IPCS Harmonization Project – IPCS Risk Assessment Terminology

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

IPCS Harmonization Project

IPCS Risk Assessment T

Part 1:
IPCS/OECD Key Generic Term used in Chemical Hazard/Risk

Part 2:
IPCS Glossary of Key Exposu Assessment Terminology

IOMC

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

Harmonization Project Document No. 1

IPCS RISK ASSESSMENT TERMINOLOGY

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

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

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

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FOREWORD

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

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

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

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

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

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

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

LIST OF ACRONYMS AND ABBREVIATIONS

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

INTRODUCTION

Background

Over the past decades, the International Programme on Chemical Safety (IPCS) and the Organisation for Economic Co-operation and Development (OECD), as well as many other international organizations and programmes, have been faced with the problem of misunderstandings concerning terms used in the environmental health field. The main reasons for this problem were the interdisciplinary character of environmental health and the fact that each of the disciplines had developed, within its own framework, a specific "language culture." Due to the lack of an internationally agreed upon glossary of environmental health terms, almost every single programme/project had developed, for practical reasons, its own "working terminology."

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

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

Objective

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

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

Context

This project focuses on the harmonization of terms used in the hazard/risk assessment of chemicals (including pesticides) in the context of chemicals management (i.e., notification, registration, classification, etc.).

Scope

The project covers two categories of terms:

- *Generic terms*: general terms used in the process of determining hazard and risk. Part 1 of this report presents the results of this category.
- *Technical terms*: those terms used in human health and environmental hazard and risk assessment, including scientific–technical terms used in effects assessment (e.g., nomenclature of tumours and other pathological lesions and technical terms used in hazard characterization, such as teratogenicity). Technical terms will be published separately (see, for example, Part 2), as they are developed.

Terms common to Part 1 (generic) and Part 2 (exposure assessment)

Although the work on generic terms commenced well in advance of the work on the exposure assessment-specific terms, there was opportunity in the final stages for the IPCS Exposure Assessment Terminology Working Group to review the proposed final generic terms, in order to identify any inconsistencies. Four terms were identified to be overlapping: i.e., *dose*, *exposure*, *exposure assessment*, and *exposure scenario.* The Exposure Assessment Terminology Working Group advised that the proposed definitions of these four terms in both Part 1 (generic terms) and Part 2 (exposure assessment terms) were consistent and interchangeable, and hence both sets of definitions were preserved. The user may refer either to the generic definition in Part 1 or to the exposure assessment definition in Part 2, the latter being specifically tailored for use in the exposure assessment field.

PART 1

IPCS/OECD KEY GENERIC TERMS USED IN CHEMICAL HAZARD/RISK ASSESSMENT

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1. APPROACH TO THE WORK ON GENERIC TERMS

The International Programme on Chemical Safety (IPCS) and the Organisation for Economic Co-operation and Development (OECD), in consultation with other organizations from the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), first developed a list of terms and identified "key documents and sources" from which definitions would be extracted. Note that in this context, "key documents and sources" were those that have regulatory implications (e.g., European Community Directives, US Environmental Protection Agency documents) or are widely used and cited. The terms were divided into "higher" and "lower" priority categories.

Next, existing definitions for the higher-priority generic terms were extracted from the "key documents and sources" and were circulated widely (e.g., through networks of the IOMC organizations) for review and preference indication. Respondents were asked to:

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

The comments and suggestions received were subsequently critically analysed by an IPCS/OECD Terminology Planning Working Group, as described below.

In November 1996, the IPCS/OECD secretariats circulated the list of 50 selected generic terms, together with the various descriptions for each of the items as identified in the key documents and sources, to their respective networks of experts. The list of selected items is provided in Annex 1 to Part 1 of this document, and the list of the source documents is provided in Annex 2. The survey results are summarized in Annex 3.

The IPCS/OECD Terminology Planning Working Group and World Health Organization (WHO) terminology experts critically analysed the survey results during two successive meetings in Carshalton, United Kingdom, in March 1998 and in Geneva, Switzerland, in October 1998. Several proposals were considered to find compromises for descriptions where there was no clear preference for any particular description. Details of the process used by the Terminology Planning Working Group are described in Annex 4. After several rounds of comments, the OECD and IPCS secretariats jointly edited the most recent proposal of the Terminology Planning Working Group and consulted a senior expert in hazard and risk assessment (Professor Robert Kroes from the Netherlands) for a final review. Several changes were made in the Terminology Planning Working Group's proposal to improve consistency, comprehensibility, and coherence of the descriptions of related terms. This version was submitted to the OECD Joint Meeting of the Working Party on Chemicals, Pesticides and Biotechnology for final review and declassification, as well as to the Core Group of the IPCS Harmonization Project Steering Committee for final review. A number of minor, mostly editorial comments and a few suggestions for improvement of the descriptions of some of the more contentious terms were received. These were all considered in the final report.

