



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

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## **Date(s)**

Adopted on 08/12/1982

## **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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