Unclassified **ENV/JM/MONO(99)10**

Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

OLIS : 21-Apr-1999
Dist. : 23-Apr-1999

English text only

ENV/JM/MONO(99)10
Unclassified

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS

OECD SERIES ON TESTING AND ASSESSMENT
Number 17

Environmental Exposure Assessment Strategies for Existing Industrial Chemicals in OECD Member Countries

English text only

77030

Document complet disponible sur OLIS dans son format d'origine
Complete document available on OLIS in its original format

ENV/JM/MONO(99)10

OECD Environmental Health and Safety Publications

Series on Testing and Assessment

No. 17

ENVIRONMENTAL EXPOSURE ASSESSMENT STRATEGIES FOR EXISTING INDUSTRIAL CHEMICALS IN OECD MEMBER COUNTRIES

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 1999

Also published in the Series on Testing and Assessment:

No. 1, *Guidance Document for the Development of OECD Guidelines for Testing of Chemicals* (1993; reformatted 1995)

No. 2, *Detailed Review Paper on Biodegradability Testing* (1995)

No. 3, *Guidance Document for Aquatic Effects Assessment* (1995)

No. 4, *Report of the OECD Workshop on Environmental Hazard/Risk Assessment* (1995)

No. 5, *Report of the SETAC/OECD Workshop on Avian Toxicity Testing* (1996)

No. 6, *Report of the Final Ring-test of the* Daphnia magna *Reproduction Test* (1997)

No. 7, *Guidance Document on Direct Phototransformation of Chemicals in Water* (1997)

No. 8, *Report of the OECD Workshop on Sharing Information about New Industrial Chemicals Assessment* (1997)

No. 9, *Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application* (1997)

No. 10, *Report of the OECD Workshop on Statistical Analysis of Aquatic Toxicity Data* (1998)

No. 11, *Detailed Review Paper on Aquatic Testing methods for Pesticides and industrial Chemicals* (1998)

No. 12, *Detailed Review Document on Classification Systems for Germ Cell Mutagenicity in OECD Member Countries* (1999)

No. 13, *Detailed Review Document on Classification Systems for Sensitizing Substances in OECD Member Countries* (1999)

No. 14, *Detailed Review Document on Classification Systems for Eye Irritation/Corrosion in OECD Member Countries* (1999)

No. 15, *Detailed Review Document on Classification Systems for Reproductive Toxicity in OECD Member Countries* (1999)

No 16, *Detailed Review Document on Classification Systems for Skin Irritation/Corrosion in OECD Member Countries* (1999)

ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 29 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonize policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised Committees and subsidiary groups composed of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

The work of the OECD related to chemical safety is carried out in the **Environmental Health and Safety Programme**. As part of its work on chemical testing, the OECD has issued several Council Decisions and Recommendations (the former legally binding on Member countries), as well as numerous Guidance Documents and technical reports. The best known of these publications, the **OECD Test Guidelines**, is a collection of methods used to assess the hazards of chemicals and of chemical preparations such as pesticides and pharmaceuticals. These methods cover tests for physical and chemical properties, effects on human health and wildlife, and accumulation and degradation in the environment. The OECD Test Guidelines are recognised worldwide as the standard reference tool for chemical testing.

More information about the Environmental Health and Safety Programme and its publications (including the Test Guidelines) is available on the OECD's World Wide Web site (see page 8).

The Environmental Health and Safety Programme co-operates closely with other international organisations. This document was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

This publication is available electronically, at no charge.

For the complete text of this and many other Environmental Health and Safety publications, consult the OECD's World Wide Web site (http://www.oecd.org/ehs/)

or contact:

OECD Environment Directorate,
Environmental Health and Safety Division

2 rue André-Pascal
75775 Paris Cedex 16
France

Fax: (33-1) 45 24 16 75

E-mail: ehscont@oecd.org

TABLE OF CONTENTS

1.0 SCOPE **10**
2.0 BACKGROUND **10**
2.1 Objective of Exposure Assessment 10
2.2 Representation of Exposure Values 10
2.3 Representation of Variability 10
3.0 OVERALL ASSESSMENT STRATEGIES **11**
3.1 Fate and Pathways Analysis 11
3.2 Iterative or Tiered Approach 11
3.2.1 Bounding Point Estimates 12
3.2.2 Realistic Point Estimates 12
Screening *12*
Typical Values *13*
3.2.3 Realistic Exposure Distributions 13
4.0 ESTIMATION OF PECs **13**
4.1 Use of 'Weight or Multiple Lines of Evidence' Approach 13
4.2 Use of Ambient Monitoring Data 13
4.3 Use of Models 13
4.4 Spatial Scales 14
4.5 Temporal Scales 14
4.6 Environmental Compartments 14
4.7 Background Exposure 14
4.8 Connecting Measured PECs to Source(s) of Interest 15
4.9 Bioavailability of Measured PECs 15
4.10 Persistence and Bioaccumulation 15
4.11 Uncertainty and Variability 15
5.0 BIBLIOGRAPHY **16**
ANNEX **18**

ENVIRONMENTAL EXPOSURE ASSESSMENT STRATEGIES FOR EXISTING INDUSTRIAL CHEMICALS IN OECD MEMBER COUNTRIES

1.0 SCOPE

This paper reviews some general strategies used by OECD Member countries when assessing exposure in the context of risk assessments for existing industrial chemicals. It is intended as an initial overview, not as a comprehensive review. Strategies for source assessment, one of the elements of environmental exposure assessment, are in particular not fully described.