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

2. DEFINITIONS OF KEY GENERIC TERMS

The alphabetical list of selected generic terms in hazard and risk assessment and their descriptions are provided in Table 1, followed by a compilation of remarks and background notes to each of the terms included in this overview (see section 3).

Table 1: Alphabetical list of selected key generic terms in hazard and risk assessment and their definitions.

Term	*Description*
Acceptable daily intake	Estimated maximum amount of an agent, expressed on a body mass basis, to which individuals in a (sub)population may be exposed daily over their lifetimes without appreciable health risk. Related terms: *Reference dose, Tolerable daily intake*
Acceptable risk	This is a risk management term. The acceptability of the risk depends on scientific data, social, economic, and political factors, and the perceived benefits arising from exposure to an agent.
Adverse effect	Change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.
Analysis	Detailed examination of anything complex, made in order to understand its nature or to determine its essential features.
Assessment	Evaluation or appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process.
Assessment end-point	Quantitative/qualitative expression of a specific factor with which a risk may be associated as determined through an appropriate risk assessment.
Assessment factor	Numerical adjustment used to extrapolate from experimentally determined (dose–response) relationships to estimate the agent exposure below which an adverse effect is not likely to occur. Related terms: *Safety factor, Uncertainty factor*
Concentration	Amount of a material or agent dissolved or contained in unit quantity in a given medium or system.

Term	*Description*
Concentration–effect relationship	Relationship between the exposure, expressed in concentration, of a given organism, system, or (sub)population to an agent in a specific pattern during a given time and the magnitude of a continuously graded effect to that organism, system, or (sub)population. Related terms: *Effect assessment, Dose–response relationship*
Dose[1]	Total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population.
Dose–effect relationship	Relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the magnitude of a continuously graded effect to that organism, system, or (sub)population. Related terms: *Effect assessment, Dose–response relationship, Concentration–effect relationship*
Dose-related effect	Any effect to an organism, system, or (sub)population as a result of the quantity of an agent administered to, taken up by, or absorbed by that organism, system, or (sub)population.
Dose–response	Relationship between the amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the change developed in that organism, system, or (sub)population in reaction to the agent. Synonymous with *Dose–response relationship*. Related terms: *Dose–effect relationship, Effect assessment, Concentration–effect relationship*
Dose–response assessment	Analysis of the relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the changes developed in that organism, system, or (sub)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population. Dose–response assessment is the second of four steps in risk assessment. Related terms: *Hazard characterization, Dose–effect relationship, Effect assessment, Dose–response relationship, Concentration–effect relationship*
Dose–response curve	Graphical presentation of a dose–response relationship.
Dose–response relationship	Relationship between the amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the change developed in that organism, system, or (sub)population in reaction to the agent. Related terms: *Dose–effect relationship, Effect assessment, Concentration–effect relationship*
Effect	Change in the state or dynamics of an organism, system, or (sub)population caused by the exposure to an agent.

Term	*Description*
Effect assessment	Combination of analysis and inference of possible consequences of the exposure to a particular agent based on knowledge of the dose–effect relationship associated with that agent in a specific target organism, system, or (sub)population.
Expert judgement	Opinion of an authoritative person on a particular subject.
Exposure[1]	Concentration or amount of a particular agent that reaches a target organism, system, or (sub)population in a specific frequency for a defined duration.
Exposure assessment[1]	Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives). Exposure assessment is the third step in the process of risk assessment.
Exposure scenario[1]	A set of conditions or assumptions about sources, exposure pathways, amounts or concentrations of agent(s)involved, and exposed organism, system, or (sub)population (i.e., numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation.
Fate	Pattern of distribution of an agent, its derivatives, or metabolites in an organism, system, compartment, or (sub)population of concern as a result of transport, partitioning, transformation, or degradation.
Guidance value	Value, such as concentration in air or water, that is derived after allocation of the reference dose among the different possible media (routes) of exposure. The aim of the guidance value is to provide quantitative information from risk assessment to the risk managers to enable them to make decisions. (See also *Reference dose*)
Hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that agent.
Hazard assessment	A process designed to determine the possible adverse effects of an agent or situation to which an organism, system, or (sub)population could be exposed. The process includes hazard identification and hazard characterization. The process focuses on the hazard, in contrast to risk assessment, where exposure assessment is a distinct additional step.

