WORLD HEALTH ORGANIZATION
DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

Development of a WHO Risk Assessment Toolkit (RA Toolkit)

WHO/IPCS Meeting to Lead into the Test Phase of the draft WHO Risk Assessment Toolkit (RA Toolkit)

29-30 July 2009
Chulabhorn Research Institute, Bangkok, Thailand

Final Meeting Record

WELCOME TO MEETING

1. The meeting was opened by Dr Kersten Gutschmidt, WHO, Genoa, on behalf of the World Health Organization. Dr Gutschmidt, Dr Mathuros Ruchirawat, Chulabhorn Research Institute (CRI), Bangkok, and Ms Neslihan Grasser, Rotterdam Convention Secretariat, Geneva welcomed participants to the meeting and thanked them for assisting in the testing and further development of the WHO RA Toolkit. The List of Participants is at Attachment 1.

AIM AND AGENDA OF MEETING

2. The aim of the meeting was: (i) to introduce, discuss and familiarize participants with the draft RA Toolkit; (ii) to formulate problem statements for which to test the RA Toolkit; (iii) to lay-out roles and responsibilities as well as workplans for the RA Toolkit testing phase; and (iv) to provide further input into the development of the RA Toolkit as discussion take place. The meeting adopted the provisional agenda (Attachment 2) under the conditions that more time is allocated to the discussions leading into the pilot phase and less time is used for introducing the toolkit. The meeting was facilitated by Dr Gutschmidt.

DRAFT WHO RISK ASSESSMENT TOOLKIT (RA TOOLKIT) SESSION

3. The Secretariat provided an introduction into the RA Toolkit project (Attachment 3).
**RA Toolkit Project**

4. Many scenarios/problems that involve chemicals require the application of risk assessment methodology to support environmental health decision-making. A range of international chemical risk assessment methodologies are available including guidance from the WHO/IPCS. Many of these tools are available on the internet and in print. However risk assessment bodies in developing countries and countries with economies in transition do no necessarily have the resources to locate these tools and become informed about their possible applications in their own countries in support of chemicals management and their obligations under international agreements on chemicals. In parallel, information on the hazards of chemicals is becoming more readily accessible, for example, the WHO INCHEM database and a number of other databases through the OECD eChemPortal.

5. The purpose of the RA Toolkit is to make these RA methodologies, tools and related information more readily-accessible, especially to relevant stakeholders in developing countries and countries with economies in transition, including public health and environmental or other professionals involved in conducting risk assessments and/or making decisions on whether and how to manage/reduce chemical risks.

6. The RA Toolkit is organized into sections that provide (i) an overview of chemical RA, including the RA framework and uses of RA; (ii) generic road maps for how to conduct RA, including information about a tiered approach; (iii) listings of international resources that are useful for conducting RAs; and (iv) examples of how that information can be applied to a RA question, including case-specific roadmaps.

7. Initially, three case studies have been developed, including: (i) a drinking water case study that involves the regular discharge of liquid waste from industrial operation into surface water; (ii) an air quality case study on the development of a national standard to regulate ambient PM$_{2.5}$ concentrations; and (iii) a pesticide case study addressing notification under Article 5 of the Rotterdam Convention.

8. The RA Toolkit project was launched at the, Task Group meeting, March 2008, Montreux, Switzerland. Initial work on the road map for the water scenario has been by March 2009. The first comprehensive draft RA Toolkit, including three case scenarios was developed by July 2009. Testing and review of RA Tookit is scheduled for August to October 2009. The final review meeting is scheduled for 3 days later in October/November/December 2009 in Geneva. Finalization of first draft including three case scenarios is scheduled for first quarter of 2010.

9. Given that the RA Toolkit is accepted by partners, next steps in its further development include (i) the preparation of additional case studies with case-specific roadmaps; (ii) an ongoing review of newly available international and perhaps national RA tools and information; (iii) promotion of RA Toolkit, and (iv) perhaps the development of an e-Toolkit, including a website.
Draft RA Toolkit section by section

10. Following the introduction into the RA Toolkit, Dr David MacIntosh introduced the RA Toolkit section by section. Each presentation was followed by a brief discussion about the content of the RA Toolkit. The draft RA Toolkit is available in Attachment 4. From the discussions, comments were received to improve the toolkit, including (i) to align roadmaps with Figure 2.1, (ii) to add sections on uncertainties, problem formulation, exposure factors, and exposure tools, (iii) to reference a glossary of terms, (iv) to incorporate concepts from the global burden air pollution assessment into the particulate matter case study, and (v) to expand the discussion of bridging in the Rotterdam case study.

11. In addition, Ms Grasser, Rotterdam Convention Secretariat, presented supporting information to the case study on the pesticide (section 7 of the RA Toolkit), including presentations on the Rotterdam Convention and the Prior Informed Consent (PIC) procedure. In addition, she provided information on the "bridging" procedure and a recent example of bridging in the context of a notification of final regulatory action on endosulfan (Attachment 5).

PILOT PHASE SESSION

Introduction of pilot phase

12. The aim of the pilot phase is to test the RA Toolkit by addressing a specific risk assessment problem and to provide comments to the WHO secretariat, including comments on the concept (generic and case-specific roadmaps), information resources and tools, comprehensiveness, readability and utility.

13. An evaluation questionnaire provided by WHO will be used to collect views on general and specific sections of the RA Toolkit. The evaluation questionnaire will be filled in for each testing scenario/chemical (problem statement that has been addressed) and submitted to the secretariat.

14. In addition, participants in the testing will prepare an executive summary that is intended to inform the WHO secretariat about (a) the chemical problem that has been addressed by using and testing the RA Toolkit as well as the findings of the RA and (b) the process that has been applied (with information on team composition, roles and responsibilities, methods and information resources used, etc.) In addition, the executive summary will address specific challenges that have been encountered while testing the toolkit. The executive summary will be between 2-4 pages.

15. Meeting participants go back to their countries and share outcomes of the meeting with stakeholders in the country and facilitate piloting of the draft RA Toolkit. Their roles include, (i) to identify, contact and inform contributing partners; (ii) to coordinate RA contributions; (iii) to submit the executive summary; (iv) to collect views of partners on RA Toolkit; and (v) to fill in and submit the evaluation questionnaire.
16. In terms of timing, the pilot phase started with this meeting. Evaluation questionnaires and executive summaries should be submitted to WHO latest by 9 October 2009 (gutschmidtk@who.int). The RA Toolkit, including comments and experience received from the pilot phase will be reviewed at a three-day Task Group meeting during Oct/Nov/Dec 2009, Geneva. (Attachment 6)

**Problem formulations for which to test RA Toolkit**

17. Meeting participants were divided into working groups to develop scenarios (problem statements) for which to test the RA Toolkit. Three working groups were created to draft problem statements for potential testing scenarios, including (a) chemical releases into surface water; (b) air pollution and health issues, and (iii) pesticide notification under the Rotterdam Convention. Further information on the group work, including sample problem statements are given in Attachment 7.

18. Group work was presented and discussed in plenary. Ultimately it was agreed to test the toolkit for the following problem statements. Pilot phase facilitating institutes are given in brackets:

\(a\) What are the likely health risks associated with cumulative discharges of heavy metals from multiple industrial sources along a river, some of which that have discharge permits and others that do not? (University Kebangsaan, Malaysia)

\(b\) What are the likely health risks to children of lead and manganese in drinking water in rural areas (specific locations to be determined) of Thailand? OR What are the risks of potential intake of lead in drinking water obtained from air conditioning condensate in urban areas of Thailand? (Chulabhorn Research Institute, Thailand)

\(c\) What are the human health risks associated with the standards for 24-hour average and annual average PM\(_{10}\) concentrations in China taking into account the scientific basis of the WHO Air Quality Guideline for PM\(_{10}\), the composition of PM\(_{10}\) in China, and population, lifestyle and building characteristics in China? (Department of Environmental Pollution and Health, Chinese Research Academy of Environmental Sciences (CRAES), Ministry of Environment Protection, China)

\(d\) What are the human health risks associated with the standards for 24-hour average and annual average PM\(_{10}\) concentrations in Thailand taking into account the scientific basis of the WHO Air Quality Guideline for PM\(_{10}\), the composition of PM\(_{10}\) in Thailand, and population, lifestyle and building characteristics in Thailand? (Chulabhorn Research Institute, Thailand)

\(e\) What are the risks of benzene levels of 10 \(\mu g/m^3\) in outdoor air of an industrial (petrochemical) area in Thailand? (Chulabhorn Research Institute, Thailand)
What are the health risks of carbofuran as used in Thailand? Should use of carbofuran be restricted in Thailand and listed in that manner with the Rotterdam Convention? (Chulabhorn Research Institute, Thailand)

Furthermore, it was agreed that Ms Hafizah Mohd, Ministry of Agriculture, Malaysia, and Dr. Zhengjun Shan, Ministry of Environmental Protection would contact the DNA for the Rotterdam Convention within their country to discuss possible additional testing scenarios for pesticide case studies. Also, the Rotterdam Convention Secretariat will contact the DNAs in the two countries to further raise awareness about the project.

**Testing procedure**

20. In Thailand, the Chulabhorn Research Institute will be the facilitating agency. The Institute suggests a two-day face-to-face meeting in September. Invited stakeholders include, Ministry of Health, Ministry of Environment, Ministry of Agriculture and other stakeholders, if necessary.

21. The Chulabhorn Research Institute has a longstanding history in teaching risk assessment methodology to national and international experts. Dr Ruchirawat, Vice President for Research, is also member of the WHO/IPCS RA Toolkit Task Group. A proposal has been made to test the toolkit with students of a training course on "Risk Assessment and Management of Toxic Chemicals" later in December 2009, in Bangkok (final dates to be confirmed).

22. Malaysia suggests a similar approach to that of Thailand including a face-to-face meeting involving partners from various Ministries and agencies. Also, the University Kebangsaan, Malaysia, has a longstanding history in dealing with risk assessment, especially around water problems. Also, Dr Salmaan H Inayat-Hussain, the main collaborating partner, is a member of the WHO/IPCS RA Toolkit Task Group.

23. Likewise, China suggests a similar approach with the Department of Environmental Pollution and Health, Chinese Research Academy of Environmental Sciences (CRAES), Ministry of Environment Protection, being the facilitating agency. Efforts will be made to involve Professor Bingheng Chen School of Public Health, Fudan University, China in the pilot project. Also, Professor Chan is a member of the WHO/IPCS RA Toolkit Task Group.

**SUMMARY**

24. Participants appreciate the development of the RA Toolkit. Participants agree that the RA Toolkit might help the anticipated target group in conducting chemical risk assessments. Participants feel, however, that substantial comments and suggestions for its improvement can't be made before finishing the pilot phase.

25. So far, six problem statements have been drafted for which to test the toolkit, including two water scenarios, three air pollution scenarios and one pesticide
scenario. Efforts will be made to contact DNAs of the Rotterdam Convention in China and Malaysia in order to identify two additional pesticide scenarios.

26. Three agencies in the three piloting countries have been identified to facilitate the testing phase, including the Chulabhorn Research Institute, Thailand; the University Kebangsaan, Malaysia; and the Department of Environmental Pollution and Health, Chinese Research Academy of Environmental Sciences (CRAES), Ministry of Environment Protection, China. All institutes have a role in chemical risk assessment, including a teaching role. Staff of the Thai and Malaysian Institute are members of the WHO/IPCS RA Toolkit Task Group. It is hoped that Professor Chan (also a member of the WHO/IPCS RA Toolkit Task Group) can join the testing effort in China.

27. All facilitating agencies propose a face-to-face meeting involving relevant national partners to test the toolkit. An executive summary will inform the WHO secretariat about (a) the chemical problem that has been addressed by using and testing the RA Toolkit as well as the findings of the RA, (b) the process that has been applied (with information on team composition, roles and responsibilities, methods and information resources used, etc.) In addition, the executive summary addresses specific challenges that have been encountered while testing the toolkit. The executive summary will be between 2-4 pages.

28. An evaluation questionnaire provided by WHO will be used to collect views on general and specific sections of the RA Toolkit. The evaluation questionnaire will be filled in for each testing scenario/chemical (problem statement that has been addressed) and submitted to WHO.

29. The pilot phase started with this meeting. Evaluation questionnaires and executive summaries should be submitted to WHO latest by 9 October 2009 after which comments and experience received by the pilot phase will be presented and discussed at Task Group Meeting at three-day meeting during Oct/Nov/Dec 2009, Geneva (to be confirmed).
WHO Briefing Meeting

To Lead into the Test Phase of the WHO Draft Risk Assessment Toolkit (RA Toolkit)

29-30 July 2009, Chulabhorn Research Institute, Bangkok, Thailand

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WHO Briefing Meeting

To Lead into the Test Phase of the WHO Draft Risk Assessment Toolkit (RA Toolkit)

29-30 July 2009, Chulabhorn Research Institute
Bangkok, Thailand

PROPOSED PROVISIONAL AGENDA

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<td>09:00-09:45 Opening:</td>
<td></td>
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<tr>
<td>• CRI, WHO, Rotterdam Convention Secretariat</td>
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<tr>
<td>• Introduction of participants</td>
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<tr>
<td>• Objectives of the meeting (WHO)</td>
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<tr>
<td>09:45-10:30 Leading into the RA Toolkit Project (WHO)</td>
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<tr>
<td>Output: Participant understand background of the project. Participants are familiar with the general structure of the RA Toolkit.</td>
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<td>10:30-11:00 Coffee break</td>
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<td>11:00-12:30 RA Toolkit by Section:</td>
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<tr>
<td>• Purpose and scope (Section 1) (WHO)</td>
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<td>• Chemical Risk Assessment (Section 2) (WHO)</td>
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<td>• Description of Toolkit, including generic road maps (Section 3) (WHO)</td>
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<td>• International Risk Assessment Resources (Section 4) (WHO)</td>
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<tr>
<td>• Discussion (All)</td>
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<tr>
<td>Output: Participants understand purpose, scope and target group of the RA Toolkit. Participants are familiar with the technical section, especially the generic road maps. Participants have an idea about information resources included in the RA Toolkit.</td>
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<tr>
<td>12:30-14:00 Lunch break</td>
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<td>14:00-15:30 RA Toolkit by Section (Cont'd):</td>
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<td>• Drinking Water Case Study (Section 5) (WHO)</td>
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<td>• Fine Particle Matter Case Study (Section 6) (WHO)</td>
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<td>• Rotterdam Convention Pesticide Study (Section 7), including Introduction into Rotterdam Convention (WHO and RC Secretariat (UNEP/FAO))</td>
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<td>• Discussion (all)</td>
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<td>Output: Participants are familiarized with the case scenarios and the case specific road maps.</td>
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<td>15:30-16:00 Coffee break</td>
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<td>16:00-17:30 Introduction into pilot phase:</td>
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<td>• Aim, expected results, roles and responsibilities, evaluation questionnaire (WHO)</td>
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<td>Output: Pilot countries agree on roles and responsibilities during the testing phase, including broad timelines.</td>
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<td>Time</td>
<td>Session</td>
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<tr>
<td>09:00-10:30</td>
<td><strong>Scenarios and/or chemicals to be used to test the RA Toolkit:</strong></td>
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<tr>
<td></td>
<td>• Introduction (WHO)</td>
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<td>• Working in Groups:</td>
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<td></td>
<td>○ Water test scenario (Working Group 1)</td>
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<td></td>
<td>○ Air test scenario (Working Group 2)</td>
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<td></td>
<td>○ Pesticide test scenario (Working Group 3)</td>
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<tr>
<td>10:30-11:00</td>
<td>Coffee break</td>
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<td>11:00-11:45</td>
<td><strong>Scenarios and/or chemicals to be used to test the RA Toolkit (cont’d):</strong></td>
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<td>• Reporting of WGs</td>
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<td>• Discussion (all)</td>
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<td><strong>Output:</strong> Test scenarios and/or chemicals identified, including rational for decisions.</td>
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<tr>
<td>11:45-12:30</td>
<td><strong>Drafting of test plans by scenario/chemical:</strong></td>
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<td></td>
<td>• Introduction (WHO)</td>
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<td>• Working in Groups (COMMENT: test plans might be different in countries for the same scenario/chemical):</td>
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<td>○ Water test scenario (Working Group 1)</td>
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<td>○ Air test scenario (Working Group 2)</td>
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<td>○ Pesticide test scenario (Working Group 3)</td>
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<td>12:30-14:00</td>
<td>Lunch break</td>
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<td>14:00-15:30</td>
<td><strong>Drafting of test plans by scenario/chemical (cont’d):</strong></td>
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<td>• Reporting of WGs</td>
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<td>• Discussion (all)</td>
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<td><strong>Output:</strong> For each scenario/chemical in each pilot country identified lead partner, associated partners, roles and responsibilities, important milestones etc..</td>
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<td>15:30-16:00</td>
<td>Coffee break</td>
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<td>16:00-17:30</td>
<td><strong>Conclusions and recommendations:</strong></td>
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<td>• Discussion (all)</td>
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<td>17:30</td>
<td><strong>Closure of the meeting</strong></td>
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Leading into the RA Toolkit Project

WHO Briefing Meeting To Lead into the Pilot Phase of the draft WHO Risk Assessment Toolkit (RA Toolkit)

29-30 July 2009, Chulabhorn Research Institute
Bangkok, Thailand

Dr. Kersten Gutschmidt
Department for Public Health and Environment (PHE)
World Health Organization, Geneva
Background

- Chemical scenarios are many; assessment of risks involves application of methodologies and tools.

- There are a range of international methodologies and tools available for RA, e.g. WHO/IPCS and OECD.

- RA bodies in developing countries lack resources to locate these tools and become informed about applications.

- In parallel, information on hazards and guidelines are becoming more readily accessible, e.g. WHO INCHEM and OECD eChemPortal.
Objectives

To make international RA tools, methodologies and relevant information (e.g. hazard, GLs) more readily-accessible, especially to relevant stakeholders in developing countries, including

- Public health and environmental specialist, others involved in:
  - Conducting health risk assessments; and
  - Making decisions on whether and how to manage/reduce risks.
The RA Toolkit is organized into sections that provide:

- An overview of chemical RA, including the RA framework and uses of RA;

- Generic road maps for how to conduct RA, including information about a tiered approach;

- Listings of international resources that are useful for conducting RAs; and

- Examples of how that information can be applied to a RA question, including case-specific roadmaps.
Case studies

Initially, three case studies are being developed, including:

– A drinking water case study: Liquid waste from industrial operation into surface water;

– An air quality case study: Development of a national standard to regulate ambient PM$_{2.5}$ concentrations; and

– A pesticide case study: Notification under Article 5 of the Rotterdam Convention.
Process

- Toolkit concept, Task Group meeting, March 2008, Montreux, Switzerland;
- Initial work, March 2009;
- First comprehensive draft RA Toolkit, including three case scenarios, July 2009;
- Review and testing (concept, content, tools):
  - Testing in Thailand, Malaysia, China; Aug-Oct 09.
  - Review/testing by other partners; Aug-Oct 09.
- Finalization of first draft including three case scenarios, first quarter of 2010;
Outlook (tbc)

- Testing/Application of RA Toolkit in other WHO regions.
- Development of additional case studies, including case-specific roadmaps.
- Ongoing review of newly available international and available national RA tools and information.
- Promotion of RA Toolkit.
- Development of e-Toolkit, including website.
Thank you very much!

For more information, please contact:

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www.who.int/environmental_health_emergencies/en/index.html
www.who.int/ipcs/emergencies/chemical_incidents/en/index.html
WHO Briefing Meeting
To Lead into the Test Phase of the
Draft WHO Risk assessment Toolkit (RA Toolkit)
29-30 July 2009
Chulabhorn Research Institute
Bangkok, Thailand

Draft WHO Risk Assessment Toolkit (RA Toolkit)

International Programme on Chemical Safety
World Health Organization

Draft version of July 20, 2009
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1.0 INTRODUCTION

This Risk Assessment Toolkit was developed by WHO/IPCS to help people make decisions about chemicals and their risks. The Toolkit is a manual on how to identify chemicals, assess exposures to these chemicals, and determine whether these exposures are dangerous to public health.

The Toolkit is organized into sections that provide:

- an introduction to the purpose and scope of the document
- a detailed description of the Toolkit
- references to international guidance on risk assessment methods
- recommendations for international sources of information useful for conducting chemical risk assessments
- case studies that illustrate how the Toolkit can be used to address a health risk assessment question.

1.1 Purpose of the Toolkit

The Toolkit will help its users make timely decisions and balance resources regarding environmental risks. In so doing, the tool will help its users: (1) identify and find the information needed to assess chemical exposures, hazards, and risks and (2) determine when there is sufficient information and understanding to decide whether actions are necessary.

Although the Toolkit alone cannot answer all of the questions regarding risks from chemical exposures, it will provide important information to public health and environmental specialists, regulators, industrial managers, and other decision makers involved with chemical safety and protection. The Toolkit has particularly been developed for people who are responsible for:

- conducting health risk assessments, for example, public health and environmental, scientific, or engineering professionals; and
- making decisions on whether to take action to manage environmental risks, for example, officials in health or environmental regulatory bodies or in private businesses

1.2 Scope of the Toolkit

Commensurate with the purpose described above, the Toolkit:

- provides a framework for conducting chemical risk assessments,
- identifies information that must be gathered to complete an assessment, and
- lists, describes, and provides unique record locators (URLs) for publicly available resources that an assessor can use to obtain or derive information and methodologies essential to an assessment (Section 3).
The framework presented in the Toolkit depicts the starting and ending points of a chemical risk assessment and the pathways that connect various types of information. In this way, the Toolkit is analogous to a road map that describes how to conduct a chemical risk assessment and interpret its results using publicly available resources from international organizations. The road map concept is illustrated in case studies of risk assessments for a chemical in drinking water, fine particulate matter air pollution, and an insecticide. The general description of the Toolkit and each case study walk the user through the components of a chemical risk assessment, linking each component of the risk assessment to relevant resources and information. While the intergovernmental information described herein are essential for risk assessment, it is important to note that valuable knowledge may also be gained from the workers, plant managers, or members of the community. These individuals may have useful and important information about the history of the site, process, or problem, chemical usage, human activities, and past, current, and future land uses that can be used to identify chemical hazards or to assess chemical exposures.

