



Decision of the Council concerning
the Minimum Pre-Marketing Set of
Data in the Assessment of
Chemicals

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Background Information

The Decision concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals was adopted by the OECD Council on 8 December 1982 on the proposal of the Management Committee of the Special Programme on the Control of Chemicals (now called Chemicals Committee). This instrument requires that, in Adherent countries, sufficient information is available on the properties of new chemicals before they are marketed, and recommends that the minimum pre-marketing set of data listed in the Annex to the Decision serves as a basis for a meaningful first assessment of the hazards of a chemical to health and the environment.

THE COUNCIL,

HAVING REGARD to Articles 2 a), 2 d), 3, 5 a) 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 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 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 August 1976, concerning Safety Controls over Cosmetics and Household Products [C(76)144(Final)];

HAVING REGARD to the Recommendation of the Council of 7 July 1977, establishing Guidelines in respect of Procedures 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 Decision of the Council of 12 May, 1981, extending the duration of that Programme [C(78)127(Final), and C/M(81)7(Final), Item 86];

HAVING REGARD to the conclusions of the First High-Level Meeting of the Chemicals Group of 19 May 1980, dealing with the control of health and environmental effects of chemicals [ENV/CHEM/HLM/80.M/1];

CONSIDERING the need for concerted action amongst OECD Member countries to protect man and his environment from exposure to hazardous chemicals;

CONSIDERING the importance of international production and trade in chemicals and the mutual economic and trade advantages which accrue to OECD Member countries from harmonization of policies for chemicals control;

CONSIDERING the need to reduce the cost burden associated with testing chemicals and the need to utilise more effectively scarce test facilities and specialist manpower in Member countries;

CONSIDERING the close relationship between the Mutual Acceptance of Data [C(81)30(Final)], the OECD Test Guidelines and OECD Principles of Good Laboratory Practice and the OECD Minimum Pre-marketing Set of Data;

CONSIDERING the need to have sufficient information in Member countries to allow an initial assessment to be made of the possible hazard presented by new chemicals;

PART I

I. DECIDES that in Member countries sufficient information on the properties of new chemicals should be available before they are marketed to ensure that a meaningful assessment of hazard to man and the environment can be carried out.

II. NOTES that some chemicals, owing to their intended use, may already be subject to specific legislation in a Member country, and insofar as this intended use is concerned are not subject to this Decision.

III. NOTES that legislation or administrative procedures in a Member country may provide for exemptions because of the nature of a chemical or the quantity manufactured.

IV. INSTRUCTS the Environment Committee to pursue a programme of work designed to lead to the development of an overall approach to step sequence testing of chemicals.

V. INSTRUCTS the Environment Committee to continue related work aimed at the harmonization of hazard assessment and the study of notification procedures associated with assessment of chemicals.

PART II

To implement the Decision set forth in Part I:

RECOMMENDS that the minimum pre-marketing set of data (MPD) together with its provisions for flexible application set forth as integral parts of this text in the Annex hereto can serve as a basis for a meaningful first assessment of the potential hazard of a chemical to health and the environment.

ANNEX

DATA COMPONENTS FOR, AND PROVISIONS FOR FLEXIBLE APPLICATION OF THE OECD MINIMUM PRE-MARKETING SET OF DATA

Data Components for the OECD Minimum Pre-Marketing Set of Data

Chemical Identification Data

Name according to agreed international nomenclature, e.g. IUPAC
Other names
Structural formula
CAS-number
Spectra ("finger-print spectral" from purified and technical grade product)
Degree of purity of technical grade product
Known impurities, and their percentage by weight
Essential (for the purposes of marketing) additives and stabilisers and their percentage by weight

Production/Use/Disposal Data

Estimated production, tons/year
Intended uses
Suggested disposal methods
Expected mode of transportation

Recommended Precautions and Emergency Measures

Analytical Methods

Physical/Chemical Data

Melting point
Boiling point
Density
Vapour pressure
Water solubility
Partition coefficient
Hydrolysis*
Spectra
Adsorption - Desorption*.
Dissociation constant
Particle size*

* Only the screening part to be done for base set.

Acute Toxicity Data

Acute oral toxicity
Acute dermal toxicity
Acute inhalation toxicity
Skin irritation
Skin sensitisation
Eye irritation

Repeated Dose Toxicity Data

14-28 days, repeated dose

Mutagenicity data

Ecotoxicity data

Fish LC50 - at least 96 hours exposure
Daphnia - reproduction 14 days
Alga - growth inhibition 4 days

Degradation/Accumulation data

Biodegradation: screening phase biodegradability data (readily biodegradable)

Bioaccumulation: screening-phase bioaccumulation data (partitioning coefficient, n-octanol/water, fat solubility, water solubility, biodegradability)

Provisions for Flexible Application of the OECD Minimum Pre-marketing Set of Data

The Member countries further note that:

1. Due regard may be given, on a case-by-case basis, to the scientific and economic factors that may influence the need for and the scope of testing.
2. Member countries may omit or substitute certain tests or ask for them in a later stage of initial assessment, as long as they can justify their course of action.

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