Term	*Description*
Hazard characterization	The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties. Hazard characterization is the second stage in the process of hazard assessment and the second of four steps in risk assessment. Related terms: *Dose–effect relationship, Effect assessment, Dose–response relationship, Concentration–effect relationship*
Hazard identification	The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population. Hazard identification is the first stage in hazard assessment and the first of four steps in risk assessment.
Margin of exposure	Ratio of the no-observed-adverse-effect level (NOAEL) for the critical effect to the theoretical, predicted, or estimated exposure dose or concentration. Related term: *Margin of safety*
Margin of safety	For some experts, margin of safety has the same meaning as margin of exposure, while for others, margin of safety means the margin between the reference dose and the actual exposure. Related term: *Margin of exposure*
Measurement end-point	Measurable (ecological) characteristic that is related to the valued characteristic chosen as an assessment point.
Reference dose	An estimate of the daily exposure dose that is likely to be without deleterious effect even if continued exposure occurs over a lifetime. Related term: *Acceptable daily intake*
Response	Change developed in the state or dynamics of an organism, system, or (sub)population in reaction to exposure to an agent.
Risk	The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent.
Risk analysis	A process for controlling situations where an organism, system, or (sub)population could be exposed to a hazard. The risk analysis process consists of three components: risk assessment, risk management, and risk communication.

Term	*Description*
Risk assessment	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. The risk assessment process includes four steps: hazard identification, hazard characterization (related term: *Dose–response assessment*), exposure assessment, and risk characterization. It is the first component in a risk analysis process.
Risk characterization	The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system, or (sub)population, under defined exposure conditions. Risk characterization is the fourth step in the risk assessment process.
Risk communication	Interactive exchange of information about (health or environmental) risks among risk assessors, managers, news media, interested groups, and the general public.
Risk estimation	Quantification of the probability, including attendant uncertainties, that specific adverse effects will occur in an organism, system, or (sub)population due to actual or predicted exposure.
Risk evaluation	Establishment of a qualitative or quantitative relationship between risks and benefits of exposure to an agent, involving the complex process of determining the significance of the identified hazards and estimated risks to the system concerned or affected by the exposure, as well as the significance of the benefits brought about by the agent. Risk evaluation is an element of risk management. Risk evaluation is synonymous with risk–benefit evaluation.
Risk management	Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk management comprises three elements: risk evaluation; emission and exposure control; and risk monitoring.
Risk monitoring	Process of following up the decisions and actions within risk management in order to ascertain that risk containment or reduction with respect to a particular hazard is assured. Risk monitoring is an element of risk management.
Safety	Practical certainty that adverse effects will not result from exposure to an agent under defined circumstances. It is the reciprocal of risk.

Term	*Description*
Safety factor	Composite (reductive) factor by which an observed or estimated no-observed-adverse-effect level (NOAEL) is divided to arrive at a criterion or standard that is considered safe or without appreciable risk. Related terms: *Assessment factor, Uncertainty factor*
Threshold	Dose or exposure concentration of an agent below which a stated effect is not observed or expected to occur.
Tolerable daily intake	Analogous to *Acceptable daily intake*. The term "tolerable" is used for agents that are not deliberately added, such as contaminants in food.
Tolerable intake	Estimated maximum amount of an agent, expressed on a body mass basis, to which each individual in a (sub)population may be exposed over a specified period without appreciable risk.
Toxicity	Inherent property of an agent to cause an adverse biological effect.
Uncertainty	Imperfect knowledge concerning the present or future state of an organism, system, or (sub)population under consideration.
Uncertainty factor	Reductive factor by which an observed or estimated no-observed-adverse-effect level (NOAEL) is divided to arrive at a criterion or standard that is considered safe or without appreciable risk. Related terms: *Assessment factor, Safety factor*
Validation	Process by which the reliability and relevance of a particular approach, method, process, or assessment is established for a defined purpose. Different parties define "Reliability" as establishing the reproducibility of the outcome of the approach, method, process, or assessment over time. "Relevance" is defined as establishing the meaningfulness and usefulness of the approach, method, process, or assessment for the defined purpose.

[1] This term is also contained in the list of IPCS key exposure assessment terminology (see Part 2); both definitions are consistent and interchangeable, depending on user preference.

3. REMARKS AND BACKGROUND INFORMATION TO THE GENERIC TERMS

When the original survey was conducted, experts provided a considerable number of remarks on each definition as well as other related terms. Such remarks and additional explanations related to each term are listed below. The numbers in brackets [ ] and the definition numbers referred to in the following sections correspond to the original survey reference numbers, which can be found in Annex 3. See also Annex 4 for details of the work process involved in the development of harmonized descriptions of the generic terms.

The below analysis was performed by the IPCS/OECD Terminology Planning Working Group. However, subsequent expert peer review resulted in some further analysis and amendments to the terminology, which are reflected solely in Table 1.