This document also presents a tiered approach to chemical risk assessment in which the methods used to assess risk reflect the problem and resources at hand. For example, a relatively low-level tier of risk assessment may consist of comparing existing information on exposure to an applicable health-based guideline published by an international organization. This Toolkit focuses on lower tiers of chemical risk assessment that are similar to this example; situations that can be described as practical applications of existing information to assess potential health risks of chemical exposure. Therefore, the Toolkit is focused on chemicals and exposure scenarios that are reasonably well described in the scientific literature and publications of international organizations such as the WHO.

The Toolkit also provides links to more resource intensive methodologies such as risk characterization for new chemicals for new health outcomes for an existing chemical. In those cases, a quantitative evaluation of toxicity based on animal models or epidemiological studies may be required. That type of assessment often requires new laboratory or observational studies to characterize the physical and toxicological properties of a chemical, all of which may take months or years to complete. The information required for a chemical risk assessment of this type is described in documents published by various organizations, such as the OECD Guidelines for testing Chemicals and the Guidance on Information Requirements and Chemical Safety Assessment produced by the European Union in support of the REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) legislation. Additional information is available from WHO.
2.0 DESCRIPTION OF CHEMICAL RISK ASSESSMENT

2.1 Definition of Risk Assessment

Risk assessment is a process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. It is the first component in a risk analysis process which also includes risk management and risk communication. ‘Chemical risk assessment’ refers to methods and techniques that apply to the evaluation of hazards, exposure, toxicology, and harm posed by chemicals which in some cases may differ from approaches used to assess risks of biological and physical agents.

The risk assessment process includes four steps: hazard identification, hazard characterization (related term: Dose–response assessment), exposure assessment, and risk characterization. The risk assessment paradigm, incorporating problem formulation, is illustrated in Figure 2.1. A full description of the concepts presented in the figure may be found in EHC 239.

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2.2 Uses of Chemical Risk Assessment

Chemical risk assessments can be performed to evaluate past, current and even future exposures to any chemical found in air, soil, water, food, products or other materials. They can be quantitative or qualitative in nature. Risk assessments are often limited by a lack of complete information. To be protective of public health, risk assessments are

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typically performed in a manner that is unlikely to underestimate the actual risk. Regardless, chemical risk assessments rely on scientific understanding of pollutant behavior, exposure, dose, and toxicity. In general terms, risk depends on the following factors:

- the amount of a chemical present in an environmental medium (e.g., soil, water, air),
- the amount of contact (exposure) a person has with the pollutant in the environmental medium, and
- the toxicity of the chemical.

Obtaining data and other information to describe these three factors is the cornerstone or foundation of most chemical risk assessments. Since these data are not always available, many risk assessments require that estimates or judgments be made regarding some data inputs or characterizations. Consequently, risk assessment results have associated uncertainties, which should be characterized as possible.

Despite these uncertainties, chemical risk assessment can help to answer basic questions about potential dangers from exposure to chemicals, such as:

- What chemical exposures pose the greatest risks? Can the chemical risks be ranked to allow a country to spend their resources in the most risk-efficient way?
- What are the risks of drinking this water? Should drinking water be provided from a different, safer source?
- Is this chemical spill dangerous? What is the appropriate emergency response?
- Is it “safe” to build homes on this old hazardous waste site?
- Should we clean up this contaminated soil?
- What, if any, limits on chemical exposure should be established in occupational settings, in consumer products, in environmental media, and in food?
- Should limits be set for chemical emissions from industrial, agricultural, or other human activities?
3.0 DESCRIPTION OF THE TOOLKIT

3.1 The Toolkit as a Road Map

As described more fully below, the risk posed by a chemical or chemicals can be determined based on the toxicity of the chemicals and on who is exposed to these chemicals, in what amount and through what route. Ultimately, each of these considerations will be critical to a determination of environmental risk or a decision. Risk managers and other Toolkit users will draw on this information to help decide how to protect people from these chemicals.

For purposes of the Toolkit, the risk assessment paradigm is presented as a road map that extends from hazard identification to risk characterization (Figure 3.1). Each step in the paradigm is represented by a set of questions that an assessor can follow to resources and information that are appropriate for estimating risk. A generic road map that an assessor can follow to answer these questions is presented for each step in the following sections. As noted above, the data gathering and analysis associated with these steps for purposes of the Toolkit may differ somewhat from a de novo assessment of risk conducted for a new chemical, proposed use, or health endpoint.

Examination of Figure 3.1 reveals that the purpose of the Hazard Identification (Section 3.3.1) step is to determine the identity of the chemical and the hazardous properties and routes of exposure, if any, for the chemical. In the context of the toolkit, Hazard Identification is followed by the Exposure Assessment and Dose-Response Assessment steps, which are complementary and connected efforts. The exposure assessment (Section 3.3.3) is used to determine the most likely exposure routes, pathways, duration, and intensity to the identified chemical, while the dose-response assessment (Section 3.3.2) is used to obtain a health-based guideline for the chemical that matches the anticipated route and duration (e.g., inhalation and chronic) of exposure. Since these two steps are connected, information obtained in these two steps must be exchanged in the risk assessment process to ensure that the exposure and dose-response metrics are aligned appropriately. In the final risk characterization step, the hazard, exposure, and dose-response information are combined to yield a quantitative statement of risk. As described in Section 3.3.4, the quantitative form of the risk characterization will vary depending upon the type of information available on exposure and dose-response.
Figure 3.1 Generic overall road map of chemical risk assessment in the context of the Toolkit.

The questions posed in Figure 3.1 provide a structure for chemical risk assessment in the context of the Toolkit. By answering the questions, an assessor obtains the information needed to characterize hazard, dose-response, exposure, and risk. Output anticipated from answering the questions is shown in Table 3.1.
Table 3.1  Output from the framework for chemical risk assessment in the context of the Toolkit

<table>
<thead>
<tr>
<th>Question</th>
<th>Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Identification</td>
<td></td>
</tr>
<tr>
<td>Is the identity of the chemical known?</td>
<td>Clear identification of chemical(s) in question through Chemical Abstract Services number(s) (CAS#)</td>
</tr>
<tr>
<td>Is the chemical hazardous?</td>
<td>Description of health hazards obtained from internationally available classification schemes</td>
</tr>
<tr>
<td>Do health-based guidelines exist for the chemical?</td>
<td>List of health-based exposure concentrations or exposure rates for the chemical obtained from internationally available resources</td>
</tr>
<tr>
<td>Dose-Response Assessment</td>
<td></td>
</tr>
<tr>
<td>What assumptions about exposure and dose are incorporated into the health-based guideline for the chemical?</td>
<td>A health-based guideline that reflects exposure and dose parameters specific to the local culture and demographics.</td>
</tr>
<tr>
<td>Exposure Assessment</td>
<td></td>
</tr>
<tr>
<td>In what ways could people come into contact with the chemical?</td>
<td>Qualitative description of the relevant environmental media, exposure routes, and exposure durations for the chemical.</td>
</tr>
<tr>
<td>What metric(s) of exposure is needed to characterize health risks?</td>
<td>Determination from the health-based guideline value of whether an exposure concentration or exposure rate is needed to perform the risk characterization.</td>
</tr>
<tr>
<td>How much exposure is likely to occur?</td>
<td>A quantitative estimate of exposure for the appropriate averaging time.</td>
</tr>
<tr>
<td>Risk Characterization</td>
<td></td>
</tr>
<tr>
<td>How does the estimated exposure compare to health-based guidelines?</td>
<td>A quantitative statement of risk of non-cancer or cancer risk</td>
</tr>
</tbody>
</table>

3.2  Tiered Assessments in the Toolkit

In practical terms, the use of a risk assessment toolkit must consider the apparent magnitude of the issue at hand, the resources that can be allocated to an environmental health concern, and societal norms for risk. Depending upon the nature of the problem as well as time, cost, and human and technical resource considerations, the amount of information applied to each step may differ, with some steps requiring more and some requiring less detailed information gathering.

Varying degrees of information gathering represent tiers of analysis. These tiers are characterized by the amount of quantitative or qualitative data obtained to answer a question posed in any given step of the risk paradigm. As shown in Table 3.2, the Toolkit includes four tiers of risk assessment.
Table 3.2 Tiers of risk assessment included in the Toolkit

<table>
<thead>
<tr>
<th>Tier</th>
<th>Description</th>
<th>Hazard Identification</th>
<th>Exposure Assessment</th>
<th>Dose-Response Assessment</th>
<th>Hazard Characterization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Screening</td>
<td>Obtain from international resources; gather local observations</td>
<td>Existing qualitative or quantitative estimates</td>
<td>Obtain guideline values</td>
<td>Qualitative or quantitative</td>
</tr>
<tr>
<td>2</td>
<td>Adaptive</td>
<td>Obtain from international resources; gather local observations</td>
<td>Existing quantitative estimates</td>
<td>Guidelines adjusted for local conditions</td>
<td>Quantitative</td>
</tr>
<tr>
<td>3</td>
<td>Field-based</td>
<td>Obtain from international resources; gather local observations</td>
<td>Conduct measurement or modeling campaign</td>
<td>Adjust guidelines for local conditions</td>
<td>Quantitative</td>
</tr>
<tr>
<td>4</td>
<td>New chemical or exposure route</td>
<td>Controlled experimental trials, gather local observations</td>
<td>Estimate from measurements or models</td>
<td>New guideline values</td>
<td>Quantitative</td>
</tr>
</tbody>
</table>

Tier 1 refers to screening level risk assessments that rely solely upon existing information and make no adjustments for local conditions or other considerations. Depending upon the amount of exposure information that is available, the hazard characterization may be qualitative or quantitative. Consider an example where there is strong anecdotal information that use of a certain chemical is associated with a significant or specific health outcome among workers of a certain industry. Further, hazard identification information on toxicological properties of the chemical and experiences in other countries are consistent with the anecdotal reports. Faced with this situation, a public health official may conclude that occupational health risks of using the chemical under current conditions are intolerable. In a move intended to protect health, the official may seek to ban the chemical from that particular use or from the country at large, in spite of the fact that neither exposure nor risk have been quantified. The pesticide case study described in Section 7 of this document is an example of a Tier 1 risk assessment.

Tier 2 refers to risk assessments that reflect local exposure conditions which can be incorporated through the exposure assessment or dose-response assessment stage. In a Tier 2 assessment, local exposure conditions are derived from existing information. Such information may be the result of routine monitoring conducted for regulatory or other purposes, the application of a model to a known or suspected source of pollutant emissions, body burdens of a chemical determined from samples of blood serum or urine, or some other metric that was generated for a purpose other than the current assessment of health risk. For these reasons, most Tier 2 assessments are expected to produce a quantitative hazard characterization. However, the result will necessarily be qualitative in situations where exposure is not quantified, yet a health-based guideline that fulfills the dose-response step of the assessment is modified to reflect local conditions. The particulate matter case study presented in Section 6 is an example of a Tier 2 risk assessment that yields a qualitative result. In that case study, an assessor evaluates the relationship between concentrations of fine particles in ambient air (PM$_{2.5}$) and personal
exposure to PM$_{2.5}$ in their own country in comparison to the same relationship in the studies upon which the WHO air quality guideline for PM$_{2.5}$ was derived. The evaluation is qualitative in this example, but nonetheless involves a more rigorous analysis than a Tier 1 risk assessment.

Tier 3 risk assessments involve active characterization of exposure conditions through a measurement or modeling campaign, but otherwise are similar to a Tier 2 assessment. Tier 3 assessments require the design and execution of an exposure assessment. In many situations, the exposure assessment will consist of a survey, while in others the assessment may be hypothesis driven. A field campaign would require a plan for collection and analysis of samples as well as management and interpretation of the data. Similarly, a modeling campaign would require selection of an appropriate modeling tool, identification of values needed to parameterize the model, resources to execute the model and data management and analysis skills to manage and interpret the model results. Tier 3 risk assessments are distinct from Tier 2 in that the former requires gathering of new exposure information while the latter does not. The drinking water case study presented in Section 5 is an example of a Tier 3 risk assessment.

Tier 4 risk assessments are unique in that they require new information on the hazardous properties or dose-response relationships of a chemical to be developed. Tier 4 assessments apply to chemicals whose toxicological properties have not been evaluated previously as well as new routes of exposure to existing chemicals. In general, these assessments are beyond the scope of the Toolkit. Nonetheless, guidance from international organizations on approaches and considerations for filling the data gaps presented by these situations is identified in Section 4. Readers are referred to these documents for assessments that require techniques that are more advanced than the methods addressed in the Toolkit.

### 3.3 Generic Road Maps

#### 3.3.1 Hazard Identification

Hazard identification is generally the first step in a risk assessment and is the process used to identify the specific chemical hazard and to determine whether exposure to this chemical has the potential to harm human health. For purposes of the Toolkit, hazard identification involves determining the identity of the chemical of interest; if and how the chemical is classified as a hazard by international organizations, and if health-based guidelines for exposure have been developed. A process for gathering information in support of hazard identification is illustrated in Figure 3.2.
Figure 3.2    Generic road map for hazard identification in the Toolkit
Chemical Identity

Given sufficient time and resources, the surest way for potentially hazardous chemicals to be identified is sample collection and chemical analysis. Collection and analysis of samples, however, generally requires preliminary identification of the chemical of interest, as the appropriate collection and laboratory analysis method will depend on the specific chemical. Thus, even when chemical analyses are planned, some preliminary identification of the chemical(s) is needed. In cases where chemical analyses are not possible, this preliminary identification may comprise the entire hazard identification step.

Chemicals and their hazards can be identified from a number of internal and external sources. Internal sources include company documents and people who work with the chemical, for example a plant manager or operator. Generally, in cases where the source of the chemical(s) is easily identified, chemicals are listed as ingredients on the chemical packaging, on associated Chemical Safety Card (CSC) or Material Safety Data Sheet (MSDS), or from a list of chemicals used in the industrial processes. The same identification materials can be relied upon for cases in which the chemicals of concern come from multiple sources; however, this identification may also involve additional determinations of whether any identified chemicals will behave differently or will form different chemicals when mixed together.

If the identity of the chemical is not known, the assessor should gather information from various resources and infer the types of chemicals of concern. In situations where an industrial process or operation is of interest, then the assessor should search the Emissions Scenario Documents (ESDs) listed in Section 3.2 for information relevant to the current situation. ESDs published by the OECD contain descriptions of sources, production processes, pathways and use patterns of numerous commercial industrial operations with the aim of quantifying the releases of a chemical into water, air, soil and/or solid waste. ESDs can be used to generate hypotheses about contaminants of concern that may be associated with a particular source such as a manufacturing operation, laboratory, disposal area, or waste site. In addition to OECD’s work in this area, the EU publishes emission scenario documents in support of risk assessments for new and existing substances. The ESDs describe environmental releases for different industrial categories and biocidal products. Similar to the OECD ESDs, the EU documents are useful for understanding processes that may contribute to emissions of contaminants and support the hazard identification process.

A full-text search feature of the INCHEM database can also help to identify a chemical. In addition to these international resources, permits or building plans that may have been filed with local or provincial authorities may contain useful information on operations and emissions from a particular type of operation. Finally, initiating dialogues with representatives of the facility and other members of the community may also be helpful for identifying contaminants of concern.
Hazardous Properties

Once identified, the potential hazard of the chemical(s) can be determined from the available scientific data for the chemical(s), generally data from toxicological or epidemiological studies. A chemical may be associated with one or more hazards to human health. Standardization of hazard data is a challenge because of the myriad types of physical/chemical and toxicological evaluations performed on chemicals. Nonetheless, several schemes for classification of hazard information have been developed. In general, chemicals are classified according to the physical, human health, and environmental hazards that they pose, such as neurological, developmental, reproductive, respiratory, cardiovascular, or genotoxic effects. There are many international sources of this information as noted in Section 4.

In the case of Tier 4 risk assessments where the hazardous properties of a chemical have yet to be identified, the reader is referred to the Global Harmonisation System of Classification and Labeling of Chemicals (GHS). The GHS was initiated by the United Nations in recognition of varying criteria for determination of hazardous substances among countries and the extensive global trade of chemicals, the international governmental organizations. The GHS includes (i) harmonized criteria for classifying substances and mixtures according to their health, environmental, and physical hazards, and (ii) harmonized hazard communication elements, including requirements for labeling and safety data sheets. The human health hazard classification scheme is detailed and includes: acute toxicity, skin corrosion/irritation, serious eye damage, respiratory or skin sensitization, mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity, and aspiration hazards.

Health-Based Guidelines

The existence of a health-based guideline for exposure to a chemical is another piece of information that is useful for hazard identification. Health-based guidelines will indicate routes and levels of exposure that are considered to have the potential to pose a risk to humans. Databases of international guideline values for water, food, and air as well as an international portal to comprehensive summaries of toxicity information are listed in Table 3.3.

<table>
<thead>
<tr>
<th>Resource</th>
<th>Organization</th>
<th>Internet Unique Record Locator (URL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Intake Guidelines</td>
<td>FAO/WHO</td>
<td><a href="http://jeefa.ilsi.org/search.cfm">http://jeefa.ilsi.org/search.cfm</a></td>
</tr>
<tr>
<td>Air Quality Guidelines</td>
<td>WHO</td>
<td><a href="http://www.who.int/phe/health_topics/outdoorair_aqg/en/">http://www.who.int/phe/health_topics/outdoorair_aqg/en/</a></td>
</tr>
</tbody>
</table>

Notes:
- WHO: World Health Organization
- FAO: Food and Agriculture Organization of the United Nations
3.3.2 Dose-Response Evaluation

In dose-response assessment, the toxicological effect of a chemical is assessed in relation to exposure. The relationship between exposure and effect is frequently derived from standardized tests of laboratory animals conducted under controlled conditions. In other cases, observations of effects in human populations characterized with epidemiological methods are the basis of dose-response values used in risk assessments for chemicals. Arsenic and benzene are two examples of where dose-response values are based on epidemiological studies.

For both cancer and non-cancer effects, results from animals or humans are extrapolated to the general human population using one or more safety factors or procedures that are intended to reduce the likelihood that actual risks to humans will be underestimated. The WHO document on animal-to-human extrapolation of laboratory-based toxicology studies is available elsewhere. To account for the possibility of human contact through multiple media, dose-response values are frequently determined for both inhalation and ingestion exposure.

For chemicals that are treated as potential human carcinogens, the risk of cancer is characterized as a linear relationship with dose. These values are estimated from the slope of a line fit to the relationship between exposure to a chemical in mg/kg/d and prevalence of cancer in populations with a given level of exposure. Cancer slope factors (SF) therefore are expressed in units of (mg/kg/d)⁻¹.

For effects other than cancer, dose-response factors for risk assessment are characterized as thresholds of exposure below which adverse effects are considered unlikely to occur. Benchmarks of risk for non-cancer effects are most frequently expressed as exposure rates with units of mg/kg/d. Common terms for these values are acceptable daily intake (ADI), tolerable daily intake (TDI), and reference dose (RfD).

Numerous policy decisions and judgments are incorporated into cancer and non-cancer dose-response values established by intergovernmental and country-specific organizations. Many of the basic assumptions such as linear, low-dose extrapolation for cancer effects and thresholds for non-cancer effects are common to risk assessment protocols developed by numerous organizations. Yet, these same organizations may

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differ in certain aspects of their implementation. In part, any such differences reflect the advance of science and policy as well as different rates at which this information is incorporated into risk assessment practice. Any further information on similarities and contrasts among risk assessment methods followed by specific organizations is beyond the scope of this manual.

Table 3.4

<table>
<thead>
<tr>
<th>Type of Outcome</th>
<th>Abbreviation</th>
<th>Term (units)</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-cancer</td>
<td>TDI</td>
<td>Tolerable daily intake (mg/kg/d)</td>
<td>An estimate of the amount of a substance in air, food, soil, or drinking water that can be taken in daily over a lifetime without appreciable health risk.</td>
</tr>
<tr>
<td></td>
<td>ADI</td>
<td>Allowable daily intake (mg/kg/d)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RfD</td>
<td>Reference dose (mg/kg/d)</td>
<td>An estimate of the cancer risk associated with a unit dose of a chemical through ingestion or inhalation over a lifetime</td>
</tr>
<tr>
<td>Cancer</td>
<td>SF</td>
<td>Oral or inhalation slope factor</td>
<td></td>
</tr>
</tbody>
</table>

Health-based guidelines represent judgments of acceptable risk based on known dose-response relationships. Health-based guidelines as well as government standards are available for many pollutants. Whether these standards are applicable to a specific case depends on the information used to establish these benchmarks, the comparability of human populations with regards to their activity patterns and demographics, and the exposure averaging times, among other considerations.

More specifically, non-cancer dose-response factors such as the ADI and TDI, as well as health-based guideline values typically incorporate a number of assumptions about exposure including: contact rate, body weight, absorption fraction, and allocation of total intake. The objective of the dose-response assessment in the context of the Toolkit is to determine if the assumptions reflected in the dose-response factors and guideline value are appropriate for the current situation and assessment question.

The flow chart shown in Figure 3.3 illustrates considerations that are key to whether an international or country guideline is appropriate for a specific situation. These factors are discussed briefly here; additional information is presented in both Section 3.5 and the case studies that appear later in the document. Contact rates as shown in Figure 3.5 refer to assumptions about rates of water consumption, inhalation, food consumption and other forms of contact with environmental media. Default values are typically used for those contact rates. For example, health-based guidelines for contaminants in water may assume that an average adult consumes 2 liters of water per day. Yet, it is recognized that population average water consumption rates can vary significantly in different parts of the world, particularly where consumers are engaged in manual labor in hot climates; perhaps by a factor of 2 to 4. This example illustrates that an assessor should consider
whether the default values incorporated into a health-based guideline are appropriate for the specific population and time period of interest.