The principal documents consulted are listed in the Bibliography. Additional information on the practice of environmental exposure assessment in OECD Member countries is provided in the attached Annex.

2.0 BACKGROUND

2.1 Objective of Exposure Assessment

Environmental exposure assessments are intended either to describe the exposure of one or more populations of organisms to a chemical stressor (e.g., Environment Canada, 1997; US EPA, 1992a and 1996), or as in the European Union, to describe the concentration of a chemical in various environmental compartments which has the potential to affect organisms (European Commission, 1996). Exposure data are compared to effects data to characterize risk.

2.2 Representation of Exposure Values

Exposure is usually estimated as a "Predicted Environmental Concentration (PEC)” for impacted environmental compartments from either calculated or measured concentrations, or both. In some cases (e.g., for bioaccumulative substances), calculated or measured environmental concentrations are used to estimate doses (e.g., PECoral), especially to top predators (Cowan et al., 1995a; Environment Canada, 1997; European Commission, 1996).

2.3 Representation of Variability

Concentrations of chemicals in environmental compartments vary both spatially and with time. PECs typically attempt to describe different aspects of the variability of concentrations to which populations of organisms are exposed. As noted in US EPA (1992a), for a given set of exposure conditions (e.g., near an identified point source), or for a given exposure scenario (if a model is used), exposure values may be intended to represent:

(i) a value that likely exceeds actual exposures (a "bounding" or "worst-case" estimate),
(ii) a value that is representative of the "high end" of actual exposures (a "reasonable worst-case" estimate),
(iii) a value that is representative of "typical" exposures, or
(iv) the complete set of actual exposure values resulting from those conditions.

Type (i), (ii) and (iii) PECs are point estimates which can be used in risk quotient (e.g., PEC/PNEC) calculations. Type (iv) PECs are represented as frequency distributions, which can be incorporated into risk analyses graphically (e.g., US EPA, 1996). For a given exposure scenario, PECs may vary depending upon the nature and behavior of receptor organisms. Thus one population’s typical exposure may be another population’s high end exposure.

Often exposures associated with several different exposure scenarios (or sets of exposure conditions) are examined in one assessment. For example, in large scale regional or national assessments, several geographically distinct point sources may be of interest. In such cases PECs may represent, for example, a bounding value for all possible exposure conditions, or several "typical" or "high end" values for a range of exposure conditions (e.g., near several different sources).

3.0 OVERALL ASSESSMENT STRATEGIES

3.1 Fate and Pathways Analysis

Before exposure concentrations are estimated, environmental fate and pathways should be examined, taking into account information on the:

- physical/chemical properties of the substance, including its degradation and transformation, and bioaccumulation potential (see Section 4.10);
- nature of degradation or transformation products;
- nature of commercial uses, and amounts used;
- nature and location of principal sources of releases (taking into account the life-cycle of the substance);
- amounts, forms and timing of releases; and the
- nature of the receiving compartments.

Whenever possible this should be done quantitatively, using appropriate mathematical models (e.g., a generic fugacity model). Otherwise a qualitative analysis should be undertaken, using a conceptual fate model.

The fate and pathways analysis is intended to identify important fate processes affecting a substance, to determine the environmental compartments (air, surface or ground water, soil, sediment, biota) in which the substance is most likely to accumulate, and to define the appropriate spatial and temporal dimensions (e.g., local, regional, continental) for the assessment.

3.2 Iterative or Tiered Approach

Assessments are normally done in an iterative or "tiered" fashion. The tiers may be thought of as benchmarks, in the more-or-less continuous process of refining assessments.

The quality of an initial exposure assessment is usually driven by the quality of available information. To conserve resources when data are limited, a bounding PEC may be estimated first, with successive iterations adding more realism and detail (e.g., US EPA 1992a; Cowan et al, 1995a; Environment Canada, 1997; European Commission, 1996**;** ECETOC 1994; Wagner, 1997). When better quality information is readily available, however, the bounding step may be omitted. Although tiered systems vary, other steps often involve estimation of realistic "high end" or typical PECs for a particular exposure scenario, and finally estimation of an entire distribution of PECs (see Annex, Sections 4.2.1 and 4.3.1).

3.2.1 Bounding Point Estimates

The output from this screening may be described as a "bounding" (US EPA 1992a), "worst-case", or "hyperconservative" (Environment Canada, 1997) point estimate of exposure. Such PECs are intended to exceed maximum exposure values under the exposure condition(s) of interest (US EPA, 1992a).

A bounding estimate is usually determined by assuming that several factors that influence concentration or dose are at their maximum. For example, when exposures are calculated, concentrations are often estimated at the point of entry, assuming that releases are as high as possible, that dilution is zero, and that none of the substance is lost from the receiving compartment. In circumstances where bioavailability is expected to be limited, a bounding exposure estimate may also be based on a maximum total measured concentration (e.g., of a metal in a soil), by making the unrealistic assumption that all of the total measured concentration is available to biota (Environment Canada, 1997).

