

# **DESCRIPTIONS OF SELECTED KEY GENERIC TERMS USED IN CHEMICAL HAZARD/RISK ASSESSMENT**

**International Programme on Chemical Safety**

**Joint Project with OECD**

**on the Harmonisation of Hazard/Risk Assessment Terminology**

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## **BACKGROUND**

1. Over the past decades OECD and IPCS, as well as many other international organisations and Programmes, have been faced with the problem of misunderstandings concerning terms used in environmental health. The main reason for this problem is the interdisciplinary character of environmental health, and the fact that each of the disciplines developed within their own frameworks a specific “language culture”. Due to the lack of an internationally agreed upon glossary of environmental health terms, almost every single programme/project has developed for practical reasons its own “working terminology”.

2. Although work has been done previously on the development of internationally-agreed upon definitions for terms used in chemical hazard/risk assessment (e.g. by OECD, IPCS and others), inconsistencies in the definitions and use of many of these terms still exist. For example, inconsistencies were recognised in the OECD Pilot Project to Compare Pesticide Data Reviews. During this project, in which data review reports on seven pesticides were compared, inconsistency in terminology was found in all test areas, but was particularly prevalent for certain aspects related to human health (e.g. reproductive and developmental toxicity, carcinogenicity). IPCS, through its various activities and, in particular, through its project on Harmonisation Approaches to the Assessment of Risk from Exposure to Chemicals, has also identified the development and consistent use of terminology as a priority area.

3. Inconsistencies in terminology used can be impediments to the harmonisation of risk assessment approaches by hindering the mutual understanding of the different approaches currently in use. Furthermore, the barriers created by these inconsistencies in terminology reduce the possibility for the sharing and use of assessment between countries. Resolving these differences is therefore a high priority for OECD and IPCS.

## **OBJECTIVE**

4. The objective of this joint OECD/IPCS project is to develop internationally harmonised generic and technical terms used in chemical hazard/risk assessment which will help facilitate the mutual use and acceptance of the assessment of chemicals between countries, saving resources for both governments and industry.

5. Target groups of users of the glossary of harmonised terms are health and environment professionals and political actors at all levels. The harmonised terms may be also used as a basis in preparing other publications primarily aimed at public information and health education.

## **CONTEXT**

6. This project was focused on the harmonisation of terms used in the hazard/risk assessment of chemicals (including pesticides) to be used in the context of chemicals management (i.e. notification, registration, classification, etc.)

## SCOPE

7. The project covers two categories of terms:

Generic Terms: general terms used in the process of determining hazard and risk. This publication presents the results of this category.

Technical Terms: those terms used in human health and environmental hazard and risk assessment including scientific–technical terms used in effects assessment (e.g. nomenclature of tumors and other pathological lesions and technical terms used in hazard characterisation (e.g. teratogenicity). Technical terms are published separately, as they are developed.

## APPROACH OF THE WORK

8. The project is being carried out in a step-wise fashion beginning with the generic terms as described below:

### Generic Terms:

9. OECD and IPCS, in consultation with other organisations from the Inter-Organization for the Sound Management of Chemicals (IOMC), first developed a list of terms and identified “key documents and sources” from which definitions were extracted. Note that in this context, “key documents /sources” were those that have regulatory implications (e.g. European Community Directives, US EPA documents) or are widely used and cited. The terms have been divided into “higher” and “lower” priority.

10. Next, definitions for the higher priority generic terms were extracted from the “key documents and sources” and were circulated widely (e.g. through networks of the IOMC organisations) for review and preference. Responders were asked to:

- identify or provide their preferred definition for each term
- identify terms considered as synonyms
- indicate whether any important key documents or sources were omitted

11. The comments and suggestions received were subsequently critically analysed by an OECD/IPCS Terminology Planning Working Group.

12. In November 1996 the OECD/IPCS secretariats circulated the list of selected 50 generic terms, together with the various descriptions for each of the items as identified in the Key Documents and other sources, to their respective networks of experts. The list of selected items is provided in [Annex 1](#) and the list of the source documents is provided in [Annex 2](#) to this document. The survey results are summarised in [Annex 3](#).

13. The OECD/IPCS Terminology Planning Group and WHO terminology experts critically analysed the survey results during two successive meetings in Carshalton, UK in March 1998 and in Geneva, Switzerland in October 1998. Several proposals were considered to find compromises for descriptions where there was no clear preference for any particular description. Details of the process used by the Terminology Planning Group are described in [Annex 4](#). After several commenting rounds the OECD and IPCS secretariats jointly edited the most recent proposal of the Terminology Planning Group and consulted a senior expert in hazard and risk assessment (Professor Robert Kroes from the Netherlands) for a final review. Several changes were made in the Planning Group’s proposal to improve consistency,

comprehensibility and coherence of the description of related terms. This version was submitted to the OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology for final review and declassification, and also to the Core Group of the IPCS Harmonisation Steering Committee for final review. A number of small, mostly editorial comments and a few suggestions for improvement of the descriptions of some of the more contentious terms, were received. These were all considered in the final report.

14. In addition to the descriptions of the various generic terms, the Working Group also considered the inclusion of remarks, annotations and background information to the various terms. Most of these remarks were provided by experts who responded to the original survey.

15. The alphabetical list of selected generic terms in hazard and risk assessment and their descriptions are provided in the table below, followed by a compilation of remarks and background notes to each of the terms included in this overview.

### **Technical Terms:**

16. Once the work on the generic terms was well underway, work on the technical terms was also initiated. OECD and IPCS have started to identify:

- those areas which should be included (divide technical terms into broad areas such as reproductive toxicity, genetic toxicity, etc.)
- other key organizations that should be involved (e.g. academia, government, and industry).

17. Considering the amount of work involved in this exercise, and its high priority, the initial focus is on the harmonisation of terms used in human health hazard/risk assessment. Input is sought from international scientific societies to assist with the technical description of technical terms.