Health-based guidelines for a given medium may also assume that total exposure to a chemical occurs via multiple routes or media. For example, guideline values for a chemical in water may assume that a certain amount of exposure to that chemical also occurs through ingestion of food. Variation in natural resources, culture, and lifestyle among populations may invalidate some assumptions about allocation of total intake. For example, in areas where the intake of a particular contaminant in drinking-water is known to be much greater than that from other sources (e.g., food and air), it may be appropriate to allocate a greater proportion of the TDI to drinking water to derive a guideline value more suited to the local conditions. Where relevant exposure data are available, authorities are encouraged to develop context-specific guideline values that are tailored to local circumstances and conditions.

Cases in which a health-based guideline or dose-response value for a chemical has yet to be established by an international or other organization (Tier 4 risk assessment) are generally outside the scope of the Toolkit. Guidance on the hazard identification step for this situation is identified in Section 3.3.1. For the dose-response assessment, readers are referred to:


3.3.3 Exposure Assessment

Exposure assessment is used to determine if people are in contact with a potentially hazardous chemical(s) and if so, to how much, by what route, through what environmental media, and for how long. Because hazard and dose-response is often dependent upon the route (oral, inhalation, dermal) and timing (short-term, intermittent, long-term) exposure, knowledge of how people may be exposed is relevant to the
determination of an appropriate health-based guideline value. When combined with information on dose-response or a health-based guideline, exposure information is used to characterize health risks.

Means of Contact

As indicated in Figure 3.4, the assessor must determine the following parameters to initiate the exposure assessment portion of the risk evaluation:

- the environmental media expected to contain the contaminant;
- the relevant route(s) of exposure; and
- the appropriate averaging time.
Figure 3.4 Generic road map for exposure assessment in the Toolkit.

The medium of exposure refers to the environmental compartment, namely air, water, soil, or food, that is thought to contain the chemical of interest (3.5). Ingestion exposure is associated with chemicals in food, water, and soil, both indoors and outdoors. Inhalation exposure requires that chemicals are present in air, although it is important to recognize that chemicals with moderate to high vapor pressure and low solubility can
volatilize from water or soil and then be inhaled. The presence of organic solvents, such as trichloroethylene, in potable water is one example. Inhalation can also be an important route of exposure to less volatile chemicals such as polychlorinated biphenyls when present at elevated concentrations in soil. Finally, dermal absorption requires contact between a chemical and skin which can occur in water, during contact with soil, and in the presence of high concentrations in air.

![Figure 3.5 Possible Exposure Media and Corresponding Means of Contact](image)

The scope of an exposure assessment can be narrowed with information about the chemical and its properties, from which the important environmental media and exposure routes can be inferred. For example, health relevant exposures to some chemicals, such as ozone, occur through only one medium, in this case air. For chemicals that can be found in several media, such as lead, pesticides, and chloroform, information about the chemical properties and behavior can point to environmental media or locations where the highest levels of the chemical are likely. In addition, this information can suggest relevant pathways and routes of exposure.

Route of exposure refers to intake through ingestion, inhalation, or dermal absorption. The exposure routes may have important implications in the hazard characterization step, as the danger posed by a chemical may differ by route. For example, the toxic potency of DDT as measured by the LD50 decreases 10-fold when changing the route of
administration from intravenous to oral, and another 10-fold when moving from oral to dermal.\textsuperscript{5}

The duration of exposure is a critical element in assessment and estimation of health risks as the relevant period of exposure is defined by knowledge or theory of the mechanisms of injury or disease. Exposures are further classified by their duration, generally as:

- **Acute**: one or a few exposures occur over a few days
- **Subchronic or Intermediate**: repeated exposures from 14-90 days duration
- **Chronic**: repeated exposures beyond one year and up to a lifetime

Acute or short-term average exposures, perhaps over minutes, hours, or days, are relevant for chemicals that have an immediate or rapid adverse effect on the body at certain concentrations. Examples of chemicals for which assessment of acute exposure is important include water soluble gases such as sulfur dioxide and an asphyxiant such as carbon monoxide.

Subchronic or intermediate exposure is important for chemicals that are thought to exert adverse effects over a period of contact that ranges from weeks to months in duration. Respiratory irritants such as hydrogen sulfide gas is a class of chemicals for which some public health organizations have developed guidelines for intermediate exposure.

For chemicals that pose a hazard as a result of cumulative or long-term low dose exposure, chronic or long-term average exposures are most relevant for characterization of adverse effects. Chemicals such as polychlorinated biphenyls that have been associated with learning deficits and diabetes are in this category. For assessment of cancer risk, lifetime average exposure is generally of interest, a special case of chronic exposure.

**Exposure Concentration and Exposure Rate**

In practice, exposures are generally expressed as either a concentration or a rate of contact with a chemical over a specific duration. As described in Section 3.3.2 health-based guidelines or benchmark values for risk assessments are often expressed as or derived from exposure concentrations or exposure rates as well. Therefore, this step of the Toolkit must produce an estimate of exposure that is in the same form as the health-based guideline – ie, either an exposure concentration or rate.

Exposure concentrations are usually expressed with units of \(\mu g/m^3\) for air, \(\mu g/L\) for water, and \(mg/kg\) or ppm for solids such as soil, dust, and food. Exposure rate for a chemical is typically referred to as average daily intake or average daily dose (ADD), with units of milligrams of chemical per kilogram of body weight per day (mg/kg/d). In general, exposure rate is calculated as the concentration of a chemical in an exposure

medium multiplied by the rate at which a person inhales or ingests that medium, divided by a representative body weight.

As shown in Equation 3.1, the period of exposure and averaging time of exposure are considered explicitly as well.

$$ADD = \frac{\text{Concentration} \times \text{Intake Rate} \times \text{Absorption Factor} \times \text{Exposure Duration}}{\text{Body Weight} \times \text{Averaging Time}}$$  \hspace{1cm} (3.1)

where,

- **Concentration** = amount of chemical per mass or volume of environmental medium
- **Intake Rate** = mass or volume of environmental medium in contact with the body
- **Absorption factor** = fraction of chemical in contact with the body that is absorbed
- **Exposure duration** = period of time that person is in contact with the chemical
- **Body weight** = body weight over the averaging time
- **Averaging time** = period of time over which the exposure is relevant for health risk characterization

The averaging time used in calculation of ADD is typically different for estimation of non-cancer and cancer risks. For chemicals that pose a non-cancer hazard, the average exposure during the period of contact with a chemical is generally the relevant duration of exposure for risk assessment. This quantity can be referred to as the period average daily dose (PADD). For cancer risk assessment, however, the averaging time is fixed at a lifetime, which is commonly assumed to be 70 years in risk assessments. Therefore, the quantity lifetime average daily dose (LADD) is the exposure rate used in assessments of cancer risk. To illustrate this difference, consider a scenario where people are exposed to a chemical present in air for 11 hours per day, 5 days per week, 50 weeks per year over a 3-year period. The exposure duration for this scenario is 0.94 years for both non-cancer and cancer risk assessment. However, the exposure duration is 3 years for estimation of PADD for non-cancer risk and 70 years for estimation of LADD for cancer risks.

**Magnitude of Exposure**

Exposures can be measured directly, estimated using models, or generalized from existing data. Each requires that exposures be determined for time periods relevant to possible adverse health outcomes. For example, if the relevant health hazard is chronic in nature, exposure values should be chronic as well. Of the three methods, estimating exposures from existing data can often be the simplest approach; however, such data are not often available or entirely relevant to the risk assessment at hand. Measurements, on the other hand, generally provide the most accurate and relevant data, but are the most time and resource intensive, obviating their use for many risk assessments. A summary of exposure measurement and generalization methods are described in WHO EHC 214.
Exposure models generally require information about the chemical concentration in an environmental medium or location and the time that individuals contact the chemical. Chemical concentrations can be measured or can be estimated from chemical usage and/or previous data. Information about chemical contact, including who is exposed and the frequency and duration of their exposure, can be obtained using a variety of information, including questionnaires or inquiries with affected individuals, demographic data, survey statistics, behavior observation, activity diaries, activity models, or, in the absence of more substantive information, assumptions about behavior. Using this information, exposures for air, water, food, or soil can be estimated using mathematical equations. A summary of principles for characterizing and applying human exposure models is described in a separate WHO report. Guidance on how to address uncertainty and data quality in exposure assessments is also available from the WHO.

Amount of exposure is often expressed as a concentration or rate. For example, concentrations may be described as parts per million (ppm) or billion (ppb) for any media. In the case of liquids or solids, ppm and ppb typically refer to mass of chemical per mass of liquid or solid, while for air those terms refer to volume of chemical per volume of air. Exposure concentrations in air are also frequently expressed as mass of chemical per unit volume of air (e.g., micrograms per cubic meter, µg/m³).

### 3.3.4 Risk Characterization

The product of a chemical risk assessment, the risk characterization, is typically a quantitative statement about the estimated exposure relative to the most appropriate health-based guideline or dose-response values. In general, the risk statement is derived by either comparing the estimated exposure to a guideline value or calculating the amount of cancer risk (see Figure 3.6).

---


Figure 3.6   Generic road map for risk characterization in the Toolkit

Comparison to a Guideline Value

Health-based guideline values have been established for a number of chemicals by international organizations. In some cases, the guideline is based on an exposure concentration or rate below which adverse effects are considered to be unlikely. As
described in Section 3.5, this approach applies to toxicological effects that occur when a threshold of exposure or dose is exceeded.

Guideline values are also established for chemical exposures that are thought to have a continuous dose-response relationship. Carcinogens and some air pollutants, such as fine particulate matter, are examples of stressors that considered to pose risk of an adverse health outcome at all levels of exposure. For these substances, guideline values are exposure concentrations or rates that correspond to levels of risk that have been determined to be tolerable. For instance, long-term average exposure to inorganic arsenic in drinking water at a certain guideline value (ie, concentration) may be equivalent to a lifetime cancer risk of 1 in 100,000.  

For chemicals that are thought to be a factor in non-cancer effects, risk is frequently characterized as the ratio of the PADD (see Section 3.3.3) to the guideline value, ADI or RfD (see Table 3.4). For exposure to non-cancer chemical hazards in air, the ratio of the chemical concentration and the RfC may also be used to assess risk. The ratio of the PADD or concentration to a threshold value for possibility of effect is sometimes referred to as the Hazard Quotient (HQ). A HQ less than one indicates that the exposure is less than the benchmark and that the chemical exposure is unlikely to result in an adverse effect. For example, an evaluation of chemical concentrations in exposure media and rates of contact with those media may conclude that the PADD of a chemical is 15 times less than the allowable daily intake (ADI) established by an authoritative organization as a benchmark for risk of an adverse effect. Conversely, a HQ greater than one indicates that the exposure is greater than the benchmark and that the sources, pathways, and routes of chemical exposure should be evaluated further.

\[ HQ = \frac{PADD}{RfD} \]  

The WHO and other public health organizations have determined concentrations of contaminants in environmental media that are equivalent to a specific HQ or ELCR (see Section 3.3.3). Many different terms are used to refer to these levels including ‘guideline’, ‘maximum contaminant level’, ‘limit’, ‘minimum risk level’, ‘reference concentration’, and ‘risk-based concentration’. The term risk-based concentration, ie., RBC, will be used in this document.

RBCs are derived by determining the concentration of a chemical in an environment that is equivalent to the HQ or ELCR of interest. The mechanical steps used to calculate an RBC are: (1) solve Eq. 3.2 for PADD or Eq. 3.3 for LADD, (2) substitute the result into Eq. 3.1; (3) solve Eq. 3.1 for concentration; (4) assume a reasonable intake rate, duration of exposure, absorption fraction, and averaging time for the risk scenario, (5) calculate the RBC from the equation. Conservative values are typically selected for the exposure

and risk parameters when deriving RBCs. For instance, the exposure duration may be 95% or more of a year (e.g., 50 weeks per year) and the absorption fraction may be 1. Similarly, values for HQ and ELCR used in the derivation of RBCs are typically 1 and $10^{-5}$ or $10^{-6}$, respectively. Although the actual values used for this purpose may vary among organizations and among countries, the fundamental intent is generally the same.

In some cases, public health organizations account for exposure to a chemical in multiple media when setting a RBC for a particular medium. For example, drinking water quality guidelines established by the WHO allocate only a portion of the TDI to intake through water for some chemicals. In order to account for the variations in exposure from different sources in different parts of the world, default values, generally between 10% and 80%, are used to make an allocation of the TDI to drinking-water in setting guideline values for many chemicals. Where relevant exposure data are available, authorities are encouraged to develop context-specific guideline values that are tailored to local circumstances and conditions. For example, in areas where the intake of a particular contaminant in drinking-water is known to be much greater than that from other sources (e.g., air and food), it may be appropriate to allocate a greater proportion of the TDI to drinking-water to derive a guideline value more suited to the local conditions.

Estimation of Cancer Risk

For chemicals that may exert a carcinogenic effect, the risk characterization is typically expressed as the excess lifetime cancer risk (ELCR). Characterization of cancer risk over a lifetime has become a convention primarily because cancer is thought to be a function of chronic rather than acute exposure. ELCR is an estimate of the likelihood of cancer associated with a given level of exposure averaged over a lifetime. ELCR is a unitless value that is calculated as the product of LADD and the SF.

$$\text{ELCR} = \text{LADD} \times \text{SF} \quad \text{Eq. 3.3}$$
4.0 INTERNATIONAL RISK ASSESSMENT RESOURCES

4.1 Cross-Cutting Resources

4.1.1 Directories of Resources

Comprehensive and detailed summaries of information essential to risk assessment for a wide variety of chemicals have been compiled by numerous organizations. Notable among them are the on-line resources INCHEM and eChemPortal that are gateways to some sources of internationally and nationally peer reviewed chemical risk assessment information (see Table 4.1). Databases within INCHEM and eChemPortal that contain information specific to the principal components of a chemical risk assessment (Section 2) are described in the remainder of this section.

<table>
<thead>
<tr>
<th>Resource</th>
<th>INCHEM</th>
<th>eChemPortal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor</td>
<td>International Programme on Chemical Safety, World Health Organization</td>
<td>Organisation for Economic Cooperation and Development</td>
</tr>
<tr>
<td>Description</td>
<td>A compilation of information from a number of intergovernmental organizations whose goal it is to assist in the sound management of chemicals.</td>
<td>Databases on physical chemical properties, environmental fate and behaviour, ecotoxicity, and toxicity</td>
</tr>
</tbody>
</table>

4.1.2 Resources on Specific Chemicals

Other cross-cutting sources of risk assessment information include detailed summaries of specific chemicals that have been prepared by the WHO and other organizations.

*Environmental Health Criteria Monographs*
The WHO has published approximately monographs on 250 chemicals, each of which contains a detailed summary of the sources, pathways, and routes of exposure to each chemical. Ranges of exposures reported in the scientific literature for multiple environmental media are presented in the monographs as well. As such, the EHC monographs are valuable for helping investigators prioritize exposure media and routes as part of a risk assessment.

URL: [http://www.inchem.org/pages/ehc.html](http://www.inchem.org/pages/ehc.html)

**CICADs**

The Concise International Chemical Assessment Documents (CICADs) published by the World Health Organization join the Environmental Health Criteria monographs as authoritative sources of information on risk assessment of chemicals. In addition to characterization of hazard and dose-response of a chemical, each CICAD report contains information on sources of human and environmental exposure; environmental transport, distribution, and transformation; and environmental levels and human exposure. The section on human exposure includes numerous environmental media such as ambient air, indoor air, drinking water, surface water, sediment and soil, and food.


**Drinking Water Quality Background Documents**

The World Health Organization Guidelines for Drinking-Water Quality include facts sheets and comprehensive review documents for many individual chemicals. For many of these, guideline values are derived. All of these can be accessed through the following alphabetical URL.


4.1.3 Resources on Risk Assessment Methods

Other cross-cutting international sources of risk assessment information include guidance on principles and methods for each of the steps that comprise the risk assessment paradigm.

**Risk Assessment - General**

*Principles for the Assessment of Risks to Human Health from Exposure to Chemicals, Environmental Health Criteria 210, International Programme on Chemical Safety, World Health Organization, Geneva, 1999*


Specific Hazards


Hazard Characterization / Dose-Response Assessment


**Media and Routes of Exposure**


Air Quality Guidelines for Particulate Matter, Ozone, Nitrogen Dioxide and Sulfur Dioxide, World Health Organization, 2005


**Susceptible Populations**


4.2 Hazard Identification Resources

The resources listed below contain detailed information on the identity, hazardous properties, and toxicity of thousands of chemicals in commerce. A brief description of each database is provided with the internet address as of the drafting of this document.

4.2.1 ESIS: European chemical Substances Information System

ESIS is an electronic database that can be accessed through the eChemPortal maintained by OECD. ESIS provides information on names, synonyms, and structures of thousands of chemicals. The database also contains information on physical-chemical properties that influence transport, fate, and toxicity.


4.2.2 International Chemical Safety Cards

International Chemical Safety Cards contain a brief summary of essential information on chemical substances that was developed cooperatively by the IPCS and the Commission of the European Union (EC). In addition to potential health hazards, each card also contains a description of fire and explosion hazards as well as appropriate responses to a spill, packaging and labeling, and storage conditions. Basic physical, chemical, and toxicity properties of chemicals are also summarized in a standard format on each card.

URL: [http://www.inchem.org/pages/icsc.html](http://www.inchem.org/pages/icsc.html)

4.2.3 Screening Information Data Set for HPV Chemicals

The Screening Information Data Set for high production volume (HPV) chemicals is an extensive compilation of data on physical-chemical properties and toxicity values for the most common chemicals in commerce. In contrast to the chemical safety cards described
above which are brief summaries of these chemical characteristics, the screening information data include results for a variety of environmental conditions and species. As a result, this resource can be useful for considering potential risks in unique climates and exposure scenarios.

URL: [http://www.inchem.org/pages/sids.html](http://www.inchem.org/pages/sids.html)

### 4.2.4 Hazardous Substances Data Bank

Accessed through the OECD ChemPortal, the Hazardous Substances Data Bank (HSDB) is a detailed listing of peer-reviewed toxicological data for over 5,000 chemicals including information on human health effects, emergency medical treatment, chemical/physical properties, metabolism, pharmacokinetics, pharmacology, and laboratory methods. Unlike ESIS and International Chemical Safety Cards, the toxicity information is presented in narrative form rather than tables. The HSDB also contains excerpts from case reports of humans exposed to the chemical of interest, in addition to summaries of animal studies.


### 4.2.5 European Union Classification and Labeling System

The European Union (EU) has also developed a chemical Classification and Labeling (C&L) system (to be harmonized with GHS). The C&L was an outgrowth of a labeling requirement for any substance made in or imported into the EU and placed on the EU market. C&L involves an evaluation of the intrinsic hazard of a substance or mixture/preparation and communication of that hazard via a label. In this system, thousands of chemicals are classified according to physical and chemical properties as well as health or environmental effects. Hazards are denoted in the database using risk phrases each of which refers to type of harmful effects on humans. Example risk phrases including: “may cause cancer”; “toxic if swallowed”, “very toxic by inhalation” and others. The database also includes concentration ranges that correspond to the different risk phrases. An on-line version of the C&L database is available for use by assessors around the world.

### 4.2.6 IARC Summaries and Evaluations

The International Agency for Research on Cancer (IARC) has published summaries and evaluations of the carcinogenic risk to humans of chemicals since its inception in 1969. The monographs include single chemicals as well as chemical mixtures. The objective of the programme is to prepare, with the help of international Working Groups of experts, and to publish in the form of Monographs, critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures. The Monographs represent
the first step in carcinogen risk assessment, which involves examination of all relevant information in order to assess the strength of the available evidence that an agent could alter the age-specific incidence of cancer in humans. The Monographs may also indicate where additional research efforts are needed, specifically when data immediately relevant to an evaluation are not available.

URL: http://www.inchem.org/pages/iarc.html

4.3 Exposure Assessment Resources

The resources noted in this section include general guidance on exposure assessment as well as detailed information on exposure to a wide variety of specific chemicals. The general guidance resources listed here discuss in detail the concepts that were only briefly summarized in Section 3.3.3. The resources on specific chemicals are compendia of chemical profiles that feature information on sources, pathways, routes, and typical levels of exposure. A description of each of these resources is provided below with the internet address as of the drafting of this document.

4.3.1 OECD Emission Scenario Documents

Emission scenario documents (ESD) published by the OECD contain descriptions of sources, production processes, pathways and use patterns of numerous commercial industrial operations with the aim of quantifying the releases of a chemical into water, air, soil and/or solid waste. ESDs can be used to generate hypotheses about contaminants of concern that may be associated with a particular source such as a manufacturing operation, laboratory, disposal area, or waste site.

URL: http://www.oecd.org/document/46/0,3343,en_2649_34373_2412462_1_1_1_1,00.html

4.3.2 EU Emission Scenario Documents

The European Union publishes an emission scenario document as a component of a Technical Guidance Document in support of risk assessments for new and existing substances. The ESDs describe environmental releases for different industrial categories and biocidal products. Similar to the OECD ESDs, the EU documents are useful for understanding processes that may contribute to emissions of contaminants and support the hazard identification process.

URL: http://ecb.jrc.ec.europa.eu/tgdoc/

4.4 Dose-Response Resources
The resources noted in this section are compilations of thresholds of exposure for non-cancer effects and slope factors for cancers that have been established by numerous authoritative public health organizations. As described in Section 3.3.4, these values can be combined with estimates of exposure to calculate HQ and ELCR, indicators of non-cancer and cancer risks, respectively. In addition to the dose-response values, these resources also contain risk-based concentrations which are defined in Sections 3.3. Descriptions of these resources are provided below with the internet address for each database as of the drafting of this document.

4.4.1 International Toxicity Estimates for Risk

The International Toxicity Estimates for Risk (ITER) database is a searchable summary of dose-response values and risk-based concentrations derived by the International Agency for Research on Cancer (IARC), U.S. Agency for Toxic Substances and Disease Registry (ATSDR); U.S. Environmental Protection Agency (USEPA), Health Canada, the Dutch National Institute for Public Health and the Environment (RIVM), and independent parties. The database contains non-cancer and cancer risk information for both oral and inhalation exposures. A useful synopsis of the risk information for each chemical and hypertext links to related information are also provided.