The purpose of the hyperconservative screening is usually to identify the receptors and/or exposure pathways of most concern and to eliminate others. For example, if a bounding PEC is less than the predicted no effect concentration (PNEC) for a particular receptor organism (risk quotient <1), no further investigation of effects to this receptor is usually required. However, if a hyperconservative PEC exceeds the corresponding PNEC, such PECs should usually be estimated in a more realistic fashion.

3.2.2 Realistic Point Estimates

Screening

The first step in refining a bounding PEC may be to estimate the maximum exposure values likely to actually occur under the exposure condition(s) of interest (Environment Canada, 1997). Such estimates may be called "conservative", "reasonable worst-case" or "high end" exposure values. When data on variability are available, "high end" exposure estimates may be defined to fall within the 90th and 99.9th percentiles of the expected variability (US EPA, 1992a). If a bounding PEC has not been estimated, this realistic screening is usually the first step in the assessment process.

When calculating "high end" exposures, a limited number (sometimes only one) of the most sensitive exposure variables are maximized (US EPA, 1992a). For example, dissolved concentrations in receiving waters could be calculated assuming that releases are as high as possible, dilution is low (but not zero), and a typical value for removal during wastewater treatment. Alternatively, "high end" PECs could be based on a maximum bioavailable concentrations measured in receiving waters (e.g., Environment Canada, 1997).

Typical Values

Individual PECs may also be intended to represent ‘typical’ exposure values (US EPA 1992a). When PECs are derived from measured data, arithmetic average or median values are usually used. When exposures are calculated, an average PEC may be estimated using average values for all input variables. When exposure distributions are expected to be skewed, it is also helpful to estimate median or geometric mean exposure values (US EPA, 1992a).

3.2.3 Realistic Exposure Distributions

When exposure estimates are based on ambient monitoring data or on Monte Carlo simulations, the complete range of PECs associated with a given set of exposure conditions may be estimated and represented as frequency distributions (e.g., Environment Canada, 1997; US EPA, 1996).

4.0 ESTIMATION OF PECs

4.1 Use of ‘Weight or Multiple Lines of Evidence’ Approach

In view of the uncertainty associated with exposure estimates, whenever possible PECs should be determined using more than one method. Most jurisdictions recommend basing PECs on both monitoring data and model calculations, although it is recognized that this is not always possible (e.g., US EPA, 1992a; European Commission, 1996; Environment Canada, 1997; Hayamizu 1997). When both estimates agree, at least within an order of magnitude, confidence in the derived PECs is increased. When there is disagreement, particularly when making realistic (higher tier) exposure estimates, analysis and critical discussion of divergences are important steps. If the measured values have passed the procedure of critical statistical and geographical evaluation, a high degree of confidence can be attributed to those data and they are given preference (European Commission, 1996).

4.2 Use of Ambient Monitoring Data

Empirical data on concentrations of substances in receiving media may be used both at a screening level and in higher tier assessments (see Section 3.2). Monitoring data are generally preferred when making realistic (higher tier) exposure estimates. However, such data should be evaluated for both reliability and representativeness. This is particularly true when measured concentrations are low, for example near the limit of analytical detection. Criteria for evaluating existing monitoring data are described, for example, in US EPA (1992a). If the uncertainties associated with existing monitoring data are unacceptable, additional monitoring data may be collected or confirmatory modelling data may be sought.

4.3 Use of Models

Models may be used to calculate PECs for both screening level and more realistic (higher tier) assessments (see Section 3.2). In the European Union, for example, initial PECs for surface waters may be calculated using models that account for removal of substances during sewage treatment, and for dilution and adsorption in receiving waters (European Commission, 1996; see Annex, Section 4.2.3). Models used may be either generic or site-specific (see Annex, Sections 4.2.1 and 4.3.1). Strategies for selecting and validating exposure models are discussed, for example by Cowan et al. (1995b), and are reviewed by US EPA (1992a).

Limitations on the amount and quality of emission data are major sources of uncertainty in model calculations. In an attempt to standardize approaches and reduce uncertainties associated with calculated PECs, generic emission scenario documents are being developed in the European Union and the United States for specific combinations of chemical use and industry categories (European Commission, 1996; see Annex, Section 3).

Because the uncertainties associated with model outputs may be large, uncertainty should be evaluated with particular care when realistic PECs are calculated using models. If the uncertainties are too large, model input data may be refined or confirmatory monitoring data may be sought.

4.4 Spatial Scales

As indicated in Section 4.1 of the Annex, assessments may be conducted at local, regional, national, or continental scales (European Commission, 1996; OECD, 1996). Releases from point sources have largest impacts on environmental concentrations locally, but can also contribute to environmental concentrations on a larger scale. Assessments of releases from point sources should therefore include at least a local and possibly a larger (e.g., regional) component. When releases are from diffuse sources, generally only larger scale (e.g., regional) assessments are required (European Commission, 1996).

4.5 Temporal Scales

PECs for a particular location are usually estimated as arithmetic average concentrations for a specified time interval. Averaging periods may be as short as a day, or as long as a year or more. PECs representing steady state concentrations are considered to represent long-term average exposure levels.

Exposure assessors should consult with effects assessors when determining the most appropriate averaging times. Short-term averages may be used when releases are episodic, particularly when determining PECs on a local scale (EC, 1996) and chemicals have short half-lives in environmental media. Longer-term averages are normally used when releases are continuous, especially when assessing persistent contaminants. PECs calculated as short-term averages should be compared to PNECs representing short-term toxicity; long-term PECs should be compared to PNECs representing long-term toxicity (Environment Canada, 1997; EC, 1996).