Acceptable daily intake

All definitions start with some expression of quantification; variants include *estimate of the amount*, *estimate of the largest amount*, *estimate of the daily exposure dose*, *amount*, and *maximum amount*. The quantification is occasionally qualified by the use of such adjectives as *maximum* and *largest*.

The object of the quantification is named in different ways, ranging from the more general *substance* to various more specific designations, such as *chemical*, *pesticide*, or *food additive*. Definitions 1 and 2 focus on *food and drinking water*, while Definition 6 refers to *diet*.

The route of exposure is limited to *ingestion* and "*taken … in the diet.*" The same is implied in the language of the definitions, where the word "*intake*" is simply repeated. Definitions 3 and 4, on the contrary, refer to *exposure* in general.

The time factor is accounted for on a daily basis in all definitions except those that refer to accumulation during the lifetime of the person: *over a lifetime*, *during lifetime*, and *during an entire lifetime*.

The consequences are expressed in a variety of ways: *without appreciable health risk*, *without deleterious effect*, *not anticipated to result in adverse effects*, *without risk*, *without appreciable risk to the health of the consumer*, or *without appreciable risk.*

Two respondents suggested the inclusion of reference to a *maximum* amount; two others indicated the need for the possible use of time scales other than lifetime and reference to some critical groups. Some argued that "*acceptable daily intake*" or "*ADI*" had been devised historically with reference to food safety (as confirmed by the word "*intake*") and that any application to other exposure assessment mechanisms was essentially wrong. For those other exposures, another term had been coined: *tolerable daily intake* or *TDI*. There was also a suggestion that "*acceptability*" applied to intentional addition of a given substance, such as additives, to food items, while "*tolerability*" could apply to fortuitous or unintentional additions, such as contaminants. See further discussion under *tolerable daily intake*, where this intentionality is questioned.

Acceptable risk

The only definition provided was rejected by the majority of respondents (58.1%). The relevance of the inclusion of the term in the consensus list may even be questioned, as only one definition was found in the reference sources.

The main difficulty encountered by respondents focuses on the interpretation of "*acceptable*," which is considered more of sociopolitical than scientific significance; i.e., the term relates "*more to risk management than to risk assessment*." Given the variety of sociopolitical

environments in the world, a number of respondents suggested that the term should be deleted from the scope of the hazard/risk assessment terminology, because it is not in use (varies regionally/internationally in meaning), it is not adequate for scientific work (too subjective), or it is too vague/broad in its formulation, except with reference to specific sets of regulatory instruments. Others suggested that the definition should be generalized to cover the field of sociopolitics. The term was concluded to be inappropriate in relation to environmental sciences.

Typically, however, the term could be used to designate the outcome of *risk evaluation*, where in fact the risk–benefit relationship is evaluated. Indeed, the term should preferably be used in a *risk management* perspective.

Adverse effect

The four definitions present only minor editorial differences. Only 10% of the respondents rejected all the proposed definitions. Some 86.7% of the respondents agreed with one of the three quasi-identical definitions.

Comments ranged from "*If the concept is useful, it requires a clearer definition*" to "*self-evident term. No definition required*."

Suggestions included the need to add specific references to, for example, "functions," "organ systems," "lifestyles," or "reproduction." Some indicated that "adverse effect" should not be confused with "adverse reaction." The term is loosely related to "harm." Synonyms mentioned include *harmful effect*, *toxic effect*, *harmful health effect*, *hazardous effect*, *adverse impact*, *undesired effect*, *side effect*, and *detrimental effect*.

The following semantic features have been identified: {*change*} [by {*agent*}] in an {*object*} resulting in {*loss*}, where {*object*} is the target for the change caused by an agent. It may be considered in its globality (e.g., organism, human being, ecosystem) or from a particular angle (e.g., morphology, physiology, growth, development, etc.). The semantic feature {*change*} refers to any departure from a baseline status or condition. The baseline may be set at total integrity or any condition arbitrarily regarded as normal or as a reference point. Reproductive capacity, for instance, varies with age, so that an adverse effect on the reproductive capacity of the object will have a different meaning for different age groups. The element called {*loss*} relates to outcome of the change in the target system, as an *adverse effect* can never be regarded as a positive outcome.

Analysis

The intentional Definition 1 of *risk analysis* in the survey materials, combined with the dictionary definition, provides useful indications on the semantic content of the term. It is defined as a process intended to break up (see etymol. *ana+lúein* = dissolve) an object of study into its constituent parts, to capture their determinants, and to characterize them as accurately as possible and necessary, in order to understand their relations. It is essentially based on facts and figures (*quantified calculation*) and excludes judgement or interpretation

("*without taking any judgements…*"). The IPCS/OECD Terminology Planning Working Group agreed to add this term after the original survey had been conducted.