4.5 Risk-Based Concentration Resources

4.5.1 WHO Drinking Water Guidelines

The World Health Organization had developed guidelines for concentrations of chemicals and other contaminants in drinking water. The guideline values and the methodology employed to derive them are detailed in a report that is available on the Internet. The guidelines are expressed in units of mass concentration in drinking water – milligrams per liter – and assume a water consumption rate of 2 L/d and a body weight of 60 kg. For risk of cancer, the guideline values are equivalent to lifetime exposure that yields an ELCR of $10^{-5}$. For chemicals that are likely to be present in multiple media, the guidelines account for intake through air, food, and soil. In this case, the guideline value is determined based on the fraction of total or aggregate intake expected to occur as a result of a chemical’s presence in drinking water. Consider a case where drinking water is thought a priori to account for one-half of all intake of a chemical. Then, the guideline would be set such that consumption of drinking water at the prescribed value would account for half of the TDI for that chemical. The chlorinated organic solvent trichloroethylene is an example of this scaling process. Variation in the allocation to water can be an important consideration when considering whether the WHO drinking water guidelines should be adapted for country use.
4.5.2 WHO Air Quality Guidelines

The World Health Organization publishes air quality guidelines for ubiquitous pollutants in ambient, i.e., outdoor, air: particulate matter, ozone, nitrogen dioxide, and sulfur dioxide. Separate guidelines are included for particulate matter less than both 2.5 and 10 microns in aerodynamic diameter (PM$_{2.5}$ and PM$_{10}$). The WHO guidelines are intended for worldwide use but have been developed to support actions to achieve air quality that protects public health in different contexts. Notably, the air quality guidelines are derived from an extensive body of epidemiological studies relating air pollution and its health consequences in human populations. The risk based concentrations for these air pollutants are not based directly upon assumptions about intake rates, body weight, and other factors, unlike the drinking water guidelines described above. Instead, the relationships between ambient air pollution and personal exposure to air pollution in those studies should therefore be considered in comparison to local circumstances before adopting the guidelines as an air quality standard in a country.

URL: [http://www.who.int/phe/health_topics/outdoorair_aqg/en/](http://www.who.int/phe/health_topics/outdoorair_aqg/en/)

4.5.3 Joint FAO/WHO Meeting on Pesticide Residues

The UN Food and Agricultural Organization and the World Health Organization established the Codex Alimentarius Commission over 40 years ago to protect the health of consumers and ensure fair practices in food trade. The Codex Alimentarius or ‘food code’ is a collection of internationally adopted food standards, guidelines, and codes of practice. One part of the codex establishes maximum residue limits (MRL) for chemicals in foods - the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or in food commodities and animal feeds.

URL: [http://www.who.int/ipcs/food/en/](http://www.who.int/ipcs/food/en/)

4.5.4 Maximum Residue Limit Database

The Maximum Residue Limit Database is compilation of tolerances or risk-based concentrations for over 400 chemicals in food established by 70 countries, the European Union, and the Codex Alimentarius. The database provides users with a list of maximum residue limits by active ingredient and geographic region. The database does not include processed food products. Over 300 fruit, vegetable and nut commodities are covered, as well as grains, poultry, eggs, meat and dairy.

URL: [http://www.mrldatabase.com/](http://www.mrldatabase.com/)
5.0 DRINKING WATER CASE STUDY

5.1 Objective

The objective of this case study is to demonstrate how the principles and roadmaps that comprise the Toolkit can be used by a public health or related professional to evaluate potential risks of chemical contaminants in drinking water as a result of emissions from a discrete or point source. The specific roadmaps for this scenario are shown in Figures 5.1 to 5.4

5.2 Statement of the Problem

A metal finishing facility is located on the bank of the Flowing River in central Africa. Liquid waste from the plating operations pour from a discharge pipe directly into the river in conjunction with the 24 hour a day, 7 day per week operating schedule of the facility. Additional information on the plant operations such as the rate of production and the content of the liquid waste is not available. The Flowing River flows directly through the community of Rivertown which is a short distance downstream of the plating facility. Water from the river is used by the residents of Rivertown for drinking, cooking, and bathing. Preliminary research by the official Rivertown Department of Environmental Health (RDEH) has identified cadmium as a byproduct of chrome-plating operations. To address public health concerns, RDEH undertakes an evaluation of potential health risks of cadmium releases into the Flowing River.

5.3 Hazard Identification

5.3.1 Is the identity of the chemical known?

Determining the identity of the chemical of interest is the first step in the hazard identification process. In this case, the RDEH is interested in potential risks of cadmium, thus the identity of the chemical is known. The Chemical Abstract Services number (CAS#) for cadmium should be obtained in order to ascertain a unique identifier of the chemical. An electronic search of the International Chemical Safety Cards database (http://www.inchem.org/pages/icsc.html) for ‘cadmium’ returns 6 documents, five of which refer to specific cadmium compounds and one of which is labeled ‘cadmium’. Selecting the entry for cadmium brings the user to the International Chemical Safety Card for that chemical. The CAS # is found in the first row of the card: CAS No. 7440-43-9. Other information contained on the card includes the molecular weight of cadmium and a brief list of acute hazards and symptoms.

If the identity of the chemical is not known, the assessor should gather information from various resources and infer the types of chemicals of concern. In situations where an industrial process or operation is of interest, then the assessor should search the
Emissions Scenario Documents listed in Section 4.3 for information relevant to the current situation. The full-text search feature of the INCHEM database can also be helpful. Had the RDEH not previously identified cadmium as a chemical of concern, a search of ‘metal finishing’ on the INCHEM database would have returned descriptions of cadmium in liquid waste from this industry. In addition to these international resources, permits or building plans that may have been filed with local or provincial authorities may also contain useful information about health hazards associated with the metal finishing operation. Finally, initiating dialogues with representatives of the facility and other members of the community may also be helpful for identifying contaminants of concern.

Output: Identification of cadmium is confirmed through Chemical Abstract Services number(s) (CAS# 7440-43-9)

5.3.2 Is the chemical hazardous?

To determine whether a chemical is hazardous, the assessor should examine international resources on toxicological properties of chemical substances. These resources consistently indicate that cadmium exposure poses a potential hazard to human health.

Output: Cadmium is identified as a hazardous chemical, with the principal toxic endpoints considered to be kidney dysfunction, lung damage, hepatic injury, bone deficiencies, hypertension, and cancer

5.3.3 Do health-based guidelines exist for the chemical?

The existence of a health-based guideline for intake of cadmium or information on toxicological properties of cadmium would provide sufficient evidence that cadmium exposure poses a potential hazard to human health. Databases of international guideline values for water, food, and air as well as an international portal to comprehensive summaries of toxicity information are listed in Table 5.1.

<table>
<thead>
<tr>
<th>Resource</th>
<th>Organization</th>
<th>Internet Unique Record Locator (URL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Intake Guidelines</td>
<td>FAO/WHO</td>
<td><a href="http://jecfa.ilsi.org/search.cfm">http://jecfa.ilsi.org/search.cfm</a></td>
</tr>
</tbody>
</table>
Output: International guidelines for cadmium in drinking water and food have been established, with cadmium again identified as a hazardous chemical.

A road map for the hazard identification step of the drinking water case study is shown in Figure 5.1. Bold lines indicate the flow of information gathering and analysis that is described below.
Is the identity of the chemical known?

Yes

Is the chemical hazardous?

Yes

Proceed to dose-response and exposure assessment

No

No

Gather information on chemical byproducts and waste streams associated with the source or process

Search emission scenario documents for the industry or process of interest

Full text search of INCHEM database

Review any available public documents on the specific source or site

Communicate with parties who may have knowledge of the source or site

Local officials and stakeholders

WHO IPCS

Determine if health-based guidelines have been established for the chemical

Examine information on classification and labeling provided by international organizations

Figure 5.1 Case-specific road map for hazard identification; drinking water case study (bold lines indicate the flow of information gathering and analysis)
5.4 Dose-Response Assessment

Are the assumptions about contact rate, body weight, absorption fraction, and allocation of total intake incorporated into the guideline value appropriate for the current situation?

As described above in Section 3, risk-based guideline values expressed as concentrations in environmental media or exposure rates assume a specific rate of contact with an exposure medium. The objective of the dose-response assessment in the context of the toolkit is to determine if the assumptions about contact rate, body weight, absorption fraction, and allocation of total intake incorporated into the guideline value are appropriate for the current situation and assessment question. These parameters are discussed below in the context of cadmium exposure in Rivertown.

The WHO drinking water guideline for cadmium is described in Section 12.17 of the *Guidelines for Drinking Water Quality, 3rd (current) edition*. According to the table of key items presented in that section, the guideline value is based on a default water consumption rate of 2 liters per day (L/d), a body weight of 60 kilograms (kg) and allocation to water of 10%. It is recognized that population average water consumption rates can vary significantly in different parts of the world, particularly where consumers are engaged in manual labor in hot climates; perhaps by a factor of 2 to 4. Similarly, typical body weights can also vary among countries or regions, although the range of uncertainty is likely to be less than ±25%. Overall, the range of uncertainty about water consumption rates and body weights is quite small in comparison with the much larger range in toxicological uncertainty that exists for the vast majority of chemicals. Consequently, the default assumptions for those parameters are likely to be adequate in nearly all situations.

In order to account for the variations in exposure from different sources in different parts of the world, default values, generally between 10% and 80%, are used to make an allocation of the tolerable daily intake (TDI) to drinking water in setting guideline values for many chemicals. Where relevant exposure data are available, authorities are encouraged to develop context-specific guideline values that are tailored to local circumstances and conditions. For example, in areas where the intake of a particular contaminant in drinking-water is known to be much greater than that from other sources (e.g., food and air), it may be appropriate to allocate a greater proportion of the TDI to drinking water to derive a guideline value more suited to the local conditions. In the case of Rivertown, the RDEH would require detail information on food consumption patterns, cadmium levels in specific foods, as well as levels of cadmium in air and soil to consider deriving a context-specific drinking water guideline for cadmium.

In the absence of information on contact rates, body weight, absorption fraction, and total exposure to cadmium specific to local conditions, the RDEH elects to rely upon the WHO drinking water guideline value for cadmium of 0.003 mg/L in the risk assessment. This is an appropriate decision as the WHO drinking water guidelines account for
ingestion through food and are considered, in most cases, sufficient to account for intake of contaminants through inhalation and dermal absorption.

*Output: The most appropriate health-based guideline for this case is the WHO drinking water guideline value for cadmium of 0.003 mg/L in the risk assessment.*

A road map for the dose-response assessment step of the drinking water case study is shown in Figure 5.2. Bold lines indicate the flow of information gathering and analysis that is described below.
Figure 5.2  Case-specific road map for dose-response assessment; drinking water case study (bold lines indicate the flow of information gathering and analysis)
5.4 Exposure Assessment

In the context of the risk assessment tool kit, the goal of the exposure assessment is to obtain an estimate of exposure concentration or rate that can be compared to the appropriate guideline value. As described in Section 3, several combinations of guideline values and exposure metrics are possible depending upon the environmental medium (or media) and exposure route(s) that are most appropriate for the situation.

5.4.1 In what ways could intake of the chemical occur?

The assessor must determine the following parameters to initiate the exposure assessment portion of the risk evaluation:

- The environmental media expected to contain the contaminant;
- The relevant route(s) of exposure; and
- The appropriate averaging time.

In this case study, the assessor knows that cadmium is present in potable water of a community and that the water is used for drinking, cooking, and bathing. Therefore, water is the environmental medium of interest, while ingestion and dermal absorption are the most relevant routes of exposure. The assessor also has knowledge that the facility operates 24 hours a day, 7 days per week. Therefore, long-term average conditions and chronic exposure are of primary interest. The assessor should also consider variation in operations of the facility or flow of the river that could result in transient increases of exposure concentrations.

Output: Qualitative description of water as the relevant environmental media, ingestion and dermal absorption as the primary exposure routes, and long-term averaged exposures as the appropriate exposure duration for this population.

5.4.2 What exposure metric is needed to characterize health risks?

Having selected the environmental media, exposure route, and exposure duration of interest, the next step is to determine if an international exposure guideline value exists that corresponds to those criteria. In this case, data gathering conducted in support of the hazard identification step revealed that the WHO has established a health-based guideline value of 0.003 milligrams per liter for long-term average concentrations of cadmium in drinking water. The form of the guideline value dictates the form of the exposure estimate required for the risk characterization step. Thus, the risk assessor in this case study requires an estimate of long-term average concentrations of cadmium in water drawn from the Flowing River in order to proceed to the risk characterization step.

Output: Knowledge that an exposure concentration is needed to perform the risk characterization.
5.4.3 What is the exposure concentration or rate for the chemical?

The concentration of cadmium in the Flowing River could be estimated from measurements and/or models depending on the type and amount of information that is available. Measurements require that the assessor has access to appropriate protocols and supplies for sampling, storage, transport, and analysis of water samples obtained from the river. Models require information on the discharge rate of cadmium through the effluent pipe that extends from the facility to the river. Guidance on appropriate measurement and modeling methods are provided in several documents and other materials produced by international organizations. In particular, Guidance on Information Requirements and Chemical Safety Assessment prepared in conjunction with the REACH (Registration, Evaluation, Authorisation, and restriction of Chemicals) legislation in the European Union provides a detailed discussion of measurement and modeling approaches. Measurement and modeling approaches both require a study design that will allow the assessment question to be answered. General guidance on the design and implementation of exposure investigations is provided in WHO EHC 214, Exposure Assessment.

Unable to obtain information needed to model the concentration of cadmium in water drawn from the river, the RDEH makes the decision to estimate long-term average exposure concentrations from measurements. Information on sampling and analysis methods is available in EHC and CICAD reports prepared for specific chemicals. EHC 134 Cadmium contains introductory information on analytical methods for cadmium including collection and preparation of samples, separation and concentration, methods for quantitative determination, and quality control. Specific methods for sampling water and analysis of cadmium and other metals are available from country resources such as the United States Environmental Protection Agency Method 1669 Metals, Trace at Water Quality Criteria Levels.

The RDEH collects water samples from three locations on five separate days: upstream of the metal finishing facility, downstream of the metal finishing facility, and from the tap of the town hall building. The average concentrations of cadmium in the samples obtained from those locations are shown in Table 5.2.

<table>
<thead>
<tr>
<th>Location</th>
<th>Average</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upstream of facility</td>
<td>&lt;LOD</td>
<td>&lt;LOD – 0.2</td>
</tr>
<tr>
<td>Downstream of facility</td>
<td>0.4</td>
<td>0.1 – 1.0</td>
</tr>
<tr>
<td>Town hall water</td>
<td>0.3</td>
<td>0.2 – 0.8</td>
</tr>
</tbody>
</table>

Notes
LOD limit of detection, 0.1 µg/L
<LOD less than the LOD
The results of the water sampling indicate that concentrations of cadmium downstream of the metal finishing facility are greater than concentrations upstream of the facility. The results also indicate that cadmium concentrations in potable water drawn from the Flowing River are approximately equal to the levels in the river downstream of the facility.

*Output: A quantitative estimate of cadmium exposure, with levels greater downstream as compared to upstream of the facility and with drinking water concentrations approximately equal to the downstream levels.*

A road map for the exposure assessment step of the drinking water case study is shown in Figure 5.3. Bold lines indicate the flow of information gathering and analysis that is described below.
Is the guideline value expressed as a concentration, intake rate or cancer slope factor?

- Yes
  - Is the concentration of the chemical in the exposure medium known?
    - Yes: Estimate the concentration in the exposure medium for the appropriate averaging time
    - No: Proceed to risk characterization

- No
  - Intake rate or slope factor
    - Estimate the rate of contact with the medium
    - Estimate the exposure rate

Figure 5.3 Case-specific road map for exposure assessment; drinking water case study (bold lines indicate the flow of information gathering and analysis)
5.6 Risk Characterization

How does the estimated exposure compare to health-based guideline value?

The objective of the risk characterization step is to address the risk assessment question by combining the information gathered on exposure and dose response. As noted in Section 3.3.4, health risk can be characterized in various ways. In many cases, risk characterization consists of comparing an estimate of chemical exposure to a guideline value. The exposure and guideline value can be expressed as either a concentration or an intake rate. The exposure and guideline values should reflect the same averaging time and if not, the assessor should be cognizant of any differences when interpreting the results of the risk characterization.

Referring to the first step in the flowchart shown in Figure 3.6 and this case study, the objective of the RDEH was to evaluate potential health risks of cadmium releases into the Flowing River. Based upon the available risk-based criteria for cadmium in drinking water, it is apparent that the assessment involves comparing estimated exposures to a health-based guideline value. In this case, the value is 0.003 mg/L, the WHO guideline for cadmium in drinking water. Turning to the exposure metrics, at least two are available: (i) the average concentration of cadmium in drinking water downstream of the metal finishing facility (0.0004 mg/L) and (ii) the average concentration of cadmium in water drawn from the community water supply (0.0003 mg/L). Taking the ratio of the exposure to the guideline value, the hazard quotient is calculated to be approximately 0.1 in this case. Exposures are therefore estimated to be less than the guideline value.

Output: The hazard quotient is approximately 0.1 for cadmium in drinking water. As a result, the cadmium exposures from drinking water are lower than the guideline value.

A road map for the risk characterization step of the drinking water case study is shown in Figure 5.4. Bold lines indicate the flow of information gathering and analysis that is described below.
Figure 5.4  Case-specific road map for risk characterization; drinking water case study (bold lines indicate the flow of information gathering and analysis)
5.7 Summary

An assessment was conducted of potential health risks associated with oral ingestion of cadmium introduced into a community water supply as a result of emissions to surface water from a metal finishing facility. Cadmium is reported to accumulate in the kidney, which is also the main target for cadmium toxicity. Consequently, potential health risks of long-term average exposures to cadmium in drinking water are the primary concern of local authorities. The WHO guideline for cadmium in drinking water was selected as the most appropriate health-based value for evaluation of potential risk. The exposure assessment was based on measurements of cadmium in drinking water on five separate days. Average concentrations of cadmium in river water and drinking water samples were consistent with contributions from the metal finishing facility, yet were approximately 10 times below the WHO guideline value. This evaluation indicates that risks of adverse health effects from cadmium exposures associated with the facility are relatively low. Authorities should consider obtaining additional plant information and sampling data needed to confirm these findings with exposure periods representative of longer-term average conditions.
6.0 FINE PARTICULATE MATTER CASE STUDY

6.1 Objective

The objective of this case study is to demonstrate how the principles and roadmaps of the Toolkit can be used to guide a review of the scientific factors that should be considered in the adoption or amendment of national air quality standards for PM$_{2.5}$. Specific roadmaps are shown in Figures 6.1 to 6.3.

6.2 Statement of the Problem

Given findings from epidemiological studies and a growing concern about the impacts of ambient fine particles (or PM$_{2.5}$) on health, Country A is interested in setting a national standard to regulate ambient PM$_{2.5}$ concentrations. They are limited in their effort to do so by sparse, if any, PM$_{2.5}$ monitoring data, but do have some information on ambient inhalable particle (PM$_{10}$) concentrations in their country and in surrounding countries. Further, there is limited evidence from their country of associations between increased ambient PM$_{10}$ concentrations and daily mortality, with supporting evidence from other countries in the region.

At this time, the pollutant of interest to Country A is limited to fine particles (PM$_{2.5}$), not its individual components,$^9$ and that the default governmental standard is the WHO air quality guidelines for PM$_{2.5}$.

The WHO air quality guidelines were developed based on scientific evidence of the risks posed by PM$_{2.5}$ pollution to human health. It is important to note that these guidelines are not intended to be fully protective of public health, as there is no identified “safe” concentration of ambient PM$_{2.5}$. The guidelines differ from PM$_{2.5}$ standards set by individual countries, as they were developed for a wide variety of situations across the world and do not take into account individual country characteristics and needs. For individual countries, the WHO guidelines may need to be amended in light of scientific factors, such as PM$_{2.5}$ sources, populations at risk and geography, and policy-related factors, such as technological feasibility and economic considerations.

6.3 Hazard Identification

6.3.1 Is the identity of the chemical known?

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$^9$ Information about the specific components of PM$_{2.5}$ may be important to consider for standard setting purposes, as scientific studies show individual PM$_{2.5}$ components to have different health risks. Further, for regulatory purposes, the PM$_{2.5}$ components may provide important information as they can help to establish appropriate source control strategies.
The hazard identification process for this example is relatively straight-forward and follows the flow chart presented previously. As shown in Figure B.1, determining the identity of the chemical of interest is the first step in the hazard identification process. In this case, the identity of the chemical is known to be ambient PM$_{2.5}$.

Output: Identification of PM$_{2.5}$ (with some emphasis on PM$_{10}$ as well) as pollutant of interest

6.3.2. Is the Pollutant Hazardous?

Ambient PM$_{2.5}$ is a class of pollutants for which epidemiological and toxicological studies have demonstrated a variety of adverse health impacts associated with short-term and long-term exposures, with recent scientific studies also finding adverse health impacts with even shorter exposures, on the order of one to four hours.

Output: Description of health hazards for PM$_{2.5}$ based on results from epidemiological studies.

6.3.3. Do Health-based Guidelines Exist for the Pollutant?

WHO has set international guidelines for ambient PM$_{2.5}$ of 10 ug/m$^3$ averaged over a year and 25 ug/m$^3$ averaged over 24-hours. Other countries have set their own PM$_{2.5}$ standards. For example, the United States sets a 24-hour standard of 35 ug/m$^3$ and an annual standard at 15 µg/m$^3$ measured over three calendar years. The European Union has established an annual limit of 25 ug/m$^3$ measured over one calendar year but no daily standard, with this issue to be revisited in subsequent years. Interestingly, standards and guidelines for PM$_{2.5}$ are somewhat unique in that they have been established primarily based on findings from epidemiological studies and not toxicological studies.

