IPCS

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

WHO

IPCS Harmonization Project

# WHO Human Health Risk Assessment Toolkit: Chemical Hazards


IOMC

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

World Health Organization

This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization, the International Labour Organization or the United Nations Environment Programme.

**Harmonization Project Document No. 8**

# WHO HUMAN HEALTH RISK ASSESSMENT TOOLKIT: CHEMICAL HAZARDS

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

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

WHO human health risk assessment toolkit: chemical hazards.

(IPCS harmonization project document; no.8)

1.Hazardous substances - toxicity. 2.Risk assessment. 3.Environmental exposure. 4.Toxicology.
I.World Health Organization. II.International Programme on Chemical Safety.

ISBN 978 92 4 154807 6 (NLM Classification: QV 600)



Technically and linguistically edited by Marla Sheffer, Ottawa, Canada

# TABLE OF CONTENTS

PREFACE ..... viii

PROCESS FOR DEVELOPMENT OF THE TOOLKIT ..... x

ACKNOWLEDGEMENTS ..... xiii

LIST OF ACRONYMS AND ABBREVIATIONS ..... xiv

1. INTRODUCTION ..... 1
   1.1 Purpose and intended audience ..... 1
   1.2 Scope of the Toolkit ..... 2

2. DESCRIPTION OF HUMAN HEALTH RISK ASSESSMENT OF CHEMICALS ..... 4
   2.1 Definition of risk assessment ..... 4
   2.2 Uses of human health risk assessments of chemicals ..... 5

3. DESCRIPTION OF THE TOOLKIT ..... 7
   3.1 The Toolkit as a road map ..... 7
   3.2 Tiered assessments in the Toolkit ..... 10
   3.3 Generic road maps ..... 12
      3.3.1 Hazard identification ..... 12
         3.3.1.1 Chemical identity ..... 12
         3.3.1.2 Hazardous properties ..... 14
      3.3.2 Hazard characterization/guidance or guideline value identification ..... 15
         3.3.2.1 Health-based guidance values derived by international organizations ..... 18
         3.3.2.2 Media-specific guideline values (“quality guideline values”) derived by international organizations ..... 21
         3.3.2.3 Evaluating the appropriateness of available guidance or guideline values for a specific problem ..... 22
      3.3.3 Exposure assessment ..... 22
         3.3.3.1 Routes and pathways of exposure ..... 23
         3.3.3.2 Estimating exposures: modelling or measurement approaches ..... 23
         3.3.3.3 Duration of exposure ..... 26
         3.3.3.4 Concentration and rate of exposure ..... 27
         3.3.3.5 Biomarkers of exposure ..... 28
      3.3.4 Risk characterization ..... 28
         3.3.4.1 Comparison with a guidance or guideline value ..... 28
         3.3.4.2 Estimation of cancer risk ..... 30

4. INTERNATIONAL RISK ASSESSMENT RESOURCES ..... 31
   4.1 Introduction ..... 31
   4.2 Organization ..... 31
   4.3 Directories of resources ..... 32
   4.4 General resources on risk assessment ..... 32
      4.4.1 Resources on risk assessment methodology ..... 33
      4.4.2 Resources on susceptible populations ..... 33

4.5 Chemical-specific resources ....34
4.5.1 JMPR monographs ....34
4.5.2 JECFA monographs ....34
4.5.3 EHC monographs ....35
4.5.4 CICADs ....35
4.5.5 Drinking-water quality background documents ....35
4.6 Hazard identification resources ....35
4.6.1 International Chemical Safety Cards ....36
4.6.2 Screening Information Datasets for High Production Volume Chemicals ....36
4.6.3 WHO Recommended Classification of Pesticides by Hazard ....36
4.6.4 UN Recommendations for the Transport of Dangerous Goods ....37
4.6.5 IARC monographs ....37
4.6.6 Hazardous Substances Data Bank ....37
4.6.7 European Chemical Substances Information System ....37
4.6.8 EU Classification and Labelling System ....38
4.6.9 International Chemical Control Toolkit ....38
4.7 Hazard characterization/guidance or guideline value resources ....38
4.7.1 Guidance values for exposure rates ....39
4.7.1.1 Pesticides ....39
4.7.1.2 Food additives and contaminants, naturally occurring toxicants and residues of veterinary drugs in food ....39
4.7.2 Guideline values for exposure concentrations ....39
4.7.2.1 WHO drinking-water guidelines ....39
4.7.2.2 WHO air quality guidelines ....39
4.7.3 Guidance and guideline values from chemical-specific monographs ....40
4.7.4 International Toxicity Estimates for Risk (ITER) database ....40
4.7.5 Occupational exposure limits (OELs) ....40
4.8 Exposure assessment resources ....40
4.8.1 General guidance on exposure assessment ....41
4.8.2 Emission sources and scenarios ....41
4.8.3 Emission rates ....42
4.8.4 Transport and fate ....43
4.8.5 Exposure concentrations ....44
4.8.6 Exposure factors ....45
4.9 Risk characterization resources ....45

