

IPCS

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY



IPCS Harmonization Project

IPCS Risk Assessment Terminology

Part 1:

**IPCS/OECD Key Generic Terms
used in Chemical Hazard/Risk Assessment**

Part 2:

**IPCS Glossary of Key Exposure
Assessment Terminology**

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
A cooperative agreement among UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD



World Health Organization
Geneva

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Harmonization Project Document No. 1

IPCS RISK ASSESSMENT TERMINOLOGY

This project was conducted within the IPCS project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals.

Published under the joint sponsorship of the United Nations Environment Programme, the International Labour Organization, and the World Health Organization, and produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals.



World Health Organization
Geneva, 2004

The **International Programme on Chemical Safety (IPCS)**, established in 1980, is a joint venture of the United Nations Environment Programme (UNEP), the International Labour Organization (ILO), and the World Health Organization (WHO). The overall objectives of the IPCS are to establish the scientific basis for assessment of the risk to human health and the environment from exposure to chemicals, through international peer review processes, as a prerequisite for the promotion of chemical safety, and to provide technical assistance in strengthening national capacities for the sound management of chemicals.

The **Inter-Organization Programme for the Sound Management of Chemicals (IOMC)** was established in 1995 by UNEP, ILO, the Food and Agriculture Organization of the United Nations, WHO, the United Nations Industrial Development Organization, the United Nations Institute for Training and Research, and the Organisation for Economic Co-operation and Development (Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen cooperation and increase coordination in the field of chemical safety. The purpose of the IOMC is to promote coordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

WHO Library Cataloguing-in-Publication Data

International Programme on Chemical Safety.

IPCS risk assessment terminology.

2 pts. in 1 v. -- (IPCS harmonization project ; document no. 1)

Contents: Pt. 1, IPCS/OECD key generic terms used in chemical hazard/risk assessment / International Programme on Chemical Safety Joint Project with OECD on the Harmonization of Hazard/Risk Assessment Terminology --

Pt. 2, IPCS glossary of key exposure assessment terminology / IPCS project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals.

1.Risk assessment 2.Environmental exposure 3.Terminology 4.Hazardous substances 5.Chemicals I.Organisation for Economic Co-operation and Development II.Title.

ISBN 92 4 156267 6

(LC/NLM classification: QV 15)

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Printed by the WHO Document Production Services, Geneva, Switzerland

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FOREWORD

Harmonization Project Documents are a new family of publications from the International Programme on Chemical Safety (IPCS) — a cooperative programme of the World Health Organization (WHO), the International Labour Organization (ILO), and the United Nations Environment Programme (UNEP). Harmonization Project Documents join the Environmental Health Criteria (EHC) methodology (yellow cover) series of documents as authoritative documents on methods for the risk assessment of chemicals.

The main impetus for the current coordinated international, regional, and national efforts on the assessment and management of hazardous chemicals arose from the United Nations Conference on Environment and Development (UNCED) held in 1992 and was reconfirmed at the 2002 World Summit on Sustainable Development. UNCED Agenda 21, Chapter 19, the “blueprint” for the environmentally sound management of toxic chemicals under the principles of sustainable development, has guided most international and national chemical-related activities. Chapter 19 is the agreed upon, endorsed international programme of action of governments for developing and implementing national programmes for management of chemicals within the principles of sustainable development.

The IPCS project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals (Harmonization Project) is conducted under Agenda 21, Chapter 19. The Intergovernmental Forum on Chemical Safety (IFCS) Forum III, held in Salvador da Bahia in October 2000, agreed on Priorities for Action Beyond 2000, which further define the actions recommended to be taken. Forum III declared that by 2004, IPCS and the Inter-Organization Programme for the Sound Management of Chemicals (IOMC, which comprises seven intergovernmental organizations) should have ensured that recommendations for harmonized assessment approaches were available for terminology, cancer, and reproductive and developmental toxicology and that common principles for the assessment approach to other specific toxicological end-points, such as immunotoxicology, endocrine disruptors, and ecotoxicology, should be adopted wherever possible.

The IPCS Harmonization Project, which is ongoing, states that “harmonization,” in the context of chemical risk assessment, should not simply be equated with standardization. It is not a goal of the project to standardize risk assessments globally, as that is considered to be neither appropriate nor feasible. Instead, harmonization is thought of as an effort to strive for consistency among approaches and to enhance understanding of the various approaches to chemical risk worldwide. Thus, harmonization is defined, in a step-wise fashion, as an understanding of the methods and practices used by various countries and organizations so as to develop confidence in, and acceptance of, assessments that use different approaches. It further involves a willingness to work towards convergence of these approaches or methods as a longer-term goal.

Achieving harmonization of approaches is considered to provide a framework for comparing information on risk assessment; understanding of the basis for exposure standards for specific chemicals in different countries; savings of time and expense by sharing information and avoiding duplication of work; and credible science through better communication among organizations and peer review of assessments and assessment procedures. The stated project

mission is to ensure better chemical risk assessment and hence management practices that promote the protection of human health and the environment within the framework of sustainable development.

This ongoing project is overseen by a geographically representative Harmonization Project Steering Committee and a number of ad hoc Working Groups that manage the detailed work. Finalization of documents includes a rigorous process of international peer review and public comment.

LIST OF ACRONYMS AND ABBREVIATIONS

ADI	acceptable daily intake
bw	body weight
COHb	carboxyhaemoglobin
DDT	dichlorodiphenyltrichloroethane
EEC	estimated exposure concentration
EED	estimated exposure dose
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
IFCS	Intergovernmental Forum on Chemical Safety
ILO	International Labour Organization
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
LC50	median lethal concentration
LD50	median lethal dose
LOAEL	lowest-observed-adverse-effect level
NEL	no-effect level
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEM	personal exposure monitor
PNEC	predicted no-effect concentration
RfD	reference dose
TDI	tolerable daily intake
TI	tolerable intake
UF	uncertainty factor

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