Guidelines and standards for a larger class of particle pollution – inhalable particles or PM$_{10}$ – have also been established. In the absence of little to no information about PM$_{2.5}$, it is also possible to use guidelines and standards based on PM$_{10}$ to inform standard setting for PM$_{2.5}$. This borrowing of information from PM$_{10}$ relies on the fact that PM$_{10}$ concentrations are often more widely measured than PM$_{2.5}$ and that ambient PM$_{2.5}$ and PM$_{10}$ concentrations are often closely related. For example, the WHO guideline for PM$_{10}$ sets an annual limit of 20 ug/m$^3$ and a 24-h limit of 50 ug/m$^3$, which was established assuming a ratio of PM$_{2.5}$ to PM$_{10}$ of 0.5, which WHO believes to be typical of developing country urban areas. Using the WHO method, a country could use the same or a more relevant PM$_{2.5}$/PM$_{10}$ ratio to convert its PM$_{10}$ standard to PM$_{2.5}$.

Output: List of health-based guidelines or standards for PM$_{2.5}$.

6.4 Exposure Assessment

6.4.1 How, where and with what frequency are people exposed to the chemical?
In the context of the risk assessment tool kit and this example, the goal of the exposure assessment is to designate an appropriate exposure concentration and averaging time to set as a national standard. As indicated in Figure B.2, the assessor must determine the following parameters to initiate the exposure assessment portion of the standard setting process:

- The environmental media expected to contain the contaminant;
- The relevant route(s) of exposure; and
- The appropriate averaging time.

In this case study, the assessor knows that PM$_{2.5}$ is present in ambient air. Therefore, air is the environmental medium of interest, with inhalation being the only route of exposure. The frequency of exposure is likely at all times, as people may be exposed to ambient PM$_{2.5}$ even when inside, as ambient PM$_{2.5}$ can readily enter homes and other buildings. Although the level of exposures may differ inside as compared to outside, epidemiological studies are generally based on ambient concentrations. As a result, risks estimated by these studies intrinsically take into account the building types and activity patterns of their study populations. Since these factors can differ substantially by country and even city, Country A should consider giving more weight to risk estimates obtained from epidemiological studies conducted in populations with activity patterns and housing stock that are similar to those in Country A.

Output: Identification of air as the relevant environmental media, inhalation as the exposure route, and exposure frequency as constant. Also, qualitative determinations of the importance of housing stock and activity patterns in evaluating PM$_{2.5}$ exposures.

What exposure averaging time is needed to characterize health risks?

Decisions about the appropriate averaging time for the PM$_{2.5}$ standard are more complicated, as consideration should be paid not only to the exposure averaging time (e.g., year, day, daily maximum, or hour), but also to how concentrations for this averaging time will be calculated and from which measurements and monitoring sites. Exposure averaging times will generally be based on findings from epidemiological studies, as these studies are the basis of existing PM$_{2.5}$ standards and guidelines. As reflected in the WHO annual and daily guidelines, health effect studies conducted in countries across the world have shown both acute and chronic adverse effects to be associated with ambient PM$_{2.5}$ concentrations, suggesting that both a short-term and a long-term standard are appropriate. To address acute adverse effects, WHO set guidelines based on a 24-h averaging time, while WHO addresses chronic effects using an annual average guideline. Correspondingly, air quality standards established by the US also establish a daily and annual level. In contrast, the European Union establishes only an annual standard but no daily standard, preferring to regulate PM$_{10}$ on a 24-h level instead of PM$_{2.5}$. To determine the appropriate averaging time for a PM$_{2.5}$ standard, countries can rely on the WHO guidelines or standards set by other countries with similar populations, source profiles, and topography. In addition, a variety of other resources
may be useful, including (1) PM$_{2.5}$, or if not available PM$_{10}$, monitoring data that shows the relation between annual and daily concentrations and (2) findings from health studies that identify the exposure windows of concern, taking into account country specific factors, such as geography, sources and their location, and the country’s inhabitants.

Output: Determination of the appropriate averaging times for an ambient PM$_{2.5}$ standard, including an evaluation of the importance of separate standards for daily and yearly mean PM$_{2.5}$ concentrations.

How Should Exposure Averaging Times be Characterized and Calculated?

Once the appropriate averaging time is selected, the method used to calculate the exposure averaging time and the location of the compliance monitors must be determined. For the same exposure level and compliance monitoring network, the most stringent standard will generally be based on concentrations averaged over the selected averaging time, such as a single year or single day. This calculation method is stipulated by the WHO guidelines and the EU standard, as both set their annual concentration limits for PM$_{2.5}$ based on data from one year, with the WHO also setting its 24-h limit based on data averaged across one day. In contrast, the US annual PM$_{2.5}$ standard is based on the 3-year average of the weighted annual mean PM$_{2.5}$ concentrations from single or multiple community-oriented monitors. Similarly, the US daily standard is based on the 3-year average of the 98th percentile of 24-hour concentrations at each population-oriented monitor within an area. The US calculations are intended to de-emphasize years or days with unusually high concentrations.

The final component of a PM$_{2.5}$ standard is generally the location of the compliance monitors, which are the monitors from which concentrations will be obtained to determine whether the PM$_{2.5}$ standard is met or violated. Specification of the compliance monitor locations is generally a key component of a PM$_{2.5}$ standard, as it will help determine the stringency of the PM$_{2.5}$ standard and may cause emissions from certain PM$_{2.5}$ sources to have more impact on standard compliance than others. Possible locations for compliance monitors could include population-oriented urban settings, rural areas, near roadway or near source locations, or averages of monitors located across the country.

Output: Specification of (1) the calculation used to estimate PM$_{2.5}$ concentrations for the specified exposure averaging times to allow comparisons to the PM$_{2.5}$ standard and (2) the location and number of compliance monitors.

6.5 Dose-Response Assessment

The objective of the dose-response assessment in the context of the toolkit is to determine the level of the PM$_{2.5}$ standard for the exposure averaging times specified in Section B.3. This determination should begin with consideration of whether Country A should adopt existing WHO guidelines or another country’s standards for PM$_{2.5}$, since these guidelines
and standards were established based on an extensive evaluation of scientific evidence of the dose-response relation for ambient PM$_{2.5}$ and a variety of adverse health impacts.

As discussed above, air quality standards for PM$_{2.5}$ are expressed as concentrations in ambient air given a specific averaging time and often also specifying the location of compliance monitors. The WHO guidelines or standards set by the EU, US, and other countries reflect assumptions about the relative importance of observed health outcomes (such as mortality being more or less important than asthma incidence), population characteristics and activity patterns of the population (e.g., number of potentially susceptible individuals, time spent outside, indoor PM$_{2.5}$ sources), and source characteristics and locations (e.g., local versus regional sources, location of major PM$_{2.5}$ relative to populations).

The relative importance of these assumptions to the standard-setting process likely varies by country and over time. Further, their relative importance is likely subjective, as is their relevance and applicability to the standard-setting country. If, however, the assumptions are found to be appropriate for the standard-setting country as well, then risk assessors may decide to adopt the PM$_{2.5}$ guideline or standard set by WHO or other governmental group or country. Otherwise, risk assessors may want to seek additional information to identify dose-response information applicable to their country. This information can be obtained from a variety of sources, including (1) a review the scientific literature for PM$_{2.5}$, with specific emphasis on studies from Country A or surrounding countries, (2) PM$_{10}$ standards for Country A or other countries, and (3) measurements or estimates of background PM$_{2.5}$ concentrations, which can include PM$_{2.5}$ that originates from anthropogenic sources outside Country A.

**Output:** Quantitative determination of the level of the PM$_{2.5}$ standard for specified exposure averaging times.

### 6.6 Risk Characterization

In the context of this tool-kit, the risk characterization step is not necessary for this example.
Is the identity of the chemical known?

Yes

Is the chemical hazardous?

Yes

Are there international guidelines for ambient PM$_{2.5}$?

Yes

Does a relevant ambient PM$_{10}$ standard exist?

Yes

Do PM$_{2.5}$ and PM$_{10}$ have a known relationship?

No

Proceed to exposure assessment

Figure 6.1 Case-specific road map for hazard identification; particulate matter case study
Figure 6.2 Case-specific road map for exposure assessment; particulate matter case study
Review the exposure averaging-specific PM$_{2.5}$ concentrations established as limits by the international or country guidelines for PM$_{2.5}$.

Determine if the assumptions of the guideline value are appropriate for Country A.

Is the assumed activity patterns and housing stock relevant for Country A’s population?

- Yes
  - Determine the impact of Country A’s population and housing stock on estimated health risks.

- No
  - Determine the appropriate level for the ambient PM$_{2.5}$ standard for the specified exposure averaging times and compliance networks.

Figure 6.3 Case-specific road map for dose-response assessment; particulate matter case study.
7.0 ROTTERDAM CONVENTION PESTICIDE CASE STUDY

7.1 Objective

The objective of this case study is to illustrate how the Toolkit can assist in gathering the information required to propose listing of a chemical under Article 5 or Article 6 of the Rotterdam Convention. The case study focuses on provision of information required by Article 5, however, because the information requirements for Article 5 and 6 are very similar, the case study is relevant to Article 6 as well. Case-specific road maps are shown in Figures 7.1 to 7.5.

7.2 Background

The Rotterdam Convention (RC) is an international agreement with the objectives:
- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;
- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.

At present, 39 chemicals are listed by the RC including 24 pesticides, 4 severely hazardous pesticide formulations, and 11 industrial chemicals. To be listed, a chemical must be must be proposed by Parties according to procedures stated in Article 5 or Article 6 of the RC.

Article 5 applies to chemicals that have been banned or severely restricted for health or environmental reasons by Parties to the RC. Parties shall notify the Secretariat of the final regulatory action for these chemicals and provide information detailed in Annex I of the RC. Annex I requires information about the identity of the chemical, the final regulatory action, properties of the chemical, and the designated national authority.

Article 6 applies to any Party that is a developing country or a country with an economy in transition that is experiencing problems caused by a severely hazardous pesticide formulation. For these substances, Parties may propose that a chemical be listed in the RC. As specified in Annex IV, a proposal from a Party must include information on chemical identity, the nature of the human health effects in the country, and any regulatory action taken or planned. If information provided by the Party is complete, then the Secretariat is responsible for collecting information on physical-chemical, toxicological, and ecotoxicological properties of the chemical, the existence of handling

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10 Defined as a chemical for which severe human health effects have been observed within a short period of time after single and multiple exposures following use.
and use restrictions in other States, risk and/or hazard evaluations where available, other formulations of the chemical, alternative pest control practices, and related information.

7.3 Statement of the Problem

A country in central Africa with a population of approximately 12 million is a Party to the RC. Public health officials in the country have observed human health effects in workers associated with use of a methyl parathion formulation to control insect populations in vegetable fields. To protect human health, the country has taken a final regulatory action to severely restrict uses of methyl parathion. As a Party to the RC, the country shall notify the Secretariat of the action in accordance with Article 5. In developing the notification, the country is required to provide the Secretariat with the information required by Annex I (see Table 7.1). The national Department of Environmental Health (DEH) is responsible for gathering that information in accordance with the RC Form for Notification of Final Regulatory Action to Ban or Severely Restrict a Chemical.

7.4 Categories and Sources of Information Required by Annex I

The information required by Annex I as represented on the notification forms provided by the RC is summarized as a road map in Figure 7.1. The information is divided among four primary categories: (1) identity of the chemical; (2) final regulatory action; (3) properties of the chemical; and (4) the designated national authority. As shown in the figure, one or more subcategories of information are required for each of the primary categories.

Information required for the notification form is available from two broad sources: (a) observations made and data generated within the country and (b) international and other resources.

Items required by Annex I that are expected to be obtained from observations within a country are indicated in Figure 7.1 by topic boxes without shading. Consider item 1.3 for example, “Trade names and names of preparations used in the country”. The primary source of this data is expected to be information gathered on the formulations of methyl parathion used within the country. A formal process for registering pesticides uses within the country would be the primary source of this information, if in fact a registration process existed. In the absence of a registry, this information may be available from industrial permits, import/export records, or results of surveys administered by the ministry of agriculture or interior. Surveys of wholesale or retail agricultural supply companies may be another source of this information. Ultimately, the information should be accessible from owners or managers of agricultural property.

The numbered outline shown in Figure 7.1 corresponds to the numbered outline in the forms for notification provided by the Rotterdam Convention.
Nonetheless, the basic principles and concepts of risk assessment presented within the Toolkit are relevant to some of the country-specific items shown in Figure 7.1. Item
Figure 7.1 Case-specific overall road map of information required for notification of a chemical (Article 5) under the Rotterdam Convention (adopted from protocol provided by the Rotterdam Convention Secretariat)
2.5.3.2 is an example of this, where the country is asked to provide information on risks of alternatives to the banned or severely restricted use chemical. In this case, the overall and generic roadmaps for hazard identification, dose-response evaluation, exposure assessment, and risk characterization in the Toolkit may be useful to the notifying Party (Figures 3.1 to 3.4 and 3.6).

The types of information required by Annex I that are readily available from international and other resources are shaded grey in Figure 7.1. Item 3 provides several clear examples of this type of information such as hazard classification according to the WHO or IARC systems (item 3.1) and chemical and toxicological properties of the chemical (items 3.2.1 and 3.2.2). These items are directly relevant to the Toolkit and are discussed in the following sections.

### 7.5 Hazard Identification

Numerous items required in Annex I are fundamental pieces of information gathered in the hazard identification step of the Toolkit. The international resources listed in Section 3.1 are reliable sources of this information as illustrated following the roadmap for hazard identification presented in Figure 3.2.

#### 7.5.1 Is the identity of the chemical/formulation known?

**Item 1.1 Common name.** The DEH identified the common name of the chemical as methyl parathion.

**Item 1.2 Chemical name according to an internationally recognized nomenclature.** An electronic search of the International Chemical Safety Cards (ICSC) database (http://www.inchem.org/pages/icsc.html) for ‘methyl parathion’ returns the IUPAC name of IUPAC: O,O-Dimethyl O-4-nitrophenyl phosphorothioate

**Item 1.4 Code numbers.**
- 1.4.1 CAS# 298-00-0 (ICSC database)
- 1.4.2 Harmonised system customs code 2920.11 (Rotterdam Convention)
- 1.4.3 Other codes, EC: 206-050-1

Information on formulations of methyl parathion available from the HSDB (see section 3.1.4) indicates that the chemical is available in technical grade products and numerous ready-to-use products. The technical grade products include pure methyl parathion as a solid and an 80% solution of methyl parathion in xylene. Ready-to-use products appear to be 2% methyl parathion available as dusts, emulsifiable concentrates, ultra-low volume liquids, and wettable powders.

In addition to the codified chemical identity information, interviews with insecticide applicators and observations of application procedures made by DEH personnel indicate that wettable powders and emulsifiable concentrates of methyl parathion are the primary
forms of methyl parathion used in the country. The DEH noted the product names Kilex Parathion and Metaphos during their inspections and recorded that the labels indicated 2% methyl parathion concentrations.

7.5.2 Is the chemical hazardous?

Item 3.1 Information on hazard classification.

UN System: Hazard Class 6.1
Pack Group II

EU System: T+ (Very Toxic)
N (Dangerous for the environment)
Risk Phrases
R5: heating may cause an explosion
R10: flammable
R24: toxic in contact with skin
R26/28 very toxic by inhalation and if swallowed
R48/22 harmful: danger of serious damage to health by prolonged exposure if swallowed
R50/53 very toxic to aquatic organisms/may cause long-term adverse effects in the aquatic environment

IARC: Group 3 (not classifiable as to its carcinogenicity to humans)

WHO: 1a (extremely hazardous)

Item 3.2.1 Physico-chemical properties. Information extracted from the Hazardous Substances Data Bank (see Section 3.1.4) and included in Appendix 7.1.

Item 3.2.2 Toxicological properties. Toxicity summary extracted from the Hazardous Substances Data Bank (see Section 3.1.4)

Toxicity Summary:
IDENTIFICATION: Methyl parathion is an organophosphorus insecticide that is relatively insoluble in water, poorly soluble in petroleum ether and mineral oils, and readily soluble in most organic solvents. Pure methyl parathion consists of white crystals; technical methyl parathion is a light tan color with a garlic-like odor. It is thermally unstable. HUMAN EXPOSURE: The production, formulation, handling, and use of methyl parathion as an insecticide are the principal potential sources of exposure of humans. Skin contact and, to a lesser degree, inhalation are the main routes of exposure to workers. The general population may be exposed to air-, water-, and food-borne residues of methyl parathion as a consequence of agricultural or forestry practices, the misuse of the agent resulting in the contamination of fields, crops, water, and air through off-target spraying. Methyl parathion is a highly toxic organophosphorus ester insecticide. Overexposure from handling during manufacture,
use, and/or accidental or intentional ingestion may cause severe or fatal poisoning. **Methyl parathion** formulations may, or may not, be irritating to the eyes or to the skin, but are readily absorbed. Several cases of acute **methyl parathion** poisoning have been reported. Signs and symptoms are those characteristic of systemic poisoning by cholinesterase-inhibiting organophosphorous compounds. They include peripheral and central cholinergic nervous system manifestations appearing as rapidly as a few minutes after exposure. In case of dermal exposure, symptoms may increase in severity for more than one day and may last several days. Studies of **methyl parathion** suggest a decrease in blood cholinesterase activities without clinical manifestations. No cases of organophosphorous-induced, delayed peripheral neuropathy have been reported. An increase in chromosomal aberrations has been reported in cases of acute intoxications. No human data were available to evaluate the teratogenic and reproductive effects of **methyl parathion**. The available epidemiological studies deal with multiple exposure to pesticides and it is not possible to evaluate the effects of long-term exposure to **methyl parathion**. ANIMAL STUDIES: **Methyl parathion** poisoning causes the usual organophosphate cholinergic signs attributed to accumulation of acetylcholine at nerve endings. **Methyl parathion** becomes toxic when it is metabolized to methyl paraoxon. In short term toxicity studies, using various routes of administration on the rat, dog, and rabbit, inhibition of plasma, red blood cell, and brain ChE, and related cholinergic signs were observed. There is no evidence of carcinogenicity in mice and rats, following long-term exposure. In reproduction studies, at toxic dose levels (ChE inhibition), there were no consistent effects on litter size, number of litters, pup survival rates, and lactation performance. No primary teratogenic or embryotoxic effects were noted. **Methyl parathion** is readily absorbed via all routes of exposure (oral, dermal, inhalation) and is rapidly distributed to the tissues. The liver is the primary organ of metabolism and detoxification. The elimination of **methyl parathion** and metabolic products occurs primarily via the urine. [World Health Organization/International Programme on Chemical Safety. Environmental Health Criteria 145 Methyl Parathion pp. 11-18 (1993)]**PEER REVIEWED**

7.5.3 Do health-based guidelines exist for the chemical?

The existence of a health-based guideline for intake of methyl parathion indicates that a risk or hazard evaluation has been conducted, the topic of Item 2.4 in the Article 5 form for notification provided by the RC. Health-based guidelines available from international resources are referenced here.

Occupational Exposure Limits: Threshold limit value of 0.2 mg/m³ as 8-hour time-weighted average concentration for air, accessed via [ICSC](http://www.icsc.org) (see Section 3.1.2)

Reference Dose for non-cancer health effects: \(2.5 \times 10^{-4}\) mg/kg/day, U.S. EPA accessed via [ITER](http://www.iter.org) (see Section 3.3.1)
Maximum Residue Limits for food (milligrams of methyl parathion per kilogram of food item), Codex Alimentarius (see Section 3.4.3)

<table>
<thead>
<tr>
<th>Commodity</th>
<th>MRL (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple</td>
<td>0.2</td>
</tr>
<tr>
<td>Beans (dry)</td>
<td>0.05</td>
</tr>
<tr>
<td>Cabbages, Head</td>
<td>0.05</td>
</tr>
<tr>
<td>Dried grapes (=currants, raisins and sultanas)</td>
<td>1</td>
</tr>
<tr>
<td>Grapes</td>
<td>0.5</td>
</tr>
<tr>
<td>Nectarine</td>
<td>0.3</td>
</tr>
<tr>
<td>Peach</td>
<td>0.3</td>
</tr>
<tr>
<td>Peas (dry)</td>
<td>0.3</td>
</tr>
<tr>
<td>Potato</td>
<td>0.05</td>
</tr>
<tr>
<td>Sugar beet</td>
<td>0.05</td>
</tr>
</tbody>
</table>

According to the WHO a drinking water guideline value for methyl parathion has not been established because any health-based value is likely to be much greater than concentrations likely to be found in water. Similarly, the WHO has not published an air quality guideline value for methyl parathion.

A road map for the risk characterization step of the drinking water case study is shown in Figure 7.1. Bold lines indicate the flow of information gathering and analysis that is described above.
Figure 7.2  Case-specific road map for hazard identification; Rotterdam Convention pesticide case study (bold lines indicate the flow of information gathering and analysis)
7.6 Exposure Assessment

_In what ways could intake of the chemical occur?_

*What exposure metric is needed to characterize health risks?*

*What is the exposure concentration or rate for the chemical?*

In the context of notifying the Secretariat of the RC of a final regulatory action, the country should have completed an exposure assessment for the chemical to determine the uses and formulations that were either banned or severely restricted. Similar to any exposure assessment, the assessor must determine:

- The environmental media expected to contain the contaminant;
- The relevant route(s) of exposure; and
- The appropriate averaging time.

The primary use of methyl parathion in the country is known to be application to vegetable fields using a rotary disc sprayer carried on the back of a worker. As a result of this use, agricultural media including plants, air, and soil are expected to contain methyl parathion. The corresponding routes of exposure to workers are expected to be dermal absorption, inhalation, and ingestion. Acute exposures to workers are expected to occur during application events, while intermediate and chronic exposures may occur following application until the commodity is harvested.

