerning International Economic Aspects of Environmental Policies [C(72)128];

HAVING REGARD to the Recommendation of the Council of 26 August 1976 concerning Safety Controls over Cosmetics and Household Products [C(76)144(Final)];

HAVING REGARD to the Recommendation of the Council of 28 September 1976 on a Comprehensive Waste Management Policy [C(76)155(Final)];

HAVING REGARD to the Report by the Environment Committee of 1 April 1977 on Anticipating the Effects from Chemicals in the Environment [ENV(77)20 and Addendum 1];

CONSIDERING the importance of international trade in chemicals and the fact that OECD Member countries account for most of the global production of chemicals towards the rest of the world;

CONSIDERING the value of internationally agreed guidelines at a time when governments are in the process of revising their approach to the control of chemicals by extending such controls from the protection of human health to the protection of the environment at large;

CONSIDERING the need to improve the acceptability to one country of information generated in another, and to avoid the creation of non-tariff barriers to trade;

On the proposal of the Environment Committee;

I. **RECOMMENDS** that Member countries in establishing new procedures or extending existing procedures for anticipating the effects of chemicals, take into account the Guidelines contained in Annexes I and II attached to this Recommendation, of which they form an integral part.

II. **INSTRUCTS** the Environment Committee to review action taken by Member countries in pursuance of this Recommendation, and to report thereon to the Council.

III. **INSTRUCTS** the Environment Committee to pursue a programme of work designed to facilitate the practical implementation of this Recommendation, with particular attention to the need for further development and improvement in respect of experimental techniques and for the validation of the capability of laboratories for performing tests.

ANNEX I

GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT

Introduction

1. The purpose of the Guidelines set out hereafter in this Annex is to assist Member countries in implementing new procedures or extending existing procedures for anticipating the effects of chemicals on man and in the environment.

2. Chemicals are not generally subjected to assessment for potential effects by legal or other official requirements. Existing official procedures are directed mainly towards human health effects, i.e. those governing radioactive substances, food and feed, pharmaceuticals and veterinary products, food and feed additives, cosmetics and toiletries, certain household products. Detergents are often required to be assessed for environmental but not for human effects. Pesticides are assessed for both human and environmental effects. Assessment of waste before disposal is also required by legislation in a few countries.

3. Recent legislation passed, proposed or in preparation in a number of Member countries, will now empower the authorities to request information from industry about any chemical irrespective of its intended purpose, and provides for the systematic assessment of such information with the aim to minimize exposure of man and the environment to chemicals which present unacceptable hazard.

4. Although it would be desirable to subject all chemicals to detailed assessment for potential hazard, the limited resources available in terms of laboratories as well as expertise, must be employed selectively. It is recognised that there are urgent problems of many existing chemicals that require detailed investigation but resources may not allow every existing chemical to be tested. It is, however, essential to ensure assessment of all new chemical substances so as to avoid unacceptable effects in the future from the uncontrolled introduction and use of hazardous materials.

5. The scheme outlined in the following Guidelines is intended to ensure that when chemicals are subjected to systematic assessment, they are considered in terms of both human health and environmental hazard. This can be achieved through the establishment of new assessment procedures or through the extension of existing procedures.

6. The assessment scheme also constitutes an important step towards facilitating the exchange of data about chemicals between countries. Such exchange is necessary in order to avoid wasteful use of resources by the renewed generation of data for the same chemical in each country. Further work is, however, necessary to improve the acceptability of data between countries.

I. Scope of Application

7. In the majority of cases, it is possible to determine no more than the likelihood of effects from chemicals on man or in the environment. Moreover, this can only be done through the application of expert judgment based on information generated by methods that are technically practicable as well as economically acceptable.

8. With a view to efficient use of the limited resources available, the assessment scheme is directed towards new chemical substances which enter a country for the first time, through manufacture or import, with the exception of those intended for limited research purposes, or which may be exempted by national authorities for specific reasons.

9. The scheme may further apply to existing chemical substances which are employed in distinctly new applications, or in considerably increased quantities, or selected because of newly discovered or possible harmful effects on human health or the environment.

10. The scheme could also be applied to determine the type of detailed investigations needed to elucidate the potential effects of other existing chemical substances which may cause particular concern. It is understood that in some countries resources will be devoted to such problems.