5. DRINKING-WATER CASE-STUDY ....46
5.1 Objective ....46
5.2 Statement of the problem ....46
5.3 Hazard identification ....47
5.4 Hazard characterization/guidance or guideline value identification ....49
5.5 Exposure assessment ....50
5.6 Risk characterization ....55
5.7 Summary ....57

6. RESPIRABLE PARTICULATE MATTER ($PM_{10}$) CASE-STUDY ....58
6.1 Objective ....58
6.2 Statement of the problem ....58
6.3 Hazard identification ....59
6.4 Hazard characterization/guidance or guideline value identification ....59

6.5 Exposure assessment....62
6.6 Risk characterization....65
6.7 Summary....66

7. PESTICIDE CASE-STUDY....67
7.1 Objective....67
7.2 Statement of the problem....67
7.3 Hazard identification....67
7.4 Hazard characterization/guidance or guideline value identification....69
7.5 Exposure assessment....71
7.6 Risk characterization....75
7.7 Summary....77

8. REFERENCES AND WEB LINKS....79

## LIST OF FIGURES

Figure 1 An environmental health paradigm and its relationship to the human health risk assessment framework .....6
Figure 2 Generic road map for chemical risk assessment in the context of the Toolkit following the conventional risk assessment paradigm.....8
Figure 3 Generic road map for hazard identification in the context of the Toolkit .....13
Figure 4 Generic road map for hazard characterization/guidance or guideline value identification in the context of the Toolkit .....17
Figure 5 Generic road map for exposure assessment in the context of the Toolkit .....24
Figure 6 Possible exposure media and corresponding means of contact .....25
Figure 7 Generic road map for risk characterization in the context of the Toolkit.....29
Figure 8 Case-specific road map for hazard identification: drinking-water case-study ...48
Figure 9 Case-specific road map for hazard characterization/guidance or guideline value identification: drinking-water case-study.....51
Figure 10 Case-specific road map for exposure assessment: drinking-water case-study ...54
Figure 11 Case-specific road map for risk characterization: drinking-water case-study ....56
Figure 12 Case-specific road map for hazard identification: particulate matter case-study.....60
Figure 13 Case-specific road map for hazard characterization/guidance or guideline value identification: particulate matter case-study .....63
Figure 14 Case-specific road map for exposure assessment: particulate matter case-study.....65
Figure 15 Case-specific road map for hazard identification: pesticide case-study .....70
Figure 16 Case-specific road map for hazard characterization/guidance or guideline value identification: pesticide case-study .....72
Figure 17 Case-specific road map for exposure assessment: pesticide case-study.....76
Figure 18 Case-specific road map for risk characterization: pesticide case-study .....78

## LIST OF TABLES

Table 1 Paradigm for risk assessment, including problem formulation ..... 4
Table 2 Output from the framework for chemical risk assessment in the context of the Toolkit.....9
Table 3 Tiers of risk assessment included in the Toolkit.....11
Table 4 Human health effects included in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).....15
Table 5 Guidance and other values commonly used in chemical evaluations.....18
Table 6 Sources of guidance values for chemicals developed by international organizations.....20
Table 7 Sources of guideline values for chemicals developed by international organizations.....21
Table 8 Two compilations of hazard identification, hazard characterization, exposure assessment and risk characterization information for chemicals.....32
Table 9 WHO documents on principles of human health risk assessment for chemicals.....33
Table 10 International sources of information on harmonization of risk assessment methodology .....33
Table 11 International sources of information on susceptible populations .....34

Table 12 WHO resources on identification of chemical hazards....35
Table 13 General content of international hazard identification resources ....36
Table 14 International resources on hazard characterization....39
Table 15 Examples of freely available national resources for occupational exposure limits (OELs) ....41
Table 16 International sources of information on media and routes of exposure....41
Table 17 International sources of guidance on exposure assessment ....42
Table 18 Widely accepted resources on emissions....43
Table 19 Summary of selected exposure factors published by WHO ....45
Table 20 International guidance and guideline values for cadmium ....49
Table 21 Cadmium concentrations in five samples of water obtained from each of three locations in the vicinity of Rivertown....53
Table 22 WHO air quality guideline values for $PM_{10}$ ....61
Table 23 WHO interim targets for $PM_{10}$: annual mean concentrations....61
Table 24 Relevance of study findings to an African country: template ....74