Assessment

Only two definitions of the single-word term are available. While 62.1% of the respondents selected Definition 1, comments indicated that the term *assessment* as such is perceived as too general a term, which should be used only in combination with other terms, e.g., in *risk assessment*.

Definition 2 was selected by only three respondents. Many others commented that Definition 2, as it stands, applies only to a very limited subject field and therefore does not meet the requirements as the definition of a generic term.

Assessment consists of two elements: "*analysis*" and "*policy-related activities*." Comments do not generally question the need for the first component (also referred to as *facts*, *data*); the interpretation of data and the inference of possible consequences (*identification of issues*, *comparison of risk and benefits*, *potential for damage*) must retain their scientific rather than managerial or policy nature. Policy decisions should then be made on the basis of conclusions by experts.

The object of the analysis is not mentioned in the general definition, which a number of respondents consider disturbing — hence their suggestion that the term *assessment* be used only in conjunction with a stated object.

The knowledge representation reads as follows: {*analysis*} AND {*inference*}, where {*analysis*} means the detailed examination of anything complex, conducted in order to understand its nature or to determine its essential features; it is carried out using all necessary data measurements, calculations, and scientifically established facts about the object of study. The term {*inference*} refers to conclusions that logically follow from the consideration of facts, at least from one particular viewpoint.

Respondents suggested a number of synonyms: *analysis*, *evaluation*, *calculation*, *estimation*, and *judgement*. *Analysis* is not a valid synonym, as it does not take into account consequences. *Evaluation* has an *a posteriori* connotation that does not correspond to the predictive essence of *assessment*. *Calculation* is purely mathematical and does not cover the entire concept, for instance with regard to *judgement*. It is actually rather one of the means through which *analysis* is conducted. *Estimation* evokes approximation.

Assessment end-point

Only one definition was provided for this term. Only 59.6% of the respondents selected it. The explicit emphasis on *environmental value* correlates with the fact that 75% of the environmental health risk assessors chose the definition and only 50% of the human health risk assessors. Other categories show a similar trend, only in smaller numbers.

The majority of rejecters indicated that this term is not necessary/useful, not known (not familiar, not understood, etc.), or too restrictive/too broad/too vague. Several modifications suggested restriction to environmental parameters and recommended association with risk assessment. Environmental value as such, as well as "that is to be protected," is not clearly understood.

Additional comments from respondents selecting the definition included essentially proposals for rewording or synonyms. Rewording proposals included "*[ecological risk assessment] An explicit expression of the environmental value or resource that is to be protected*," "*An explicit expression of a toxic response to an environmental substance that is used as the basis of a health or environmental evaluation*," and "*A quantitative or quantifiable expression of the environmental value considered to be a risk in a risk assessment*."

Suggested synonyms included *evaluation end-point*, *estimation end-point*, *assessment objective*, *critical effect*, *measurement end-point*, *assessment calculation*, *effect parameter*, *test end-point*, *response*, and *effect*. As a result, the following generic definition may be proposed: {*value*} associated with {*a risk*} to be explored in a {*risk assessment*}.

Assessment factor

Seventy per cent of the respondents approved Definition 1. Very few substantive comments were made by those who accepted the definition. Synonyms mentioned included *safety factor*, *uncertainty factor*, *applicable factor*, *application factor*, *extrapolation factor*, *environmental assessment factor*, *adjustment factor*, *modifying factor*, *evaluation factor*, and *estimation factor*.

Comments suggested that *assessment factor* could be a term specific to ecotoxicology, equivalent to *uncertainty factor* in toxicology. There were also several suggestions that the proposed definition as it stands is too restricted to environment and that some adjustment is required to ensure a more general applicability. In view of the many suggestions to ignore the term because it is unclear, it was suggested that it be kept with the definition provided if its use is restricted to environmental assessment. For the sake of the present glossary of generic terms, a modified definition is proposed that accommodates the observations made in the comments received.

Concentration

In spite of small variations in the wording, *concentration* is defined in the reference corpus as "*the quantity of a material or substance contained in unit quantity of a given medium*." Semantically, it includes the following elements: {*quantity*} of {*a substance*} {*contained in*} {*quantity*} of {*a given medium*}, where {*quantity*} refers to an amount measured in appropriate units, depending on the substance quantified; {*a substance*} is used generically to designate anything that may be quantified in the context of a particular study and may therefore be considered as a chemical substance, a compound, or a biological or physical agent; and {*a given medium*} refers to the nature of the system in point, be it the human body or air in the atmosphere.