Although occupational exposure studies have not been conducted in the country, information from numerous investigations in other areas demonstrates the potential for elevated exposure to methyl parathion amount applicators. Supporting information excerpted from the Hazardous Substances Data Bank, Probable Routes of Human Exposure is reproduced here:

Seventy-three acres of alfalfa in Vernal, Utah, were sprayed with an emulsifiable concentrate containing 6 lb/gal ethyl parathion and 3 lb/gal methyl parathion. The material was applied at 4.15X10^{-2} gal/acre. Wind conditions were negligible. Samples were taken from the sprayed plot (sites A and B) and from an adjoining non-target pasture (site C). A dermal dose of 0.38 mg of methyl parathion would have been incurred by a bystander at Site C during spraying. Exposure would have been 4 times greater at the fence line separating treated and non-target fields. [Draper WM, Street JC; Bull Environ Contam Toxicol 26 (4): 530-6 (1981)]**PEER REVIEWED**

_Methyl parathion_ is readily absorbed through the skin, mucous membranes, & eyes & presents a potentially great danger from these avenues of absorption. It is extremely important to emphasize that available evidence indicates that the greatest danger to employees exposed to methyl parathion is from skin contact. [Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 1985. 2nd ed. Park Ridge, NJ: Noyes Data Corporation, 1985., p. 614]**PEER REVIEWED**

In recent years, methyl parathion has been produced in increasingly greater quantities in the USA & NIOSH est that approx 150,000 USA workers are potentially exposed to methyl parathion in occupational settings. This applies to manufacturers, formulatons, & applicators. [Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens,
Occupations with potential exposure to methyl parathion: Aerial application personnel; Area cleanup crews; Bagging machine operators; Basic manufacturing employees; Haulers of laundry; Drum fillers; Drum reconditioning personnel; Dump personnel; Field checkers; Fieldworkers (eg, exposed to residues on crops and foliage); Flag persons; Ground applicator vehicle drivers; Janitorial personnel; Laundry workers; Maintenance personnel; Mixer and blender operators; Refuse haulers; Tractor tank loaders; Truck loaders; and Warehouse personnel. [NIOSH; Criteria Document: Methyl Parathion p.164 (1976) DHEW Pub. NIOSH 77-106]**PEER REVIEWED**

California Department of Food and Agriculture reported incidents of worker poisonings and illnesses during mixing, loading, and application. [Purdue University; National Pesticide Information Retrieval System (1988)]**PEER REVIEWED**

In production plants, average air levels are less than 0.1 mg/cu m, max 0.2 mg/cu m. 0.7 mg/hr dermal exposure for workers checking cotton for insect damage(1). [(1) IARC; Miscellaneous Pesticides; 30: 131-52 (1983)]**PEER REVIEWED**

Methyl parathion was detected on the skin of formulators; the median (range) methyl parathion level on the foreheads (9 sq cm) of 5 workers who did not wash after work was 510 ng (90 to 11,000) and on 8 workers who washed after work was 74 ng (20 to 200); the median (range) methyl parathion level on the palms (50 sq cm) of 5 workers who did not wash after work was 9,200 ng (690 to 277,000) and on 8 workers who washed after work was 345 ng (40 to 3,000)(1). Median skin levels of methyl parathion on the forehead and palm of formulators were 1,000 and 6,100 ng for same day exposure, 74 ng and 525 ng for exposure 1 to 15 days prior to sampling, and 90 ng and 330 ng for exposure more than fifteen days prior to sampling, respectively(1). Occupational exposure to methyl parathion may occur through inhalation of spray mists and dermal contact with this pesticide during or after its application or where it is formulated(SRC). The general population may be exposed to methyl parathion via inhalation of ambient air, ingestion of contaminated food and dermal contact with this insecticide(SRC). [(1) Wolff MS et al; Bull Environ Contam Toxicol 48: 671-8 (1992)]**PEER REVIEWED**

As described in Section 7.5, the general population is not expected to be exposed to meaningful levels of methyl parathion in drinking water. The potential for inhalation exposure exists for populations that are near to agricultural applications. The general population may also be exposed to methyl parathion via residues on food that remain from agricultural applications.

A road map for the exposure assessment step of the pesticide case study is shown in Figure 7.2. Bold lines indicate the flow of information gathering and analysis that is described above.
Draw upon output from the hazard identification and dose-response steps to determine the environmental media, routes of exposure, and averaging times that are appropriate for the situation.

Is the concentration of the chemical in the exposure medium known?

Yes

Estimate the concentration in the exposure medium for the appropriate averaging time

Measurement and modeling approaches

Intake rate:
Non-occupational populations

Estimate the rate of contact with the medium

Estimate the exposure rate

Proceed to risk characterization

No

Is the guideline value expressed as a concentration, intake rate or cancer slope factor?

Concentration:
Occupational exposure limit

Estimate the concentration in the exposure medium for the appropriate averaging time

Qualitative assessment: generalize from other studies

Figure 7.3 Case-specific road map for exposure assessment; Rotterdam Convention pesticide case study (bold lines indicate the flow of information gathering and analysis)
7.7 Dose-Response Assessment

Are the assumptions about contact rate, body weight, absorption fraction, and allocation of total intake incorporated into the guideline value appropriate for the current situation?

As described in Section 7.5, applicators of methyl parathion are anticipated to have the greatest exposure among the population of the country. In the absence of information on contact rates, body weight, absorption fraction, and total exposure to methyl parathion specific to local conditions, the DEH elects to rely upon the health-based dose-response values provided in Section 7.4.3.

A road map for the exposure assessment step of the pesticide case study is shown in Figure 7.3. Bold lines indicate the flow of information gathering and analysis that is described above.
Figure 7.4 Case-specific road map for dose-response assessment; Rotterdam Convention pesticide case study (bold lines indicate the flow of information gathering and analysis)
7.8 Risk Characterization

How does the estimated exposure compare to health-based guideline values?

The DEH has not estimated exposure to methyl parathion for workers or consumers in the country, but believes that the potential for exposure to workers is high based on studies in other areas as summarized in Section 7.5. To minimize exposure among occupational populations, other States recommend that workers use personal protective equipment including respirators, gloves, protective clothing and goggles. Supporting information excerpted from the Hazardous Substances Data Bank, Protective Equipment and Clothing is reproduced here:


Respirator selection for methyl parathion at concn of 2 mg/cu m or less: 1) Half mask pesticide respirator, 2) Type C supplied air respirator, demand type (negative pressure), with half mask facepiece; At 10 mg/cu m or less: 1) Fullface gas mask (chin style or chest- or back mounted type), 2) Type C supplied-air respirator, demand type (negative pressure), with full facepiece or suit, 2) Pressure demand type respirator with full facepiece and impervious plastic shroud; Emergency (includes entry to vessels, bins, or other containers which are likely to be contaminated with methyl parathion): 1) Self contained breathing apparatus, positive pressure type, with full facepiece, 2) Combination supplied-air respirator, pressure demand type, with auxiliary self contained air supply. [NIOSH; Criteria Document: Methyl Parathion p.15 (1976) DHEW Pub. NIOSH 77-106]**PEER REVIEWED**


Eyewash fountains should be provided in areas where there is any possibility that
workers could be exposed to the substance; this is irrespective of the recommendation involving the wearing of eye protection. [NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997., p. 215]**QC REVIEWED**

Facilities for quickly drenching the body should be provided within the immediate work area for emergency use where there is a possibility of exposure. [Note: It is intended that these facilities provide a sufficient quantity or flow of water to quickly remove the substance from any body areas likely to be exposed. The actual determination of what constitutes an adequate quick drench facility depends on the specific circumstances. In certain instances, a deluge shower should be readily available, whereas in others, the availability of water from a sink or hose could be considered adequate.] [NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997., p. 215]**QC REVIEWED**


Recommendations for respirator selection. Condition: Emergency or planned entry into unknown concn or IDLH conditions: Respirator Class(es): Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode. Any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure

SRP: Contaminated protective clothing should be segregated in such a manner so that there is no direct personal contact by personnel who handle, dispose, or clean the clothing. Quality assurance to ascertain the completeness of the cleaning procedures should be implemented before the decontaminated protective clothing is returned for reuse by the workers. Contaminated clothing should not be taken home at end of shift, but should remain at employee's place of work for cleaning. **PEER REVIEWED**

The country does not have an infrastructure for ensuring appropriate training and implementation of occupational health and safety measures in agricultural operations. Without a management system for protecting workers from excessive exposure to methyl parathion, the DEH concludes that risks to human health are likely to be unacceptable under current conditions.

A road map for the exposure assessment step of the pesticide case study is shown in Figure 7.3. Bold lines indicate the flow of information gathering and analysis that is described above.
Figure 7.5 Case-specific road map for risk characterization; Rotterdam Convention pesticide case study (bold lines indicate the flow of information gathering and analysis)
7.9 Summary

A case study of methyl parathion was used to illustrate how principles, roadmaps and resources contained in the Toolkit can be used to facilitate notifications of final regulatory actions under Article 5 of the RC. The case study is also relevant to proposals to list a chemical as severely hazardous pesticide under Article 6 of the convention. Roadmaps and resources in the Toolkit were cross-referenced to specific items in the Article 5 form for notification (and to the Article 5 form for proposals by extension). Electronic links to on-line databases compiled in the Toolkit were shown to provide direct access to information essential to the notification and proposal requirements of the RC. The case study demonstrated how qualitative information on chemical use in a country can be related to empirical information on exposures and risks developed in other States through the use of bridging principles that consider use patterns, formulations, and risk mitigation measures.
Appendix 7.1 Physico-chemical properties of methyl parathion extracted from the Hazardous Substances Data Bank

**Molecular Formula:**
C8-H10-N-O5-P-S
**PEER REVIEWED**

**Molecular Weight:**
263.21

**Color/Form:**


**Odor:**


**Boiling Point:**

**Melting Point:**

**Density/Specific Gravity:**

**Octanol/Water Partition Coefficient:**
log Kow □ 2.86 [Hansch, C., Leo, A., D. Hoekman. Exploring
Solubilities:  


Intense mass spectral peaks: 263 m/z (100%), 125 m/z (99%), 109 m/z (99%), 79 m/z (39%) [Hites, R.A. Handbook of Mass Spectra of Environmental Contaminants. Boca Raton, FL: CRC Press Inc., 1985., p. 296]**PEER REVIEWED**


Hydrolyzes in alkaline and acidic media (approx. 5 times more rapidly than parathion); half-life is 68 days at pH 5, 40 days at pH 7, 33 days at pH 9 (all at 25 deg C). Isomerizes on heating, to the O,S-dimethyl

Policy guidance:

Bridging Information

Introduction
The purpose of this paper is to assist the Chemical Review Committee (CRC) in judging the acceptability of a notification of final regulatory action, with respect to criterion (b) (iii) of Annex II, where the notifying Party has used a risk evaluation from another country or international body as the basis for its national decision.

At its third meeting, the Conference of the Parties agreed that, in order to satisfy criterion (b) (iii) of Annex II to the Rotterdam Convention, bridging information providing evidence of the prevailing conditions in the notifying country would have to be submitted. It was further agreed that the working paper on bridging information would need to be developed further in order to accommodate the consideration of global risk evaluations as experience was gained.

At its first meeting, the CRC considered an initial draft of this working paper which was further discussed and amended at its third meeting.
**Bridging Information**

**Introduction**

1. When examining notifications made in accordance with Article 5 of the Rotterdam Convention, the Chemical Review Committee must establish whether criteria b (i), b (ii) and b (iii) of Annex II have been met. The *working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II* includes practical examples where the Committee has determined that these criteria have been met. Meeting criterion (b) (iii), i.e. that a final regulatory action was based on a risk evaluation involving prevailing conditions within the party taking the action, has proven particularly difficult. Other than conducting risk evaluations by themselves, notifying countries may use risk evaluations and/or exposure assessments completed in another country or from an international risk evaluation. When submitting actual or estimated exposure to also ensure that 2b(i) has bee met.

2. This document provides guidance on the sort of information that will need to be considered by the Chemical Review Committee in determining that the conditions in the country which completed the original risk evaluation and exposure assessments or risk evaluations carried out under other international agreements or conventions, such as the Montreal Protocol on substances that deplete the ozone layer or the Stockholm Convention on Persistent Organic Pollutants (POPs) are similar to and compatible with those prevailing in the notifying country.

3. For those countries whose national regulatory programmes require the use of risk evaluations but which lack the capacity and resources to perform such evaluations, these guidelines may also be of interest.

4. It is important to note that when a Party submits a notification of final regulatory action, the risk evaluation and the “bridging” information must be sufficient to fulfil the criteria in Annex II (b) (iii) for this notification to be a trigger for further consideration under the Convention.

5. The use of these guidelines is intended to be voluntary. They should be interpreted flexibly.

6. The Chemical Review Committee will consider such bridging information on a case-by-case basis. In reviewing the information, the Committee will apply the following principles:

   (a) Exposure or potential exposure is a key element;

   (b) The information should be science-based, on the best available knowledge;

   (c) The information should also be sufficiently detailed to enable the Chemical Review Committee to make an assessment.
7. The following elements, if relevant for the final regulatory decision, should be considered in comparing the exposure scenario in the country that completed the original risk evaluation or the relevance of the exposure scenarios considered in the international risk evaluation to the conditions prevailing in the notifying country that has used that risk evaluation in support of its notification of final regulatory action. They address both human health and environmental exposure.

A. Pesticides

8. Information to facilitate a comparison of human exposure between countries or to demonstrate relevance of an international risk evaluation could include:

   (a) The form in which the chemical was used in both countries or a comparison of the form in which the chemical is used in the notifying country to those which were considered in the international evaluation;

      (i) Formulation type:

         - Liquid, powdered, granular and so on;
         - Concentration of active ingredient(s);

      (ii) Contaminants:

   (b) How the chemical is used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation;

      (i) Use pattern:

         - Type of use (agricultural pesticide, non-agricultural pesticide, use as disinfectants, vector control, wood preservatives)
         - Rate, frequency and period of application
         - Method of application (spray, drip, dip)
         - Application equipment (back pack sprayer, air blast sprayer etc.)
         - Greenhouse, field application, post-harvest, other
         - Storage conditions

      (ii) If applied in the field: climatic or geographic conditions, comparability between the countries or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes, or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or chemicals derived from certain heavy metals such as mercury might pose
problems for human health in the notifying country, e.g. via the food chain)

(c) Risk mitigation measures in both countries - relevance of restrictions/precautions on use in the country that undertook the risk evaluation or relevance of recommended risk mitigation measures from international evaluations, such as:

(i) Human health effects:

- Requirement for protective clothing, whether it is typically available and/or feasible in the country reporting the regulatory action
- Special application equipment, whether it is typically available and/or feasible in the country reporting the regulatory action
- Occupational exposure limit.

9. Information to facilitate a comparison of environmental exposure:

(a) The form in which the chemical was used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:

(i) Formulation type:

- Liquid, powdered, granular, etc.
- Concentration of active ingredient(s)

(ii) Contaminants

(b) How the chemical is used in both countries or a comparison of the use conditions in the notifying country to those which use forms were considered in the international evaluation:

(i) Use pattern:

- Rate and frequency of application
- Method of application (spray, drip, dip, etc.)
- Application equipment (back pack sprayer, air blast sprayer, etc.)
- Greenhouse, field application, post-harvest, etc.

(ii) If applied in the field, environmental conditions such as climatic conditions, soil type and non-target organisms; comparability between the two countries or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent, bioaccumulating and toxic
properties such as POPs, or chemicals derived from certain heavy
metals such as mercury might pose problems in the environment of the
notifying country)

(c) Risk mitigation measures - relevance of restrictions/precautions on use in the
country that undertook the risk evaluation or relevance of recommended risk mitigation
measures from international evaluations, such as:

(i) Effects on non-target organisms:

- Buffer zones to protect sensitive areas such as water bodies or species
  habitats; whether such zones are enforceable in the notifying
country

(ii) Other environmental effects.

The description of indirect exposure via the environment should address the
following:

(a) How the presence of a chemical in the environment, results in (actual or
potential) exposure of humans or organisms in the environment. Actual exposure
can be directly measured. Potential exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the
reason for the regulatory action, taking into account the hazards of the chemical.

B. Industrial chemicals

10. Information to facilitate a comparison of human exposure between countries or to
demonstrate relevance of conditions considered in an international risk evaluation could
include information on:

- Workers
- General population
- End users
- Others (for example specific subgroups of the population such as children,
pregnant women or the elderly)

11. Information to facilitate a comparison of environmental exposure between
countries or to demonstrate relevance of conditions considered in an international risk
evaluation:
12. Description of events leading to exposure either as described in the notification of another country or in the international evaluation such as one or several of the following examples:

(a) Production process: e.g., where releases to air during production or processing of the chemical leads to general population exposure;

(b) Patterns of storage and distribution;

(c) Patterns of use: e.g., where the product is used on fabric, consumers are subjected to dermal exposure from clothing made from the treated fabric;

(d) Patterns of disposal: e.g., disposal of chemical on land leads to ground water contamination.

13. Description of the key factors, such as one or several of the following examples, affecting the chain of events leading to exposure:

(a) The form in which the chemical was used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:
   - Formulation type (where appropriate)
   - Concentration of the chemical
   - Contaminants.

(b) If release is associated with the production process, description of the production process:
   (i) What are the key factors affecting release?
       - Open or closed
       - Waste water treatment (if relevant)
   (ii) What options exist for controlling release or exposure?
       - Exposure limits
       - Protective equipment.

(c) If release is associated with storage and distribution, description of the storage and distribution process:
(i) What are the key factors affecting release?
(ii) What options exist for controlling release or exposure?

(d) If release is associated with use, description of use:

(i) What are the key factors affecting release?
(ii) What options exist for controlling release or exposure?
(iii) Hazard communication

(e) If release is associated with disposal, description of the disposal process:

(i) What are the key factors affecting release?
(ii) What options exist for controlling release or exposure?

Any other relevant information demonstrating similarity in conditions as described by another notifying country, e.g. incident reports, monitoring data, or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or certain heavy metals such as mercury or their compounds might pose problems to human health (e.g. via the food chain) or in the environment of the notifying country).

The description of indirect exposure via the environment should address the following:

(a) How the presence of a chemical in the environment results in (actual or potential) exposure of humans or organisms in the environment. Actual exposure can be directly measured. Potential exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical.
BAN ON ENDOSULFAN

Having regard to the revised version of the Common Regulation for Pesticide Registration of the CILSS (Permanent Inter-State Committee on Drought Control) Member States, resulting from Resolution N° 08/34/CM/99 adopted in 1999 in N'Djamena, Chad, by the CILSS Council of Ministers;

Concerned with the protection of human and animal health as well as with the environment;

On the proposal of the Sahelian Pesticide Committee submitted at its working session on the 8th May 2007 in Bamako,

The use of Endosulfan in agriculture is prohibited in CILSS Member States for the reasons stated in the enclosed document.

Taking into account agricultural specificities and the time needed to use up all existing stocks, the decision taken by the coordinating minister on the recommendation of the Sahelian Committee to ban this pesticide enters into force on the date of the signature as for its distribution and on 31st December 2008 as for its use.

The present decision will be communicated wherever necessary.

Minister Coordinator of CILSS
Minister of agriculture and breeding
Islamic Republic of Mauritania

Ampliations
- Executive Secretary of CILSS (Original)
- Institut du Sahel (CSP)
- Regional center Agrhvmet

Annex to the decision to ban Endosulfan

Endosulfan is an organochlorine insecticide/acaricide. It is composed of isomers a and b whose main metabolite, Endosulfan sulfate, is more toxic and persistent than Endosulfan itself. Endosulfan is highly, acutely toxic (class Ib, i.e. highly toxic) and the risk of intoxication under Sahelian conditions is unacceptable.
Endosulfan is used to control pests and cotton mites following the high recrudescence of Elicoverpa armigera in 1996 and its resistance to pyrethroids. Huge quantities of the product have been used ignoring good agricultural practices and with serious risks for human health and the environment. It is applied twice during the farming season in the Sahel at doses between 300 and 750 gr. of active ingredient per hectare. It is applied with a terrestrial sprayer (rotating disc sprayer or engine-driven portable sprayer). The application is carried out by farmers without adequate protection.

Comparing the product applications in Australia and in the Unites States of America and the decisions taken in Europe and France, the following can be observed:
- The use of Endosulfan is severely restricted in Australia. The product is only used by authorized people. The use of complete protective clothing is required during sprayer filling and terrestrial application (waterproof protective clothing, long sleeve PVC gloves, waterproof boots and complete respiratory mask (full-face mask) or safety goggles with half-mask respirator.

- In the United States, Endosulfan has been registered for cotton trees. Having been assessed that the risk of worker exposure was high, a whole range of measures to reduce the risk has been adopted. These included a suit over a long-sleeve shirt and trousers, chemical resistant shoes and boots, waterproof gloves, waterproof overall for sprayer filling and a respiratory mask against organic vapor.

Endosulfan is not authorized in France in chemical formulations approved for marketing. The opinion published on the Official Gazette of 22nd February 2006 withdrew marketing authorizations for plant protection products containing Endosulfan for all agricultural and non-agricultural uses, with the following time period during which existing stock had to be used up:
- until 31st December 2006 for its distribution,
- until 30th May 2007 for its use.

The European Union refused to enter Endosulfan in Annex I because it did not meet minimal safety requirements, particularly with regards to its impact on the environment and its toxicological profile.

Although application doses are similar to those used in the Sahel, required protection clothing is neither available nor is it adequate for local conditions (heat). The training level of farmers in the Sahel is far below that of American and Australian farmers. Furthermore, it should not be forgotten that many dwellings in the Sahel are surrounded by cotton fields.

In the Sub-Saharan region, cases of intoxication have been reported in Benin and in Senegal. Endosulfan residues have been found in peanut oil in Senegal. Endosulfan is highly toxic for fish and some aquatic invertebrates. The adverse impact on aquatic ecosystems due to the contamination of surface water in cotton-tree areas in the Sahel is considered to be inacceptable.

A Risk-assessment study of pesticides used on cotton-trees has been carried out in Burkina Faso in 2003 to evaluate their impact on surface waters. According to the Pesticide Impact Rating Index, Endosulfan was the only one among all pesticides used for foliar application having been reported as having a high risk of contaminating surface waters.