11. For the purpose of these Guidelines, chemical substances are: chemical elements and their compounds as they occur in the natural state or as produced by industry. Formulations should usually be excluded from any requirements for systematic assessment, except where a new chemical substance enters the country as a component of such formulations.

II. Approach and Data Requirements

12. The principal purpose of any assessment procedure is to identify the hazard of a chemical substance in order to determine the conditions of its use, thereby minimizing the risk of exposing man as well as the environment to hazard. For the purpose of assessing the potential effects of a chemical substance and the likelihood that man and/or the environment may be exposed to such a substance, a phased approach should be applied:

a) An initial assessment to determine the likelihood of

   i) Health hazard from the substance;

   ii) Environmental hazard from the substance;

b) Further assessments to elucidate, for selected chemical substances, their effects on man and/or in the environment.

13. The initial assessment is intended to segregate:

a) Those chemical substances which are least likely to create hazard and for which no further studies are deemed necessary at the time;

b) Those chemical substances which may create health hazard but are unlikely to reach the environment, and for which further studies are needed mainly on human health effects;

c) Those chemical substances (with or without health hazard) which reach the environment and for which detailed studies are needed of effects on the natural environment.

14. The initial assessment consists of two steps:

STEP I to determine, for the chemical substance under investigation, its

a) Physical and chemical properties (to indicate its likely behaviour);

b) Potential human health hazard (in the first instance for worker protection; in addition to indicate the need for further health studies);

c) Potential for access to the natural environment (to indicate the need for an assessment of environmental hazard).

STEP II to determine, for the chemical substances that could reach the environment in quantities which are significant with regard to toxicity, other effects and properties, their

a) Potential environmental hazard (to indicate the need for further studies of effects on the natural environment).

Types of basic data that may be of value for Steps I and II of the initial assessment are indicated in Annex II.

15. Where human health hazard has been indicated through Step I of the initial assessment, detailed studies should be made for further assessment of human health effects.

16. Where environmental hazard has been indicated through Step II of the initial assessment, detailed studies should be made for further assessment of effects on the natural environment.

17. Certain groups of chemicals are already subject to special procedures for detailed assessment of either human health effects or environmental effects. Such procedures should be extended to ensure that the chemicals are considered in terms of both human and environmental hazard.

18. Chemical substances presenting unreasonable hazard to health and the environment, should - unless prohibited - be allowed only for supervised use, and only when less hazardous substitutes are not available.

III. Administrative Requirements

19. Responsibility for generating and assessing the data necessary to determine the potential effects and the safe use of chemical substances with respect to man and the environment must be part of the overall function and liability of industry.

20. In respect of administrative requirements, several options are available to the authorities. Progressive options are:

a) An obligation on the manufacturer to maintain the results of his assessment for examination by the authorities upon request. This option should be followed by the gradual implementation of a notification system for new chemical substances.

b) An obligation on manufacturers and importers to notify their authorities of all new chemical substances, with a declaration of, for example,

   i) Nomenclature (identification),

   ii) Projected quantities to be manufactured or imported during a calendar year,

   iii) Intended usage.

   This option should be followed by the selection of priority substances for examination by the authorities.

c) An obligation on manufacturers and importers to submit to their authorities a dossier for the chemical substance under investigation including the information required for an initial assessment. This option should be followed automatically by an examination of the dossier resulting in

   i) No action, or

   ii) The establishment of testing programmes, or

   iii) Regulations for use.

   Requirements for notification or submission of dossiers will be dependent upon the resources available to the national authorities.

21. Provision should be made to ensure protection of confidential information.

22. When new procedures are established for the assessment of chemical substances, an integrated approach should be sought. Several authorities may have responsibility for treating notifications, declarations and dossiers required under different laws or schemes for the control of chemicals in a country. Arrangements should be made for optimum co-ordination of such activities.

23. Unless the authorities are adequately equipped to examine and act upon the dossiers required for new chemical substances, such requirements should not be prohibitory of the production, import, sale and use of the substance. It is understood, however, that the substance may later be withdrawn, completely or for certain use, or otherwise regulated in case harmful effects are identified.

24. Provision should be made for procedures by which emergency action may be taken to prohibit the importation, use or supply of a harmful substance.

25. Provision should be made for procedures, by which manufacturers of chemical substances may seek reconsideration of decisions taken by the authorities.