The aspect of {*contained in*} has been intentionally left in the definition as a semantic feature of the concept in order to emphasize the static nature of the notion of *concentration* at any measurement point in time (as opposed to *dose*, which has a more dynamic nature, with the substance *entering* the system).

Contrasting the semantic representation of the two terms, i.e., *dose* and *concentration*, makes the difference very clear: ***dose***: {*quantity*} of {*a substance*} {*entering*} {*a target system*} ≠ ***concentration***: {*quantity*} of {*a substance*} {*contained in*} {*quantity*} of {*a given medium*}.

The IPCS/OECD Terminology Planning Working Group agreed to add this term after the original survey had been conducted.

Concentration–effect relationship

Six definitions were collected for this term, and 46.7% of the respondents preferred Definition 1. The other five definitions referred to *dose* instead of *concentration* as the first factor in the relationship, which is a reason for rejection explicitly given by some respondents. Comments included: "make sure *dose* stays out of the *concentration* definition and vice versa"; "*dose* is not synonymous with *concentration*"; "*dose* and *concentration* are not the same," etc.). Yet synonyms mentioned by respondents included *dose–response relationship*, *dose–effect relationship*, *exposure–response relationship*, and *concentration–response relationship*.

It should also be noted that some comments referred explicitly to "*concentration* <of a chemical> *in the environment*" (also called "*external concentration*"), others to "*biological tissue concentration*" (also called "*internal concentration*") to which an organism may be exposed. "*Exposure concentration*" was recommended by several experts. The ideal wording of the definition should try to prevent confusion between *concentration* and *exposure concentration*. The former may be perceived as a convenient short form for the latter, but, since they both contain the same base term, a mere substitution in the text of the definition must nevertheless be rejected.

As to the second factor in the relationship, i.e., *effect*, both the wording in the preferred definition and the comments from respondents concur with the conclusions arrived at in the discussion of *effect*. The essential elements in the definition may therefore be listed as follows: {*link*} between [*exposure concentration* = {*dose* = total amount of chemical, physical, or biological agent administered to, taken up by, or absorbed by an individual or a population} over time] and the resulting {*effect* = the magnitude of a specific continuously graded change affecting it}.

Dose

Very often, *dose* is used synonymously for *concentration*. A number of authors strongly contest what they consider an abuse of language, which may be detected in compound terms, in the language of the definitions, and most notably in the comments received from respondents, including in the listing of synonyms. It is useful to analyse both terms in order to clarify the intricacies of the semantic elements.

One of the clearest definitions of *dose* reads "*total amount of a substance administered to, taken or absorbed by an organism*" (Duffus 1993).[1] In order to facilitate the comparison with the definition of compound terms containing the word dose, the following analysis is proposed: {*quantity*} of {*a substance*} {*entering*} {*a target system*}, where {*quantity*} refers to an amount measured in appropriate units (depending on the substance, the amount may be measured in grams, milligrams, or micrograms, in millilitres or microlitres, or in becquerels), {*a substance*} is used generically to designate anything that may be quantified in the context of a particular study and may therefore be considered as a chemical substance, a compound, or a biological or physical agent, and {*a target system*} refers to the subject of study, be it the human body or air in the atmosphere. It could as well be an organism, a population, or an ecosystem.

Finally, the semantic element {*entering*} implies that the amount of substance in point is added to the system, intentionally or not. Clearly, dose is a quantity of a substance and is not related to any unitary quantity of the recipient system.

The IPCS/OECD Terminology Planning Working Group agreed to add this term after the original survey had been conducted.

Dose–effect relationship

The contrastive analysis carried out on the pairs of concepts *dose* vs. *concentration*, on the one hand, and *effect* vs. *response* (see below), on the other, has shown that, close as they may be, those concepts are not interchangeable. This also applies to the combinations of concepts with a variety of other terms, or collocates.

Six definitions were listed in the survey. Four of those were preferred by at least 15% of the respondents. The notion of relationship is common to all and is expressed as *relationship* or *association.* The first factor in the relationship is repeated in the definition as *dose*; the second factor is described more particularly. It is designated as *continuously graded effect*, *severity of effect*, or *magnitude of the biological change.* The semantic features may be represented as follows: {*link*} between {*dose*} and {*magnitude of a defined change*} in {*system under consideration*}. The emphasis on "magnitude" of the effect (rather than change in nature) is confirmed in the vast majority of the comments.

Synonyms listed by respondents included the following: *dose–response relationship*, *concentration–effect relationship*, *dose-related effect*, and *dose–response*. Here again, the list of synonyms highlights how loosely the concepts are used in various contexts.