4.6 Environmental Compartments

PECs may be determined separately for water, sediment, air, soil and biota (see Annex, Sections 4.2.1 and 4.3.1). The compartments of primary concern are typically identified during fate and pathways analysis.

4.7 Background Exposure

Both natural and ambient background concentrations may contribute to local exposures. Generally such background concentrations are deliberately incorporated into exposure estimates (e.g., European Commission, 1996). This is straightforward when PECs are based on monitoring data. When PECs are calculated, ambient background concentrations may be estimated using regional models, and added to PECs determined using local models (European Commission, 1996; see Annex, Section 4.4).

4.8 Connecting Measured PECs to Source(s) of Interest

Although monitoring data are often limited, this is not always so. In cases when monitoring data are abundant and PECs are based primarily on such data, the connection between observed PECs and releases from a particular source of interest may be unclear - especially for heavily industrialized areas. The most straightforward method of connecting exposure values to particular sources of interest is to calculate PECs by modelling emissions from those sources (US EPA, 1992a). If measured concentrations exceed calculated PECs, the “excess” may represent accumulations from sources other than those of interest. Other approaches, based for example on application of statistical methods to empirical data, have been reviewed by Gordon (1988).

4.9 Bioavailability of Measured PECs

PECs and PNECs are compared directly in risk analysis. Effects studies are frequently conducted under conditions that optimize bioavailability, while bioavailability under field conditions can range widely. For realistic exposure estimates, the bioavailability of PECs should therefore be similar to that of PNECs estimated from key toxicity tests (Environment Canada, 1997).

When a substance can occur in different chemical and/or physical forms but only one is usually bioavailable, PECs (and PNECs) should ideally be expressed in terms of concentrations of the bioavailable form. In the case of an organic compound, for example, that is often the un-ionized freely dissolved aqueous form (Environment Canada, 1997). For some substances, bioavailability is controlled by a particular chemical component of an exposure medium. For such substances bioavailability should, whenever possible, be adjusted or normalized to the controlling variable. For example, concentrations of a non-ionic organic chemical in a sediment could be normalized to the sediment’s organic carbon content (Environment Canada, 1997).

4.10 Persistence and Bioaccumulation

For organic substances persistence and bioaccumulation are key parameters determining potential to cause long-term harmful effects. Information on persistence and bioaccumulation may be used when identifying candidate substances for risk assessment or management initiatives (Environment Canada, 1995; Government of Canada, 1995)

Information on persistence and bioaccumulation is considered when scoping the fate of the substance - particularly when identifying the media in which it is most likely to accumulate and when selecting assessment endpoints (see Section 3.1). Because of the importance of these parameters Cowan et al. (1995a) have proposed special persistence and bioaccumulation assessment schemes. Their persistence assessment determines the potential for increased exposure concentration as a result of repeated additions of the substance. Their tiered bioaccumulation assessment evaluates the potential for direct and indirect effects on the species of interest due to bioaccumulation.

4.11 Uncertainty and Variability

The uncertainty of realistic PECs should be analyzed quantitatively, but if this is not possible, uncertainty should at least be characterized qualitatively. Sources of uncertainty in exposure characterization, and strategies for quantifying the uncertainty of PECs are reviewed by US EPA (1992a). When analyzing uncertainty of PECs associated with a particular set of exposure conditions, an attempt should be made to distinguish uncertainty - understood as the lack of knowledge of the correct value for a particular PEC (e.g., an average value) - from natural variability - defined as real differences in PECs over space and/or time under the conditions of interest (US EPA, 1992a and 1996). Approaches to uncertainty analysis used in OECD member countries are summarized in the Annex (Section 5.0).

5.0 BIBLIOGRAPHY

Cowan, C.E., D. J. Versteeg, R. J. Larson, P. J. Kloepper-Sams. 1995a. Integrated approach for environmental assessment of new and existing chemicals. Regulatory Toxicology and Pharmacology 21: 3-31.

Cowan, C.E., D. Mackay, T.C.J. Feijtel, D. van de Meent, A. DiGuardo, J. Davies and N. Mackay (Eds.) 1995b. The Multi-media fate model: A vital tool for predicting the fate of chemicals. Society for Environmental Toxicology and Chemistry, Pensacola, Fl.

EC. 1996. EUSES, the European System for the Evaluation of Substances. National Institute for Public Health and the Environment (RIVM), the Netherlands, European Chemicals Bureau, Ispra Italy.

ECETOC. 1994. Environmental exposure assessment. Tech. Rept. No. 61, European Centre for Ecotoxicology and Toxicology of Chemicals. Brussels, Belgium. 109p.

Environment Canada, 1995. Report of the Ministers' Expert Advisory Panel on the second Priority Substances List, under the Canadian Environmental Protection Act., Environment Canada, Hull Quebec, 26p.

Environment Canada. 1997. Environmental assessments of priority substances under the Canadian Environmental Protection Act, Guidance manual version 1.0. March 1997, EPS/2/CC/3E, Environmental Canada, Hull, Canada.

European Commission, 1996. Technical guidance documents in support of the Commission directive 93/67/EEC on risk assessment for new notified substances and the Commission regulation (EC) 1488/94 on risk assessment for existing substances - Part II, Chapter 3 and Part IV, Chapter 7. European Commission, Luxembourg.