IV. Dissemination of Information

26. The transfer of chemical substances (as defined in paragraph 11) from the primary manufacturer through the commercial chain should be accompanied by:

a) An indication of origin (name and address of manufacturer, importer or distributor);

b) Information on potential hazard and on precautions to be observed for the intended use(s) of the substance;

c) Prescribed methods of disposal.

27. For purposes of collection and adequate disposal where appropriate, the presence in units of manufactured goods of an environmentally hazardous chemical substance should be indicated.

28. Chemical substances in transport should be labelled, marked, shipped and packaged according to appropriate national or international regulations. All efforts should be made towards international harmonization of such regulations.

29. When requested by the authorities either in the country of origin of the chemical substance or in importing countries, the information, on the basis of which the conditions of use of the substance was determined, should be accompanied by a specification of the experimental techniques used to generate the data.

V. Surveillance and Monitoring

30. Confirmation of the adequacy of assessments for effects on man and in the environment should be sought where appropriate, but selectively in view of the high costs involved, for example:

a) In the factory, through epidemiological records. All efforts should be made to ensure comparability of such records so that indications of effects in one factory may be set alongside the findings of others to assist in identifying the cause of such effects;

b) In the domestic environment, through full use of National Poisons Centres whose statistics should be reviewed regularly, and/or other appropriate mechanisms as available;

c) In the natural environment, through monitoring systems (i.e. periodic measurements of air, water, soil, living organisms, and food) in order to check for the appearance and possible unexpected effects of chemical substances released in significant quantities relative to persistence and mobility.

31. International exchange of data from surveillance and monitoring programmes should be encouraged. International Organisations might play an important role in collecting, collating and reviewing such information.

ANNEX II

INITIAL ASSESSMENT: STEP ONE

(TYPES OF DATA)

Some of the types of data which might be necessary to screen a chemical substance for potential human health hazard and for potential discharge to the natural environment are set forth below. In some cases, more information may be necessary while in other cases less information may be sufficient. In order to assess the data, information is needed on the methods used to generate it.

a) Physical and chemical properties

For identification of the chemical substance the data should include nomenclature, structural formula, purity and the nature of impurities, and by-products. Among the important properties to be determined are the following: melting point, boiling point, density, physical state, partition coefficients, corrosiveness, solubility in different media, vapour pressure, thermo-stability, photo-stability, degradability, and pH stability.

b) Data relevant to human health

This data should give a preliminary indication of the potential hazard to human health and can be obtained from acute and subacute toxicity studies (such as LD_{50} and maximum tolerated dose studies). Short-term studies that could indicate the possibility of long-term effects should also be carried out. When this preliminary screening indicates significant biological activity, long-term studies would be appropriate.

c) Discharge to the natural environment

The likelihood of discharge to the natural environment of the chemical substance or its by-products from production through disposal must be assessed. For this purpose the production rates and intended uses, an estimate of the amount reaching the environment, and the size and character of the exposed populations should be considered. Also of importance at this stage is a preliminary consideration of biodegradation and breakdown products.

INITIAL ASSESSMENT: STEP TWO

(TYPES OF DATA FOR ENVIRONMENTAL ASSESSMENT)

For chemical substances that could reach the environment in quantities which are significant with regard to toxicity or other effects or properties, or over long periods of time, a further step should be added to the initial assessment. Some of the types of data that might be necessary to assess the likelihood of hazard from a chemical substance in the environment are set forth below. In some cases more information may be necessary while in other cases less information may be sufficient. (In developing environmental data, special attention must be paid to the availability of appropriate analytical methods for measuring the chemical and its degradation products.)

a) Physical and chemical properties

Among the additional properties of environmental importance are chelating ability and absorption/desorption at various interfaces.

b) Data relevant to the natural environment

For a determination of pathways to and sinks in the environment both direct discharges (to water, air or soil) and indirect discharges (e.g. sewage and disposal methods) should be considered. Persistence and potential for bioaccumulation are frequently of critical importance.

An indication should be sought of acute and subacute toxicity of the chemical substance and its degradation products for species at risk under worst case conditions in the appropriate parts of the environment.

Consideration should also be given to the possibility of environmental movement, intermedia transfer, reactivity with atmospheric constituents and interaction with chemicals being introduced into the environment (e.g. chlorine used in water treatment).

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