Dose-related effect

As *effect* can be defined as "*a change in the state or dynamics of a system caused by the action of an agent*," it follows logically that *dose-related effect* is a particular type of effect associated with the quantity of the agent rather than some other characteristic of it, such as its nature or intrinsic properties.

[1] References referred to in this section may be found in Annex 2.

In the survey, only one definition was proposed. It met with the agreement of 89.4% of the respondents.

As pointed out by some rejecters, the wording in that definition is in contradiction to the definition of *effect*. Indeed, assuming that an *effect* is defined as a change, *dose-related effect* can hardly be defined as a situation. Some commentators noted that the definition of the term itself should not necessarily refer to the magnitude of the effect or change and that the change need not be of a biological nature, but could also be, for instance, a behavioural change. Others, however, were of the opposite opinion.

From the comments, the following (quasi)synonyms have been noted: *dose–response relationship* (5 respondents), *dose–response* (7 respondents), *compound-related effect* (1 respondent), *concentration–effect relationship* (1 respondent), *concentration-related effect* (1 respondent), and *dose–effect relationship* (1 respondent), emphasizing once again the confusion between *dose* and *concentration*, on the one hand, and among *effect*, *response*, and *relationship*, on the other hand.

Dose–response

Only three definitions were found. Almost 47% of the respondents were pleased with Definition 1, and almost 28% with Definition 3. Rejecters of all of the listed definitions were quite numerous, with about 18% of the total.

The vast majority of the respondents who submitted comments suggested various wordings for new definitions that would include some reference to "relationship." Many claimed that the term itself is not relevant and should simply be replaced by other preferred terms, mostly *dose–response relationship*, but also *dose-related effect*, *dose–effect relationship*, *dose–effect*, and *dose–response evaluation*.

From the definitions themselves, supplemented by suggestions by rejecters, a relationship is clearly established between "dose" and some aspects of "response" with respect to a target system. The following shows how diverse, and indeed chaotic, the representation of the concept is for the respondents.

Dose is taken for granted and repeated as the first factor in the relationship. The second factor, *response*, is linked to the notion of *effect*, with a strong link to populations rather than individuals or organisms, as emphasized in the comments, although this is not apparent from the three definitions. This is further supported by the frequent reference to "*incidence*" or "*frequency*" and such qualifications as "*in the population*" ("*exposed population*" or "*affected population*").

Integrating the considerations on *effect* vs. *response* (see below), it appears that the two definitions by far preferred by the respondents for *dose–response* in fact correspond to *dose–effect* in their wording. Describing the "*relationship between the dose of a substance … and an effect caused by the substance*" (Definition 1) or "*the relationship between the dose of a chemical and the extent of the toxic effect produced by the chemical*" (Definition 3) keeps the perspective attached to the chemical rather than the target system.

The suggestion that *dose* is synonymous with *concentration* is incompatible with the definitions of *dose* and *concentration*, respectively. It must therefore be rejected.

Dose–response assessment

Among the 10 definitions included in the survey, preferences can be aggregated in four groups: namely, <5% (3 definitions), 5–15% (4 definitions), and more than 15% (3 definitions) [1, 5, 6]. As noted by several commentators, there is an apparent confusion between *dose* and *concentration*. Similarly, some wording may confuse the issue of the difference between *effect* and *response.* A more explicit language, accounting for the difference between *dose* and *concentration*, on the one hand, and for the shift in perspective from *effect* (substance oriented) to *response* (target system oriented), on the other, would, for instance, prevent listing of synonyms built on the *dose–effect* base words.

The notion of {*inference*}, which had emerged from the semantic analysis of *assessment*, is intuitively embedded in some definitions, for instance in such phrases as "*through extrapolation*," "*probability of occurrence of a response in a population*"; comments also indicated that the concept "may involve extrapolation outside the experimental data range."

Finally, none of the three preferred definitions referred explicitly to the "process" nature of *assessment* (although one may assume that it is hidden in such introductory words as "*estimation*," "*determination*," "*identification*," etc.), and reference to the overall process of *risk assessment*, of which *dose–response assessment* has been clearly recognized to be an integral part, is missing from most definitions.

The following terms were cited as synonyms: *dose–response*, *effect assessment*, *effects assessment*, *toxicity assessment*, *dose–effect assessment*, *effects characterization*, *dose–response evaluation*, *dose–response estimation*, *toxicity test*, and *bioassay*. In view of the above, the semantic features of the concept could be outlined as follows: analysis of {{*the link*} between {*dose* = total amount of a chemical, physical, or biological agent administered to, taken up by, or absorbed by a system} and {*response* = change developed in the state or dynamics of a system in reaction to the action of an agent}} and the inferences that may be derived from it for another comparable system.