Gordon, G.E. 1988. Receptor models. Environ. Sci. Technol. 22(10): 1132-1142.

Government of Canada, 1995. Toxic substances management policy. Government of Canada and Environment Canada, June 1995, Ottawa, Canada, 10p.

Hayamizu, T. 1997. Strategy for environmental exposure assessment used by member countries in the SIDS initial assessments (Draft). Personal communication. February 1997, 2p.

OECD. 1996. Draft interim summary of responses to the questionnaire on environmental exposure assessment. Organisation for Economic Co-operation and Development, October 1996. Paris, France. 93p.

Tanabe, K. 1997. The system of investigation of persistence in the environment concerning chemical substances. Personal communication. February 1997. 4p.

US EPA. 1992a. Guidelines for Environment Exposure Assessment. Federal Register 57: 22888-22936.

US EPA. 1992b. Potential approaches to developing screening quality estimates of releases of chemicals; Estimates of releases of new chemicals. United States Environmental Protection Agency, Office of Pollution prevention and Toxics. 9p.

US EPA. 1996. Proposed Guidelines for Ecological Risk Assessment. Federal Register 61: 47552-47631.

Wagner, B. 1997. Environmental exposure assessment strategies; Position paper of Germany. German Federal Environmental Agency (Umweltbundesamt), Berlin, 17p.

ANNEX

Practice of Environmental Exposure Assessment in Member Countries

Introduction

This Annex summarises basic methodologies of environmental exposure assessment used in Member countries. The content was extracted from the responses to the OECD survey conducted in 1996 on environmental exposure assessment. Some countries gave more than one response from different ministries/agencies/programmes.

Abbreviations used in Annex are summarised below.

AUS	Australia	NL	The Netherlands
CA	Canada	SWE	Sweden
(PS/EC)	Priority Substances Assessment Program - Environment Canada	UK	United Kingdom
(NS/EC)	New Substances - Environment Canada	(EA)	Environment Agency
(WS/EC)	Canadian Wildlife Service - Environment Canada	(NONS)	Notification of New Substances Branch
(PS/HC)	Priority Substances Assessment Program - Health Canada	US	United States (EPA)
DE	Germany	(OPPT)	Office of Pollution Prevention and Toxics
FI	Finland	(OW)	Office of Water
FR	France	(SF)	Superfund Office
IRE	Ireland	(OA)	Office of Air Quality Panning and Standards
JP	Japan	(ORD)	Office of Research and Development
(MITI)	Ministry of International Trade and Industry	(OSW)	Office of Solid Waste
(EA)	Environment Agency		

1.0 Purpose and level of environmental exposure assessment conducted in Member countries

Country	SIDS Initial Assessment	National programme for investigation of chemicals		National programme for risk management	Other	
	Screening level	Screening Level	Comprehensive	Comprehensive	Screening level	Comprehensive
AUS	x	x	x			
CA (PS/EC)		x	x			
CA (NS/EC)		x	x	x		
CA (WS/EC)		x	x		(x) #1	(x) #1
DE	x		x (BUA)	x		
FI	x	x	x	x		
FR	x		x (Same as SIDS)			
IRE				x		
JP (MITI)	x			x		
JP (EA)		x				
NL	x	x	x	x		
SWE (#2)	x			x		
UK (EA)	x			x		
UK (NONS)					x (#3)	x (#3)
US (OPPT)	x	x	x	x		
US (SF)					(x)	(x) (#4)
US (OA)		x				
US (ORD)		x				
US (OSW)		x	x			

[Note]

(x) No answers on whether screening level or comprehensive

#1 The National Wildlife Research Center is a centre of wildlife expertise for the Canadian Government. They conduct exposure assessment as requested by the responsible authority of a risk assessment program.

#2 Exposure assessment within the framework of EU Existing Chemicals Programme follow the EU-TGD. The answers below are related other practices in KemI

#3 For substances notified under the notification of New Substances Regulations. This may be a screening level or a comprehensive level, depending on the level of supply.

#4 Measure and model exposures to contaminants released from specific hazardous waste sites.

2.0 Use of Guidance Documents

Country	**Use of guidance documents**					**How the guidance is used**		
	Guidance documents in the country	**EU TGD**	**SIDS Manual**	**Other guidance documents**	**No guidance**	**strictly follow**	**basically refer, but perform on a case-by-case basis**	**completely case-by-case**
AUS	x (#1)	x (Occasionally)	x					x
CA (PS/EC)	x (#2)						x	
CA (NS/EC)	x (#3)						x	
CA (WS/EC)	x (#2, 4)			x (#11)			x	
DE		x					x	
FI		x	x				x	
FR		x				x	x	
IRE	x (#5)	x		x (#12)			x	
JP (MITI)		x	x		x		x	
JP (EA)				x (#13)			x	
NL		x	x			x	x	
SW		x	x				x	
UK (EA)		x	x				x	
UK (NONS)	x	x	x					
US (OPPT)	x (#6)		x	x (#14)			x	
US (SF)	x (#7)						x	
US (OA)	x (#8)							x
US (ORD)	x (#9)						x	
US (OSW)	x (#10)						x	

[Note]

(Guidance documents in the country)