Similar studies have been carried out in the Unites States of America where buffer zones are required. The use of Endosulfan is prohibited in areas where surface waters are abundant and potentially vulnerable.

In cotton-trees areas in the Sahel, surface waters are environmentally important. The buffer zones required in the Unites States are not respected in the Sahel.

The use of Endosulfan in the CILSS Member States is no longer justified since other valid alternatives to effectively control Helicoverpa armigera exist and are authorized by the Sahelian Pesticide Committee.
Assessment of the risks for surface and ground waters pollution by pesticides used in cotton production in Burkina Faso:
Evaluation des risques de pollution des eaux de surface et des eaux souterraines par les pesticides utilisés en culture cotonnière au Burkina Faso

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Summary

Cotton is the most important export product of Burkina Faso and the principal source of economic growth. But the cotton production uses a huge amount of pesticides. Several studies and reports have shown there is non-compliance with the Good Agricultural Practices (GAP) by the farmers. The soils are fragile, containing low organic matter, and are subject to erosion. This results in a potential for the contamination of surface water both through direct runoff and through soil erosion. In addition, the situation is compounded by the high rainfall intensities experienced during the wet season.

In spite of this potential threat on water resources related to the pesticides used in such conditions, few studies have been undertaken to assess it. This work describes the first assessment of the risks both on surface and ground water related to the pesticides used in cotton production in Burkina Faso. The primary tool used is a software package “Pesticide Impact Ranking Index” (PIRI) which has been developed by CSIRO. PIRI is used to quantify the pollution and toxicological impact by pesticides on the environment by:

- Ranking pesticides in terms of their relative pollution to ground water and/or surface water;
- Comparing different land uses in a catchment or at a regional scale in terms of their relative impact on water quality.

The application of PIRI to pesticides used in Burkina Faso on cotton production shows the following results:

- The pesticides used for weed control and for seed protection are ranked of low risk impact. They don’t represent a prominent threat either for surface water or for ground water for the conditions of their use in Burkina Faso;

- The pesticides used as insecticides in foliar spraying. For the impact of all the insecticides on the surface water, only the use of endosulfan is the greatest potential threat to the surface water. The other products don’t represent a big threat except in the situation of soils of low organic matter content and of crops near surface water. For the impact of all the insecticides on the ground water, all the products are rated at a very low risk impact except benfuracarb which is rated at an Exceedingly High risk impact in situations of soils of very low organic matter content. The overall risk remains non-significant for ground water.
Based on these case studies, the authors propose an Environmental System Management that has the potential to reduce or minimize these risks and to protect the important asset of natural water resources in Burkina Faso.

Résumé

Le coton est le plus important produit d’exportation du Burkina Faso et la principale source de croissance économique. Mais la production cotonnière utilise une grande quantité de pesticides. Plusieurs études et rapports ont montré qu’il n’y a pas un respect des Bonnes Pratiques Agricoles (BPA) par les agriculteurs. Les sols sont fragiles contenant une faible matière organique et sont sujets à l’érosion. Cela se traduit par un potentiel de contamination des eaux de surface à la fois à travers le ruissellement et l’érosion. De plus, la situation est compliquée par les fortes intensités de pluies durant la saison humide.

Malgré cette menace potentielle sur les ressources en eau liée à l’utilisation des pesticides dans de telles conditions, peu d’études ont été entreprises pour l’évaluer. Ce travail décrit la première évaluation des risques à la fois pour les eaux de surface et les eaux souterraines liés à l’utilisation des pesticides en production cotonnière au Burkina Faso.

L'outil primaire utilisé est un logiciel appelé “Pesticide Impact Ranking Index” (PIRI) ou “Index de classement des pesticides selon leur impact” lequel outil a été développé par le CSIRO. PIRI a été employé pour mesurer la pollution et l’impact toxicologique sur l'environnement par des pesticides :

- En classant les pesticides en termes de leur potentiel de pollution relative à l’eau souterraine et/ou à l’eau de surface ; et

- En comparant différentes utilisations de la terre dans une captation ou à une échelle régionale en termes de leur impact relatif sur la qualité de l'eau.

L'application de PIRI aux pesticides utilisés au Burkina Faso le coton montre les tendances globales suivantes :

- Les pesticides utilisés pour le contrôle des mauvaises herbes, et pour la protection des semences sont classés en impact faible. Ils ne représentent une menace prééminente ni pour les eaux de surface ni les eaux souterraines dans leurs conditions d’utilisation au Burkina.
Les pesticides utilisés comme insecticides en application foliaire. Pour l’impact de tous les insecticides sur les eaux de surface, l’utilisation de l’endosulfan constitue la plus grande menace pour les eaux de surface. Les autres produits ne représentent pas une grande menace excepté les situations de sols à faible taux de matière organique avec des cultures proches des cours d’eau. Pour l’impact de tous les insecticides sur les eaux souterraines, tous les produits sont classés en très faible risque d’impact excepté benfuracarb qui est classé en risque d’impact excessivement élevé seulement pour les situations de sols à très faible taux de matière organique. Le risque global reste non significatif pour les eaux souterraines.

En se basant sur ces études de cas, les auteurs proposent un System de Gestion Environnemental qui a le potentiel de réduire ou de minimiser ces risques et de protéger les valeureuses ressources en eaux du Burkina Faso.
Introduction

Cotton is the most important export product of Burkina Faso and the principal source of economic growth. In 2004-2005, the national production was 632,355 tones of cotton grain on 566,278 ha by more than 325,000 farmers [1].

Cotton has on average contributed 66.5% of Burkina Faso’s exports over the last five years. (Source: ONAC Stat. Customs – INSD (2002) quoted by TOE and KINANE [2].

Several studies and reports have shown there is non-compliance with the Good Agricultural Practices (GAP) by the farmers [3]; [4]; [5]. The soils are fragile, containing low organic matter, and are subject to erosion. This results in a potential for the contamination of surface water both through direct runoff and through soil erosion. In addition, the situation is compounded by the high rainfall intensities experienced during the wet season.

On the whole, pesticides represent real dangers at three (3) levels:

1. Toxicity of the pesticides for the users in agricultural sector and the professionals of plant health industry [6]; [7];
2. Toxicity for the consumer related to the presence of toxic residues [8];
3. Pollution and Toxicology of the Environment [9].

To quantify the pollution and toxicology to the environment by pesticides, a software package “Pesticide Impact Ranking Index” (PIRI) has been developed by CSIRO [10]. This package:

- Ranks pesticides in term of their relative pollution to ground and/or surface water; and
- Compares different landuses in a catchment or at a regional scale in terms of their relative impact on water quality.
The present study is an application of PIRI to pesticides used on cotton in Burkina Faso. The main purpose of the study is:

- To evaluate the potential risks of contamination of both surface water and ground water;
- To evaluate the indirect risks to humans and animals using the natural resource in water; and
- To work out a ranking index of the pesticides used in the production of cotton.

**Materials and methods**

The following resources were used in this study:

- The software package PIRI [10] (Appendix 1)
- Data on cotton cultivation (including data on pesticides used and their characteristics (*Table I*)
- Land Use information

We had distinguished 3 groups of pesticides:

Group 1: herbicides

Group 2: fungicides and insecticides for seed protection

Group 3: insecticides in foliar spraying

The land use information for the pesticides of group 1 and 2 (herbicides and seed protection pesticides) differs from that of group 3 in that the ground is bare with no buffer zone and they are applied once a year.

For the pesticides of group 3 (insecticides in foliar spraying) applied many times a year, for the land use information we have had defined 5 scenarios taking into account 4 factors:

- The distance between the field and the water body,
- The width of the buffer zone,
- The number of days between the application and the rainfall;
- The percentage of soil organic matter.

Scenario 1 (Table II) is most like the current situation for the pesticides of group 3 (foliar sprayed). Even though there is no special buffer zone managed by the farmers, on the whole the fields of cotton are separated from the sources of water by bush or by other crops not treated with pesticides which can to some extent be considered as a buffer zone. Scenarios 2, 3, 4 and 5 may be considered as rare situations (Table III).

### Table I Characteristics of insecticides used on cotton

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Classification</th>
<th>Spray type</th>
<th>Dosage (kg or litres product/ha)</th>
<th>Fraction active ingredient</th>
<th>Frequency of application (times/period of interest)</th>
<th>Percentage of farm</th>
<th>Toxicity (LC50, Rainbow Trout)</th>
<th>Sorption in environment (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endosulfan</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>2</td>
<td>0.35</td>
<td>1</td>
<td>35</td>
<td>0.002</td>
<td>12400</td>
</tr>
<tr>
<td>Esfenvalerate</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.015</td>
<td>1</td>
<td>35</td>
<td>0.00007</td>
<td>5300</td>
</tr>
<tr>
<td>lambda-cyhalothrin</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.012</td>
<td>1</td>
<td>35</td>
<td>0.00024</td>
<td>180000</td>
</tr>
<tr>
<td>Cypermethrin</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.03</td>
<td>1</td>
<td>35</td>
<td>0.00069</td>
<td>100000</td>
</tr>
<tr>
<td>Chlorpyrifos</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.2</td>
<td>1</td>
<td>35</td>
<td>0.03</td>
<td>6070</td>
</tr>
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<td>Cyfluthrin</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
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<td>0.018</td>
<td>1</td>
<td>35</td>
<td>0.006</td>
<td>100000</td>
</tr>
<tr>
<td>Deltamethrin</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.01</td>
<td>1</td>
<td>35</td>
<td>0.0009</td>
<td>100000</td>
</tr>
<tr>
<td>Benfuracarb</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.1</td>
<td>1</td>
<td>35</td>
<td>0.037</td>
<td>316</td>
</tr>
<tr>
<td>alpha-cypermethrin</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.015</td>
<td>1</td>
<td>35</td>
<td>0.0028</td>
<td>100000</td>
</tr>
<tr>
<td>Profenofos</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.2</td>
<td>1</td>
<td>35</td>
<td>0.08</td>
<td>2000</td>
</tr>
<tr>
<td>Dimethoate</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.4</td>
<td>1</td>
<td>35</td>
<td>6.2</td>
<td>20</td>
</tr>
<tr>
<td>Omethoate</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.3</td>
<td>1</td>
<td>35</td>
<td>9.1</td>
<td>50</td>
</tr>
<tr>
<td>Methamidophos</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.3</td>
<td>1</td>
<td>35</td>
<td>25</td>
<td>5</td>
</tr>
<tr>
<td>Pyriproxyfen</td>
<td>insecticide</td>
<td>Foliar sprayed 240+-20 microns</td>
<td>0.5</td>
<td>0.01</td>
<td>1</td>
<td>35</td>
<td>0.325</td>
<td>20142.9</td>
</tr>
</tbody>
</table>
### Table II Land Use information for Cotton

<table>
<thead>
<tr>
<th>Land use</th>
<th>Soil type of land use</th>
<th>Soil organic matter (%)</th>
<th>Total rainfall during period of interest (mm)</th>
<th>Total irrigation during period of interest (mm)</th>
<th>Recharge rate during period of interest (mm)</th>
<th>Average minimum air temperature during period of interest (degrees C)</th>
<th>Average maximum air temperature during period of interest (degrees C)</th>
<th>Depth to water table (metres)</th>
<th>Diameter of nearest water body (metres)</th>
<th>Distance from edge of crop to water body (metres)</th>
<th>Slope of land to water body (degrees)</th>
<th>Width of buffer zone (metres)</th>
<th>Estimated average soil loss (tonnes/ha) during period of interest</th>
<th>Minimum number of days from application of pesticide to first rainfall/irrigation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sand</td>
<td>1</td>
<td>1000</td>
<td>0</td>
<td>150</td>
<td>25</td>
<td>35</td>
<td>10</td>
<td>100</td>
<td>1000</td>
<td>11.4576283903</td>
<td>100</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

### Table III Scenarios considered for the study of pesticides used in foliar application for cotton

<table>
<thead>
<tr>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
<th>Scenario 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance between field / water body (m)</td>
<td>1000</td>
<td>100</td>
<td>100</td>
<td>10</td>
</tr>
<tr>
<td>Width of buffer zone (m)</td>
<td>100</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Delay between spray and rainfall in days</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Soil organic matter(%)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Results and discussion

On the whole, the pesticides used for seed protection (endosulfan, thiram, imidacloprid, metalaxyl, carbendazin and for weed control as herbicides (pendimethalin, paraquat, terbutryln, diuron, prometryn, fluometuron, clomazone) don’t represent a major threat either for surface water or for ground water. This is likely related to their conditions of use in Burkina Faso where they are applied once a year [11]. In a study based on a probabilistic risk assessment method similar low risk of impact for surface water was found for atrazine [12].

On the other hand, there is some concern about a few of the pesticides used as insecticides in foliar spraying. According to the scenarios, the results are as follows:

- **Surface water toxicity impact, insecticides.**

  On the whole, on taking into account all 5 scenarios (Table IV), we can distinguish according to the results of each individual rating, 5 situations in progressing from the lower risk to the higher risk group:

  - A group of 8 pesticides namely, cyfluthrin, deltamethrin, Alpha-cypermethrin, profenofos, dimethoate, omethoate, methamidophos, pyriproxyfen present a very low risk impact irrespective of the scenario considered;

  - A second group of 2 pesticides Lambda-cyhalothrin and cypermethrin present a low risk impact whatever the scenario considered;

  - Benfuracarb is rated with a low or very low risk impact for the first four scenarios but is rated in the medium risk category for the last scenario.

  - A second group of 2 pesticides chlorpyriphos and esfenvalerate move from a very low risk impact with the first scenario to a very high and Exc. High risk (respectively) with the last scenario;

  - Endosulfan presents a potential threat whatever the scenario considered. It is always ranked from a high risk impact to an Exceedingly High risk impact (Fig.1). The reasons of the threat to the environment (for surface water) of this organochlorine insecticide that is being used on cotton is due to its dose, and its persistence time. The
amount of endosulfan used on cotton to control insects is normally 700g/ha of a.i., its toxicity (LC50) to rainbow trout is 0.002 mg L\(^{-1}\) and it has a persistence in the environment of 50 days. This threat on surface water by endosulfan revealed by PIRI has also been confirmed by the presence of endosulfan residues carried out by GPC-ECD in water samples in the cotton region where this chemical is used [13].

Table IV  Insecticides rating for surface water on different scenarios of agricultural practice

<table>
<thead>
<tr>
<th>Pesticides</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
<th>Scenario 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>endosulfan</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Very high</td>
<td>Ex. high</td>
</tr>
<tr>
<td>esfenvalerate</td>
<td>Very low</td>
<td>Low</td>
<td>medium</td>
<td>High</td>
<td>Ex. high</td>
</tr>
<tr>
<td>chlorpyriphos</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>medium</td>
<td>Very high</td>
</tr>
<tr>
<td>Lambda-cyhalothrin</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>cypermethrin</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>benfuracarb</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Low</td>
<td>medium</td>
</tr>
<tr>
<td>cyfluthrin</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Low</td>
</tr>
<tr>
<td>deltamethrin</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>Alpha-cypermethrin</td>
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<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>profenofos</td>
<td>Very low</td>
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<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
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<td>Very low</td>
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<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>omethoate</td>
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<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>methamidophos</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
<tr>
<td>pyriproxyfen</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
<td>Very low</td>
</tr>
</tbody>
</table>
Figure 1 Insecticides used on cotton rated for surface water impact (scenario 5)

- **Ground water toxicity impact insecticides (Table V)**

For the impact of all the insecticides on the ground water, whatever the scenario considered, there is no significant change. All the products are rated at a very low risk impact except benfuracarb which is rated at an Exceedingly High risk impact scenario 5 only (Fig.2). The overall risk remains non-significant for ground water.

The threat on the environment related to the use of pesticides to some extent depends on some factors underlined in our studies. They are:

- the low organic matter content in soil the soil;
- the short distance between the field and the water body;
- the absence of any managed buffer zones;
- the short space of time between the any rainfall and the application of pesticides.
The characteristic of the pesticides is obviously a determining factor. The low impact of the pesticides as given by PIRI may be distorted depending on the value accorded to the water, because of the mosaic of the crops and of the array of pesticides being used. Pesticides with similar active ingredients are being used, and a more realistic measure of their impact would be the sum of their impacts.

In summary, the key factor susceptible to reducing or increasing the threat of the products to both the surface water and ground water seem to be the soil organic carbon content. For surface water only the buffer zone could reduce the threat. An environmental system management with a buffer zone on a soil with a good level of organic matter combined with the choice of pesticides that present less threat, is desirable.

Tools like PIRI will play a key role in the future in the assessment of pesticides risks on waters. CHEN et al.; [14] on analyzing a surface water mobility index (SWMI) based mainly on degradation half life and $K_{oc}$ (also taken into account in PIRI) to the concentrations of pesticides in agricultural drainage watersheds found that there were statistically correlated.

<table>
<thead>
<tr>
<th>Pesticides</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
<th>Scenario 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>endosulfan</td>
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<td>Very low</td>
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<td>Very low</td>
</tr>
<tr>
<td>esfenvalerate</td>
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<td>Very low</td>
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<td>Lambda-cyhalothrin</td>
<td>Very low</td>
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<td>Very low</td>
<td>Very low</td>
</tr>
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Conclusion

The overall trends related to the risks of using pesticides in Burkina Faso shows that for cotton production:

- the use of endosulfan as a foliar application for insecticides could lead to the greatest potential threat to the surface water.
The other pesticides don’t represent a large threat except with soils of low organic matter content and fields near the surface water;

It is noteworthy that these results are obtained in considering specific situations of land use. Other results with bad conditions of land use and bad Agricultural Practices could lead to severe impact of pesticides on the water resources.

In the context of Burkina Faso, water resources are very important. In the context of Burkina Faso, the surface water represents an important asset because it is drunk by humans and also by both domestic and wild animals. In addition fish from this water are consumed and sometimes the water is used for irrigation. Consequently, the protection of this natural resource is very important. In considering the major factors responsible for the threat such as: the soil organic matter content, the distance between the field and the water body, the width of the buffer zone, the number of days between the application and the rainfall, the three first factors might be monitored because they could be controlled. Another controlling factor is that the choice of pesticides can be modified by the growers.

In short, the threat of pesticides to natural water resources is evident in some extent. It must be alleviated and monitored. Up to now there is no Environmental Management System for cotton culture in Burkina Faso. This lack must be corrected. Our work sets up the basis of such upcoming programs based on relevant selections of pesticides, the setting up of appropriate buffer zones and the distance between the field and the water body.

This assessment of the risks related to the pesticides used in Burkina Faso is one of the firsts in the history of Burkina Faso and probably in many Sahelian countries. We hope that it will be regarded as a good step in the right direction. In anticipation, we thank all those Government, Companies, International Institutions, and Non Governmental Organizations for their awareness of the importance of conservation of natural water resources, who will help us to continue to examine and improve this work.

PIRI seems to be very adapted for the developing countries like Burkina Faso with poor resources and where the setting up and maintenance of laboratories are very difficult. PIRI could be a handy tool for help in decision taking.
Acknowledgements

The authors gratefully acknowledge:

- Government of Burkina Faso and his companies responsible for the production and trade of cotton (SOFITEX) and his company of formulation of pesticides (SAPHYTO).
- CSIRO for the supply of facilities for this project.
- IAEA who funded this project (№: RAF/0/018) and Fellowship BKF/01001

References


APPENDIX A  The software package PIRI

(Developed by Dr. R. Kookana, Dr. R. Correll and Mrs R. Miller, 2003)

- provides ratings for each pesticide’s pollution potential to surface and ground water;
- assesses relative impacts of different land uses in a catchment;
- serves as an education tool and enhances awareness of the potential risk of pesticides;
- is user-friendly, being simple and easy to use;
- is scientifically sound and semi-quantitative;
- considers pesticide toxicity to fish, flea, algae and humans
- integrates pesticide properties (toxicity, persistence in the environment, sorption to soil), their use scenario and specific soil and site conditions (permeability, depth of water table and water input).
- utilises built-in data bases and requires minimum input parameters. Where possible, sensible default values are provided to assist the users.
- contains a data base which includes information on a large number of pesticides – their fate data (sorption, degradation), toxicity data (LC50 for fish, daphnia, algae), drinking water Health Advisory Levels, and recommended rates for pesticide use for selected land uses.
- has been compared with the results of pesticide residue monitoring in two intensive agricultural areas and found to be correct in more than 80% of cases.
Policy guidance:

Working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II

Introduction

The purpose of this paper is to assist the Chemical Review Committee (CRC) in judging the acceptability of a notification of final regulatory action with respect to criteria (b) (i), (b) (ii) and (b) (iii) of Annex II.

The criteria for listing banned or severely restricted chemicals in Annex III of the Convention are set out in Annex II of the Convention. Paragraph 3 of Annex II requires that the CRC “establish that the final regulatory action has been taken as a consequence of a risk evaluation.” It further states that “the evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question” and lists three criteria (b (i) to (iii)) against which the supporting documentation is to be reviewed by the Committee.

This working paper, originally considered at the second meeting of the CRC, was developed based on the findings of two task groups established by the Committee at its first meeting. The guidance was amended with further examples included based on the experience gained at the second and third meetings of the CRC and guidance provided by the third meeting of the Conference of the Parties. The guidance will continue to evolve in the light of future experience.
Introduction

1. The present working paper is divided into three chapters: chapter I provides a brief background on the relationship between the information requirements for notifications submitted under Article 5 of the Convention and the criteria set out in Annex II of the Convention for listing banned or severely restricted chemicals in Annex III of the Convention; chapter II provides guidance aimed at eliminating ambiguity and improving consistency in referring to criteria (b) (i) and (b) (ii) in the analysis of the notifications; chapter III provides an initial list of examples as a basis for further guidance to the Chemical Review Committee in defining minimum requirements for information on the exposure component of a risk evaluation. This list will be expanded on an ongoing basis as further practical experience is gained in reviewing candidate chemicals.