#1 Assessor's Manual (Still in draft form and adapted largely from overseas documents)

#2 Environmental Assessments of Priority Substances under the Canadian Environmental Protection Act

#3 Evaluation Manual for New Substance (under revision)

#4 A framework for Ecological Risk Assessment at Contaminated sites in Canada, Scientific Series No. 199

#5 Parameters of Water Quality, Interpretation and Standards (P.J.F. Flanagan, Environmental Research Unit)

#6
- EPA Exposure Assessment Guidelines
- Guideline for completing initial review exposure report
- Preparation of engineering assessments, Volume I
- Guidelines for Risk Characterization, US EPA Science Policy Council, February 1995

#7
- Risk Assessment Guidance for Superfund (part A): Volume I
- Soil Screening Guidance

#8
- EPA Guidelines for Exposure Assessment
- HGM-11 Uses Guide

- Users manual for Human Exposure Model (HGM)
- Users guide for ISC3 dispersion models

#9 - Methodology for Assessing Health Risks Associated with Indirect Exposures to Combustion Emissions
- Addendum to Methodology for Assessing Health Risks Associated with Indirect Exposures to Combustion Emissions

#10 - Exposure Factors Handbook (Undergoing extensive revision by EPA/ORD at this time)
- Indirect Exposure Methodology (see #7)

(Other guidance documents)

#11 Wildlife Exposure Factors Handbook (EPA/600/R-93/187a, b, 1993

#12 - Air Quality Guidelines for Europe (WHO Regional Office for Europe)
- T.A. Luft (Air quality criteria in Germany)
- Industrial Air Pollution Guidelines (Ministry of the Environment, Denmark, Danish Environmental Protection Agency)

#13 ACGIH (US), AQUIRE (US EPA), ECDIN (EU), HSDB (US-NLM), IARC Monograph, IPCS EHC, IRIS (US EPA), IRPTC (UNEP), RBC (US EPA), RTECS (US-NIOSH), Drinking Water Guideline (WHO)

#14 Computer models documentation. This documentation offer choices of input assumptions for estimating exposures.

3.0 Methodologies for Release Estimates

Country	Monitoring data of emission are used	Other reported data by companies on emission are used to estimate.	Default release scenarios and emission factors described in Emission Scenario Documents are used.	Other
AUS		x	x (sometimes)	
CA (PS/EC)	x	x		
CA (NS/EC)		x	x	x (#1)
CA (WS/EC)				x (#2)
DE			x	
FI		x	x	
FR		x	x	
IRE			x	
JP (MITI)		x		
NL	x	x	x	
SWE	x		x	
UK	x	x	x	x(#1)
US (OPPT)	x	x	x	
US (SF)	x			
US (OA)	x	x	x	
US (ORD)	x	x		
US (OSW)		x (#3)		

[Note]
#1 If necessary, contact companies
#2 We use release information provided by responsible departmental authority
#3 Collect data from industry through mandatory surveys

4.0 Exposure Assessment Scenarios Used

4.1 Types of Environmental Exposure Assessment Being Performed

Country	Local	Regional	Continental	Top predator	Indirect Human Exposure
AUS	Always	No	No	No	No (#1)
CA (PS/EC)	sometimes	sometimes	No	No	No (#2)
CA (NS/EC)	sometimes	sometimes	Sometimes	No	No (#2)
CA (WS/EC)	sometimes	No	No	Always	No (#2)
DE	always	Only for HPVCs	Only for HPVCs	(N/A)	Only for HPVCs
FI	always	Sometimes	Sometimes	Sometimes	Yes
FR	always	Sometimes (#3)	According to EU-TGD	Sometimes (#4)	Only for HPVCs
IRE	always	No	No	No	Sometimes
JP (MITI)	Sometimes	No	No	No	No
JP (EA)	No	Always	No	No	Always
NL	Always	Sometimes	Sometimes	Always	Always
SWE	Sometimes	Sometimes	No	No	Sometimes
UK (EA)	Always	Always	Yes (#5)	Sometimes	Sometimes
UK (NONS)	Always	Sometimes (#6)	Yes	Sometimes	Sometimes
US (OPPT)	Sometimes	Sometimes	Sometimes	Sometimes (seldom)	Sometimes
US (SF)	Always	No	No	N/A	Sometimes
US (OA)	Sometimes	Sometimes	No	No	No
US (ORD)	Sometimes	Sometimes	No	No	Sometimes
US (OSW)	Sometimes	No	No	Sometimes	Always

[Note]

#1 However, the Federal Health Department assess such exposure on a case-by-case and site-specific basis and site-specific basis, usually only when there is an identified concern.

#2 Health Canada does.

#3 Only when significant releases occur or when the releases are diffuse

#4 If accumulation potential and toxic to mammals

#5 Not used directly in the assessments, but used as ‘background’ for the regional concentrations.

#6 Not normally carried out for new substances, but can be for certain substances (e.g. fuel additives) at higher tonnage.

4.2 Local exposure assessment (Exposure assessment for the immediate vicinity of an individual site)

4.2.1 Scenarios

Country	Site-specific or Generic	What scenarios are used	Definition or details of scenarios
AUS	combination	reasonable worst-case	We use relevant reasonable worst-case based on assumptions relating to know Australian practices.
CA (PS/EC)	combination	combination	Using a tiered approach; worst case as Tier 1, reasonable worst-case as Tier 2, other as Tier 3 (#1)
CA (NS/EC)	combination	reasonable worst-case	Specific to notifier. Scenario depends on level of submission (volume trigger) and level of concern
CA (WS/EC)	combination	reasonable worst-case and average	
DE	combination	reasonable worst-case	Follow EU-TGD
FI	combination	reasonable worst-case	Follow EU-TGD
FR	combination	reasonable worst-case	Emission Scenario Documents aim to be representative and to cover ca 90% of the possible situations.
IRE	combination	reasonable worst-case	
JP (MITI)	Site-specific	reasonable worst-case	
NL	combination	reasonable worst-case	Follow EU-TGD
SWE	combination	reasonable worst-case	
UK	site-specific and generic	reasonable worst-case	(#2)
US (OPPT)	combination	combination	Bounding exposure estimates (Estimates of exposure greater than any real exposure in the population of interest) and high end estimates (Estimates in the 90th percentile of exposure. Very similar to reasonable worst case estimates) (#3)
US (SF)	site-specific	reasonable worst-case and average	Described in the guidance document
US (OA)	combination	combination	High end exposure as well as average exposure using a combination of default exposure assumptions depending on available data. Where possible, exposure variables are described as distributions and uncertainty and variability are quantified using Monte Carlo technique.
US (ORD)	combination	other	“High End” which is designed to describe the upper 10th percentile of the exposed population. “Central” which is designed to describe the 50th percentile of the exposed population. (#4)
US (OSW)	combination	reasonable worst-case and average	Typically do high and central tendency estimates.

[Note]

#1 Definition is as follows:

- Worst-case: hyperconservative - for example, assume maximum bioavailability
- Reasonable worst-case: more realistic estimates of bioavailability, more realistic assumptions
- Tier 3: the most realistic, i.e. temporal or spatial variations are summarised as distributions. Bioavailability is matched to that of key effects data.

#2 If general assessment is conducted, the default figures for dilution factors, emission and sewage treatment given in the EU-TGD are used, which are considered to be a reasonable worst-case. For site-specific assessments, scenarios may be based on a mixture of reasonable worst-case default values (as for generic) and actual figures. This may modify for particular cases, e.g. for large production sites when enough information is available.

#3 The input parameters to the exposure calculation are selected to achieve the desired estimates. For example, median and/or average values are selected for the inputs to the exposure calculation if an estimate of average exposure is needed. Occasionally Monte Carlo modelling is done to estimate a distribution of exposures and then the average and high end values are taken from that distribution.

#4 Scenarios designed to be realistic and to use regional data when available. For “high end, a typical strategy involves assigning one or two parameters as 90th percentile, such as: (1) contact rate (food ingestion, inhalation rates, etc.), (2) proximity of the source, and so on. “Central” strategy involves setting all parameters to a mid-range value.

4.2.2 Environmental compartments to be considered

Country	Surface water				Sediment				STP	Soil	Ground water	Air	Biota
	River	Lake	Bay/ Estuary	Ocean	River	Lake	Bay/ Estuary	Ocean					
CA (PS/EC)	x	x	x	x	x	x	x	x		x	x	x	x
CA (NS/EC)	x	x	x		x	x	x		x	x		x	x
CA (WS/EC)	(x)	(x)	(x)	(x)	(x)	(x)	(x)	(x)		x	x	x	x
DE	x				x				x	x	x	x	
FI	x	x	x		(x)	(x)	(x)		x	x	x	x	x
FR	x	x			x	x			x	x	x	x	x
IRE	(x)	(x)	(x)	(x)								x	
JP (MITI)	x		x	x									
NL	x				x				x	x	x	x	x
SWE	(x)	(x)	(x)	(x)	(x)	(x)	(x)	(x)	x				
UK	x				x		x(#1)		x	x	x	x	x
US (OPPT)	x	x	x		x	x	x		x	x	x	x	x
US (SF)	x	x	x		x	x	x			x	x	x	x
US (OA)												x	
US (ORD)	x	x			x	x				x		x	x
US (OSW)	x	x	x		x	x	x			x	x	x	x

[Note]
(x): areas not specified
(#1): case-by-case basis

- Australia: case-by case basis as appropriate

4.2.3 Detailed scenarios for local environmental exposure assessments for surface waters by modelling, including by a simple hand calculation

Country	STP considered?	Dilution Factors	Size of dilution factors				Other processes to be considered
			River	Lake	Bay/ Estuary	Ocean	
AUS	Yes	(N/A)					
CA (PS/EC)	No	Site-specific					
CA (NS/EC)	Yes	Site-specific or default (depends on scenarios)	(not shown)				biodegradation, adsorption, hydrolysis
DE	Yes	Site-specific or default	10				adsorption to suspended matter
FI	Yes	Site-specific or default	10-1000				adsorption to suspended matter
FR	Yes	Site-specific or default	10	10	?	?	adsorption onto suspended matter
IRE	Yes	Site-specific					
JP (MITI)	Yes	Site-specific or default	100		1000	1000	
NL	Yes	Site-specific or default	10				adsorption to suspended matter
SWE	Yes	Site-specific or default					degradation, volatilisation, adsorption
UK	Yes	Site-specific or default	10		10 or 100		absorption to sediment
US (OPPT)	Yes	Site-specific					Hydrolysis, volatilisation, absorption, biodegradation, oxidation
US (SF)		Site-specific					
US (ORD)	No	Site-specific					Soil erosion, sediment delivery ratios, surface runoff
US (OSW)		Site-specific					Degradation, burial of sediments, food chain uptake