I. Background

2. Annex I of the Convention sets out the information requirements relevant to a notification of final regulatory action submitted under Article 5 of the Convention. The information requirements of Annex I were the basis for the notification of regulatory action form which was developed to provide a standardized format for reporting national final regulatory actions.

3. The information contained in the notification of final regulatory action and accompanying supporting documentation are considered by the Committee in the light of the criteria for the inclusion of chemicals in Annex III of the Convention set out in Annex II of the Convention.

4. Annex II states:

   “In reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall:

   . . .

   (b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

   (i) Data have been generated according to scientifically recognized methods;

   (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

   (iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.

II. Application of criteria (b) (i) and (b)(ii)

5. Criteria (b) (i) and (b) (ii) are particularly relevant to two specific paragraphs of the information requirements listed in Annex I.

6. Paragraph 1 of Annex I sets out the information on the properties, identification and uses of a substance, including recognized names of the substance, relevant code numbers and hazard classification, as well as physico-chemical, toxicological and eco-toxicological properties.

7. In submitted notifications, this includes lists of physicochemical parameters such as melting and boiling points or lists of toxicological or eco-toxicological endpoints including, LD50 and LC50 data for a range of laboratory animals, birds and fish. In most countries this information is not generated nationally, but may be found in a range of internationally recognized sources1. Information referenced from such sources is considered to have met criteria (b) (i) and (b) (ii).

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1 Internationally recognized sources include the Pesticide Manual, documents generated by the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), the International
8. At its third meeting, the Conference of the Parties endorsed the approach recommended in the secretariat’s note, namely that the Committee should consider risk evaluations under the Montreal Protocol and the Stockholm Convention as adequate support for meeting criteria (b) (i) and (b) (ii).

9. Paragraph 2 (a) of Annex I sets out specific information to be provided that describes the final regulatory action to ban or severely restrict the chemical. This includes information on the risk or hazard evaluation upon which the regulatory decision was based, reasons for the regulatory action relevant to human health or the environment, a summary of the hazards and risks presented by the chemical and the expected effect of the final regulatory action.

10. In notifications, this information is generally in the form of a short written statement which briefly explains the risk or hazard evaluation on which the national regulatory action was based and a reference to the relevant documentation. The supporting documentation prepared by the country submitting the notification, including a focused summary, generally provides more detailed information regarding the basis for the regulatory action. The risk or hazard evaluation may include a combination of hazard information from internationally recognized reference sources as well as information on exposure under the prevailing conditions in the notifying country.

11. On the one hand, hazard information is not for the most part generated nationally, but is drawn from a range of internationally recognized sources, and information from such sources is generally considered to have met criteria (b) (i) and (b) (ii). On the other hand, information on exposure relevant to prevailing conditions in the notifying country is largely generated at the national level, and whether or not this information meets criteria (b) (i) and (b) (ii) will need to be considered on a case-by-case basis.

12. There are four basic scenarios relevant to a consideration of criteria (b) (i) and (b) (ii) of Annex II and the information requirements of Annex I. A description of the scenarios and how criteria (b) (i) and (b) (ii) might apply to each follows:

**Scenario 1:** Data are not provided and there is no reference to a source of data in the notification or in the supporting documentation.

- Criteria (b) (i) and (b) (ii) would not be met.

**Scenario 2:** Data are provided but the source of the data is not referenced in the notification or in the supporting documentation.

- Criteria (b) (i) and (ii) would not be met as it would not be possible to verify that the data have been generated according to scientific principles and procedures or that the data reviews have been performed and documented according to generally recognized scientific principles and procedures.

**Scenario 3:** Data are not provided but there is a reference to a source of data in the notification or in the supporting documentation.

- Criteria (b) (i) and (ii) would be met where the notifying country merely references a source document, without drawing out the specific information which they have used to make their decision, provided that the reference is to an internationally recognized source including a risk evaluation undertaken under the Stockholm Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case-by-case basis.

**Scenario 4:** Data are provided and the source of the data is referenced in the notification or in the supporting documentation.

- Criteria (b) (i) and (b) (ii) would be met, provided that the data are from an internationally recognized source including a risk evaluation undertaken under the Stockholm Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case-by-case basis.

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Agency for Research on Cancer (IARC) and the United Nations Environment Programme (UNEP) as well as data from decision-guidance documents.

2 Paragraph 66 UNEP/FAO/RC/COP.3.26
III. Application of criterion (b) (iii)

13. At its first meeting, the Committee decided to accept the policy guidance on risk evaluation in the context of the Rotterdam Convention contained in document UNEP/FAO/RC/CRC.1/13 as a work in progress and to amend it as necessary in the light of further experience\(^3\). In order to facilitate the work of the Committee in reviewing risk evaluations, the guidance set out some examples as a means of defining the minimum requirements for information regarding exposure.

14. At its second meeting, the Committee considered a working paper which had been developed by the Secretariat based on the work of the task groups established at the first meeting of the Committee (UNEP/FAO/RC/CRC.2/7). The meeting commended the secretariat on the paper which they said provided very useful guidance to the Committee. It was proposed that further examples identified during that meeting would be included in subsequent revisions of the document\(^4\).

15. At its third meeting, the Conference of the Parties endorsed the approach recommended in the secretariat’s note, namely that in order for criterion (b) (iii) to be met, bridging information providing evidence of the prevailing conditions in the notifying country would need to be submitted.\(^5\)

16. The examples listed here are intended to serve as guidance to the Committee on how to document or explain the exposure component of a risk evaluation in order to facilitate its work and to help ensure transparency and consistency.

17. It is understood that the Committee will consider notifications on a case-by-case basis and that this list of examples will be expanded or refined as experience is gained in reviewing notifications in support of candidate chemicals. This guidance is intended to be interpreted flexibly.

**Example 1: Incidents involving direct exposure of humans**

Information is required describing direct exposure to a chemical and any adverse effects resulting from that exposure. Thus a description of the incident should be provided which may include, for example, the extent or number of casualties, its circumstances and a description of the signs, symptoms and/or effects.

**a) Actual or measured exposure**

This is based on a situation in which a country has taken a national regulatory action based on a risk evaluation which includes an assessment of exposure based on empirical or measured levels of a chemical that reflect the prevailing conditions in the notifying country.

**Example**

i) The regulatory action on DNOC notified by Peru and considered at the third session of the Interim Chemical Review Committee (ICRC) was based on hazard data supplemented by a study of poisoning incidents in the country. ICRC concluded that, taken together, the material demonstrated that there had been a risk evaluation that took into account prevailing conditions in that country (UNEP/FAO/PIC/ICRC.3/19, annex II).

**b) Expected or anticipated exposure**

This is based on the concept that a country can notify a national regulatory action that is based on expected exposure. Such exposure information might be developed based on modelling data generated by international organizations or other Governments and adapted to the anticipated exposure and prevailing conditions in the notifying country.

The guidance that has been developed on common and recognized patterns of use of severely hazardous pesticide formulations (UNEP/FAO/RC/CRC.9) may be relevant to certain elements of this discussion.

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\(^5\) Paragraph 66 UNEP/FAO/RC/COP.3.26
For acutely toxic pesticides or industrial chemicals, this could include information on the availability and common use of protective equipment or poisoning scenarios (if relevant and available), a description of how a chemical was used—or a description of the conditions of storage, transport or disposal and potential exposures in each scenario.

**Examples**

i) Comparison of mammalian and environmental toxicity data with anticipated exposure levels generated using models. A case example is the European Union notification regarding methyl parathion (UNEP/FAO/RC/CRC.1/28, annex V, para. 10).

   o The notification and supporting documentation showed that the final regulatory action had been based on a chemical-specific risk evaluation taking into account the conditions of exposure within the European Community. The risk evaluation of the pesticidal uses of methyl parathion concluded that, on the basis of the results of several exposure models, there were unacceptable risks to workers and non-target organisms (insects, birds, aquatic organisms and mammals) due to the acute and chronic toxic effects of methyl parathion.

ii) For non-threshold carcinogens, there may be a national policy that no exposure is acceptable. Thus, a description of the anticipated use of the chemical may be sufficient, with no specific information on exposure needed. A case example is the Canadian notification of bis (chloromethyl) ether (UNEP/FAO/RC/CRC.1/28, annex V, paras. 25-26).

   o Canada concluded that bis (chloromethyl) ether was a non-threshold carcinogen in humans. As a result it was understood that there is some probability of adverse effect at any level of exposure. Although levels at the time of the regulatory action did not pose a threat to human health, the regulatory action was put in place as a precautionary measure to protect the health of Canadians. This approach is consistent with the objective that exposure to non-threshold carcinogens be reduced wherever possible, and obviates the need to establish an arbitrary de minimis level of risk. Based on this, the Chemical Review Committee at its first session concluded that the supporting documentation showed that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within Canada.

iii) Pesticides with defined hazard classifications, e.g., WHO hazard classification 1a or 1b, may be subject to national policy that they not be registered based on the understanding that the prevailing conditions of use in a country will result in unacceptable risk to workers or the environment. In such a case, a description of the anticipated use of the chemical may be sufficient, with no specific information on exposure needed.

   o Specific example to be identified

**Example 2: Incidents involving direct exposure of the environment (wildlife, livestock, etc.)**

Information is required describing the direct exposure to the chemical and the adverse effects resulting from that exposure. Thus, a description of the incident should be provided, which may include, for example, the extent or number of casualties, its circumstances and a description of its effects.

**a) Actual or measured exposure**

For both pesticides and industrial chemicals this could include a description of how a chemical was used and or a description of the conditions of storage, transport or disposal and potential environmental exposures in each scenario.

**Examples**

i) Comparison of toxicity data for fish and monitoring data (measured exposures in surface water). A case example is the notification by the Netherlands regarding methyl bromide (UNEP/FAO/RC/CRC.1/28, annex V, para. 3).
The risk evaluation of the Netherlands focused on the behaviour and effects of methyl bromide in air, groundwater and surface water. The estimated concentration in groundwater amounted to approximately 100 µg/L, based on a soil degradation half-life of about 15 days and a sorption constant of about 2.5 L/kg. The measured concentrations in surface water amounted to approximately 9 mg/L, which resulted in the expectation of a very high risk for fish (LC$_{50}$ (96h) 3.9 mg/L). The Committee agreed that the evaluation of the risks to aquatic organisms met the requirements of the criterion with respect to the prevailing conditions of use in the Netherlands.

Comparison of toxicity data for fish and observation of effects on non-target organisms including fish and other aquatic organisms following application of endosulfan to rice paddies in Thailand for the control of golden apple snail. (UNEP/FAO/RC/CRC.2/20, Annex II, para 3).

The Committee confirmed that Thailand had severely restricted endosulfan, as commonly used in Thailand, by banning emulsifiable concentrate and granular formulations, whereas the use of capsulate formulation remained registered. This decision was based on a national risk evaluation as follows: a survey in five provinces to assess the use of endosulfan for golden apple snail control in paddy fields showed that approximately 94 per cent of farmers used pesticides and that, of those, 60–76 per cent used endosulfan. There were no measured concentrations of endosulfan in the treated paddies however the death of fish and other aquatic organisms was reported in every province and emulsifiable concentrate (EC) and granule (GR) formulations were known to be very toxic to fish and aquatic organisms.

**b) Expected or anticipated exposure**

This is based on the concept that a country can notify a national regulatory action that is based on expected exposure. Such exposure information might be developed based on modelling data that is generated by international organizations or other Governments and adapted to the anticipated exposure and prevailing conditions in the notifying country.

For both pesticides and industrial chemicals, this could include a description of how a chemical was used, or a description of the conditions of storage, transport or disposal and potential environmental exposures in each scenario.

The guidance developed on common and recognized patterns of use of severely hazardous pesticide formulations (UNEP/FAO/RC/CRC.9) may be relevant to certain elements of this discussion.

**Examples**

i) Comparison of mammalian and environmental toxicity data with anticipated exposure levels generated using models. Case examples include the following:

- Methyl-parathion - European Union (EU) notification (UNEP/FAO/RC/CRC.1/28, annex V, para. 10)

The EU notification demonstrated that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within the European Community. The risk evaluation of the pesticidal uses of methyl parathion concluded that, on the basis of the results of several exposure models, there were unacceptable risks to workers and non-target organisms (insects, birds, aquatic organisms and mammals) due to the acute and chronic toxic effects of methyl parathion.


The Netherlands notification banned all uses of endosulfan on basis of a national risk evaluation. It was found that application of endosulfan according to good agriculture practice would result in surface water concentrations that would significantly affect aquatic organisms (especially fish). Emission of endosulfan to surface water will occur as a result of spraying drift during application. The surface water concentration of endosulfan during application was estimated with a dispersion model. Assuming a drift emission factor of 10 per cent, an endosulfan concentration of 0.014 mg/l was calculated. A comparison of this concentration with the lowest LC$_{50}$ for fish (0.00017 mg/l) results in a risk quotient of 82, which was considered unacceptable.

- Dicofol – Netherlands notification (UNEP/FAO/RC/CRC.2/20 annex III paras 1 and 2)
The notification demonstrated that the final regulatory action had been based on estimated concentrations of the chemical in the environment taking into account the prevailing conditions in the Netherlands. The risk evaluation concluded that, on the basis of the results of modelled exposure there were unacceptable risks to non-target organisms (predatory birds feeding on fish) due to persistence and bioaccumulation of dicofol.

Dicofol is a persistent chemical. Laboratory experiments found the chemical to be highly accumulative (bioconcentration factor (BCF) of about 10,000), a property that might lead to effects via the food chain (secondary poisoning). In addition, further experiments revealed effects on the reproduction of owls and pigeons where eggshell thinning at a concentration of 3 mg/kg feed was demonstrated. Modelling estimations indicated that application (according to good agriculture practice) of dicofol would lead to exposure of fish-eating birds. Based on the BCF there is an estimation of about 30 mg/kg feed, assuming a diet of 100 per cent contaminated fish to be eaten by predatory birds. Concentration in fish and predatory birds may reach levels as a result of continuous build-up in the tissues which lead to significant adverse effects. This is clearly deemed unacceptable.

Example 3: Indirect exposure via the environment (air, water, soil)

The description of indirect exposure via the environment should address the following:

(a) How the presence of a chemical in the environment results in human and environmental (actual or expected) exposure. Actual exposure can be directly measured. Expected exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical, would facilitate the work of the Committee.

Examples

i) The presence of a chemical in the environment in itself is not sufficient to meet criteria b (iii).


Jordan had banned endosulfan because it was persistent in the environment and residues had been found in soil. The decision to ban endosulfan had been based on research findings pointing to the chemical’s carcinogenic properties and statements that it was found in groundwater.

Information available to the Committee (monitoring data) indicated the presence of endosulfan in the soil, but no residues of endosulfan had been reported in groundwater in Jordan. At its fifth session, the Interim Chemical Review Committee concluded that it was not clear that presence in the soil would lead to human or environmental exposure.

ii) Some chemicals have characteristics that allow them to bioconcentrate or biomagnify to levels that cause toxic effects. A regulatory action may have been taken as a precautionary measure to reduce or eliminate future risks to humans or wildlife. There may be special concerns with endangered species (environmental risk) or human subpopulations with high consumption of seafood and other traditional food (health risk). Thus, information about the persistence, biomagnification/bioconcentration and toxic properties of the chemical together with a description of the use, releases and anticipated exposure to the chemical could be the basis of the decision. A case example includes the following:

○ Mirex – Canadian Notification (UNEP/FAO/RC/CRC.2/20, annex III D)

Canada banned mirex because it is persistent, bioaccumulative and subject to transboundary movement. The decision to ban mirex was based on the fact that it has been demonstrated to cause cancer in laboratory animals and it is possibly carcinogenic in humans. Mirex contaminates several ecosystems in Canada. Human dietary exposure to mirex is generally low with the possible exception of the group dependant on a diet of fish or fish feeding birds from Lake Ontario and the St Lawrence River and of hunters eating game birds.

iii) Indirect exposure may also be considered to include indirect effects that result from the action of a chemical on another system. Such actions may in turn have direct and indirect impacts for example the direct impact of increased ultraviolet radiation on the notifying Party or an indirect

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6 Bioaccumulation is considered as a broader term covering both processes.
impact as a result of the general effects associated with the release to the environment of a chemical that contributes to the depletion of the ozone layer.

**Ozone depletion:**

*Direct effects:* The direct impact to the environment by a chemical that depletes the ozone layer could include the resultant increase in exposure to the damaging effects of UV radiation. The extent of the effect on individual countries would vary with their geographical location, as certain areas of the globe (such as polar regions) are more affected by ozone depletion. For example, ozone levels in equatorial regions have remained relatively stable, both throughout different seasons within a year and from year to year, while higher latitudes have demonstrated significant seasonal variations associated with the spring formation of ‘ozone holes’ over the poles. Human exposure to UV-B depends upon not only an individual’s location (latitude and altitude) but also the duration and timing of outdoor activities (time of day, season of the year) and precautionary behaviour (use of sunscreen, sunglasses and protective clothing). An individual’s skin colour and age can influence the occurrence and severity of some of the health effects from exposure to UV-B. There may also be effects on terrestrial plants, aquatic ecosystems and climate. A case example includes the following:


Canada banned carbon tetrachloride based on a conclusion that it had an ozone-depleting potential and created indirect hazards via the environment. In the Canadian Arctic, UV levels can increase substantially from season to season, owing to the hole in the ozone layer, which is caused by ozone-depleting substances such as carbon tetrachloride. In the light of that, the Chemical Review Committee at its first session concluded that the final regulatory action had been taken as a consequence of a risk evaluation. Other supporting documentation showed that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within Canada (UNEP/FAO/RC/CRC.1/28, annex V, section E).

*Indirect effects:* There are complex links between changes in the ozone layer and climate change effects. Ozone-depleting substances may act as greenhouse gases and may therefore contribute to global warming, while it is not clear what effect actual depletions in the ozone layer may have on climate change. Releases of ozone-depleting substances may be considered to have a global effect and a Party may make statements relating to these effects as supporting information for its decision to ban the chemical.

- Specific example to be identified

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WHO Briefing Meeting

To Lead into the Test Phase of the WHO Draft Risk Assessment Toolkit (RA Toolkit)

29-30 July 2009, Chulabhorn Research Institute
Bangkok, Thailand

Information for participants concerning the pilot phase, Jul-Oct 2009:

What is the aim of the pilot phase?

To test the RA Toolkit by addressing a risk assessment problem and to provide comments to the WHO secretariat, including comments on the concept (for example, the use of generic and case-specific roadmaps), information resources and tools, comprehensiveness, readability, and utility.

How will WHO collect this information from you?

(i) WHO will provide you with an evaluation questionnaire that you can complete with your views on general and specific sections of the RA Toolkit. The evaluation questionnaire will be filled in for each testing scenario/chemical (problem statement that has been addressed) and submitted to WHO.

(ii) You will prepare an executive summary for each problem statement that will inform the WHO secretariat about (a) the chemical problem that has been addressed by using and testing the RA Toolkit as well as the findings of the RA, (b) the process that has been applied (with information on team composition, roles and responsibilities, methods and information resources used, etc.) In addition, the executive summary should address specific challenges that have been encountered while testing the toolkit. The executive summary will be between 2-4 pages.

Who should be involved within countries?

Workshop participants return to their countries and share information with colleagues. The countries should choose a Lead Agency for each testing scenario. Contributing agencies implement work packages depending upon roles and responsibilities in the given context.

What is the role of the Lead Agency?

• Identify, contact and inform contributing partners.
• Coordinate testing of the RA Toolkit.
• Prepare executive summaries and submit them to the WHO Secretariat.
• Collect views of partners on RA Toolkit.
• Complete and submit evaluation questionnaire.

What is the timing?
The pilot phase starts on 29 July 2009. The evaluation questionnaires and executive summaries should be submitted to WHO latest by 9 October 2009.

Whom to contact for additional information and to whom to submit outputs?
Dr Kersten Gutschmidt, Public Health and Environment, WHO, Geneva, e-mail: gutschmidtk@who.int.

What is next?
Review of RA Toolkit, including comments and experience received by the pilot phase at Task Group Meeting at three-day meeting during Oct/Nov/Dec 2009, Geneva.
Working in Groups: Scenarios

WHO Briefing Meeting To Lead into the Pilot Phase of the draft WHO Risk Assessment Toolkit (RA Toolkit)

29-30 July 2009, Chulabhorn Research Institute
Bangkok, Thailand

Dr. Kersten Gutschmidt
Department for Public Health and Environment (PHE)
World Health Organization, Geneva
WG on Scenarios: Tasks (60 minutes)

- Three WGs by RA problem for (i) water scenario; (ii) air quality problem; and (iii) Rotterdam Convention.

- Each WG:
  - Discuss typical problems in countries; e.g. typical water problems, air quality setting issues; or chemicals discussed in the context of Rotterdam Convention.
  - Output: Provide list of problems.
  - Choose testing scenarios
  - Output: Provide small problem statements of chosen scenarios.
  - Quickly apply roadmaps to chosen problems.
  - Output: List of anticipated challenges during pilot phase.

- Briefly report back to plenary.

- Discuss in plenary.
Working in Groups: Problem Statements

WHO Briefing Meeting To Lead into the Pilot Phase of the draft WHO Risk Assessment Toolkit (RA Toolkit)

29-30 July 2009, Chulabhorn Research Institute
Bangkok, Thailand

Dr. Kersten Gutschmidt
Department for Public Health and Environment (PHE)
World Health Organization, Geneva
A drinking water case study:

Does the discharge of liquid waste from the industrial operation into surface water causes health risks related to the consumption of drinking-water and food as well as related to hygiene and recreational bathing?
Case studies (cont'd)

Air quality case study:

What are the human health risks associated with a daily (24 hrs) and annual PM10 Standard of 50 and 25 microgram/m^3 taking into account the knowledge base of the WHO Guidelines, key characteristics of PM, and population characteristics that might be different from WHO assumptions.
Case studies (cont'd)

RC methyl parathion case study:

Does the handling and use of methyl parathion causes unacceptable health risks to applicators, their families and the general public?