[Note]
#1 Depends on scenarios

4.3 Regional exposure assessment (Exposure assessment for a larger area including point and diffuse sources)

4.3.1 Scenarios

Country	Site-specific or Generic	What scenarios are used	Definition and details of scenarios, etc.
CA (PS/EC)	combination	combination	The same as local
CA (NS/EC)	specific region or country, and generic (national condition)	reasonable worst-case	Depends on level of assessment
DE	generic (international condition)	reasonable worst-case	Follow EU-TGD
FI	generic (international condition)	reasonable worst-case	Follow EU-TGD
FR	generic (international condition)	reasonable worst-case	Definition is the same as local. The parameters characterising the region are average, but the releases are chosen to represent a reasonable worst case.
JP (EA)	generic (national condition)	(N/A)	
NL	generic (international condition) and combination	reasonable worst-case	Follow EU-TGD
SWE	specific region or country, and combination	reasonable worst-case	
UK (EA)	generic (international condition)	reasonable worst-case	As described in the TGD.
UK (NONS)	combination		
US (OPPT)	combination	combination	The same as local
US (OA)	generic (international condition) and combination	combination	The same as local
US (ORD)	specific region or country	other	Regional assessments attempt to cover the range of exposures which are associated with the source. By “range”, what is considered include proximity to source, exposure behaviours, appropriate combinations of behaviours, etc.

4.3.2 Environmental compartments to be considered

Country	Surface water				Sediment				STP	Soil	Ground water	Air	Biota
	River	Lake	Bay/ Estuary	Ocean	River	Lake	Bay/ Estuary	Ocean					
CA (PS/EC)	x	x	x	x	x	x	x	x		x	x	x	x
CA (NS/EC)	x	x	x		x	x	x		x	x		x	x
DE	x				x				x	x	x	x	
FI	x				x				x	x	x	x	x
FR	x	x			x	x			x	x	x	x	x
JP (EA)	x	x	x		x	x	x					x	x
NL	x				x				x	x	x	x	x
SWE		x	x		x	x			x	x			
UK (EA)	x				x				x	x	x	x	x
US (OPPT)	x	x	x		x	x	x		x	x	x	x	x
US (OA)												x	
US (ORD)	x	x			x	x				x		x	x

(x): areas not specified

4.4 Combination of three scenarios (i.e. local, regional, continental)

Country	**Methodology**
AUS	Generally only PEC-local
CA (PS/EC)	No specific policy
CA (NS/EC)	Each considered separately
DE	PEC = PEC-regional + PEC-local
FI	PEC = PEC-regional + PEC-local
FR	PEC-continental is estimated only to use as import into regional system. PEC-local and PEC-regional are added.
NL	PEC = PEC-regional + PEC-local
UK	PEC = PEC-regional + PEC-local
US (OPPT)	Assessments are done independently. They are not added together.
US (OA)	Output distributions for exposure and risk are calculated for the centres of city blocks (US Census Blocks) irregardless if the analysis is local or regional. Multiple exposures from multiples sources and multiple chemicals are addressed at the centres of city blocks. On average, US Census Blocks contain 35 people. Our database contains relevant information for 6.9 million blocks in the US.
US (ORD)	Independent results are derived; most often results of local and regional assessments are not combined.

4.5 Indirect exposure to man via the environment

Routes of exposure to be considered

Country	Air	Drinking water	Food				Others
			Fish	Crops	Meat	Products (Milk, etc.)	
AUS	x (#1)		(x)	(x)	(x)	(x)	(#2)
CA (PS/HC)	x	x	x	x	x	x	x (#4 & #6) on a case-by-case basis
DE	x	x	x	x	x	x	
FI	x	x	x	x	x	x	
FR	x	x	x	x	x	x	
IRE							(#3)
JP (EA)	x		(x)	(x)	(x)	(x)	
NL	x	x	x	x	x	x	
SWE			(x)	(x)	(x)	(x)	x (#4)
UK (EA)	x	x	x	x	x	x	
US (OPPT)	x	x	(x)	(x)	(x)	(x)	x (Soil)
US (SF)			x	x	x (#5)		
US (ORD)		x	x	x	x	x	x (#6)
US (OSW)	(x) (#7)	(x) (#7)		x	x	x	

[Note]
(x) Compartments not specified
#1 Spray drift
#2 Treatment or contamination of public areas, domestic settings and contaminated sites
#3 Ingestion of fallout
#4 Migration from packaging.
#5 Game animals
#6 Soil ingestion and dermal contact
#7 Direct exposures

5.0 Uncertainty analysis

- Guidance for uncertainty analysis is available in the general guidance document for environmental exposure or risk assessment: **CA (PS/EC), DE, US (OPPT)**
- Uncertainty is considered on a case-by-case basis: **AUS, CA (NS), CA (PS/HC), DE, FI, NL, SWE (awaiting to the EU-TGD), UK, US (OPPT), US (SF), US (OA), US (ORD)**
- Uncertainty is not considered in environmental exposure assessment: **FR, IRE**