Dose–response curve

In the light of the conclusions drawn after analysing the semantic elements of the base concepts involved, namely *dose* and *response*, equating "*degree of exposure to a substance*" with *dose* [3] confuses the issue, as it brings the additional concept of *exposure* into play. Also, the preferred definition [3] makes no reference to the population dimension, which is quite clear from the discussion of *response*. In that sense, Definition 2 is consistent in its wording with the wording arrived at for the definitions of the base concepts in the combination. The notion of "relationship" is also quite obvious from both the definitions and the vast majority of comments about them, which often consider *dose–response relationship* as a synonym. Finally, as noted by some commentators, the graphical representation need not be a curve in the strict sense.

The semantic features for the term are mapped very simply as follows: {*graphical representation*} of {*dose–response relationship* = link between an administered dose of, or exposure to, a chemical, physical, or biological agent and the change developed in an system in reaction to it}.

Dose–response relationship

Preferences were quite uniformly distributed among the five definitions, ranging from almost 10% to 23.7%. Comments were very scarce, being mostly limited to an enumeration of (quasi)synonyms: *dose–effect relationship*, *dose–response curve*, *dose–response assessment*, *dose–response*, *exposure–response curve*, *dose-related effect*, and *exposure–response relationship.*

Taking into account the semantic elements identified for *dose* and *response*, respectively, the concept may be defined as follows: {*link*} between {*dose* = total amount of a chemical, physical, or biological agent administered to, taken up by, or absorbed by a system} and {*response* = change developed in the state or dynamics of a system in reaction to the action of an agent}.

Ecological risk assessment

Rejecters of both of the proposed definitions represented only 6% of the reference group. The remaining 94% were almost equally divided into two groups. Few substantive comments were made to enable a real analysis of the semantic elements that make up the definition. As noted by some respondents, Definition 1 in fact refers to the definition of *risk assessment* but applies it to ecology. In order to preserve the general applicability of the present term list, it was proposed that the term be transferred to a more subject-specific section on the environment.

Effect

The concept appears in the present study in contrast to *response*. Both are common language terms that enter into a series of collocates. Essentially, *effect* is analysed as follows: {*change*} {*caused by*} {*agent*} in {*system*}, where {*agent*} is a generic term indicating the entity or circumstance that affects a given system; {*system*} is any set of characteristics considered as belonging together, at least from a particular perspective: it may be a biological system, an organism, or an ecological system, for instance; {*change*} is any departure from a previous state, condition, or situation taken as reference; and {*caused by*} stresses the causative link between the agent and the change. An *effect* is therefore an intrinsic capability of a causative agent that may affect a target system if and only if the potential materializes. This is noted by one of the contributing sources to the definitions collected in the initial survey: "*A change in the state or dynamics of an organism or other ecological system resulting from exposure to a chemical or other stressor (equivalent to response but used when the emphasis is on the chemical)*" (van Leeuwen & Hermens 1996).

From the comments around *dose–effect relationship* and *concentration–effect relationship*, as well as those around *dose-related effect*, it appears that respondents perceive the change in

quantitative rather than qualitative terms. This is confirmed by the high prevalence of definitions referring to "*magnitude of continuously graded change*."

The IPCS/OECD Terminology Planning Working Group agreed to add the term *effect* after the original survey had been conducted.

Effect assessment

From the nine definitions collected, Definitions 1 and 3 stand out, representing 40% of the preferences. Many respondents limited themselves to indicating synonyms: *dose–response*, *dose–response assessment*, *dose–effect assessment*, *toxicity assessment*, *hazard assessment*, *hazard characterization*, *hazard evaluation*, and *hazard identification.*

As pointed out elsewhere, a difference should be maintained between *effect* and *response*. All proposed synonyms that are based on *response* should therefore be avoided, as well as use of the defined term in its own definition. Clearly, comments emphasized the idea of quantification of a substance and the consequence that may derive from an exposure to it, although usually restricting the latter to negative consequences (*adverse effects*), which is not expressed in the term itself. There is also a clear link with *dose* or *concentration* of the substance and the consequence of exposure of the target system.

Expert judgement

Some 70% of the respondents selected the only proposed definition. Some suggested adjusting the wording of the definition for specific subject fields; others claimed that the use that is made of the opinions need not be restricted to incorporation into probability estimates.

Exposure assessment

Ten out of 16 listed definitions for this term were selected by at least 5% of the respondents, ranging between 6.1% and 15.3%.

From the text of the definitions as well as from the rather scarce comments, a number of factors were cited as being part of the concept: *emissions*, *pathways*, *rates of movement*, *transformation and degradation of an agent*, *concentration or intensity*, *environmental levels*, *duration*, *route*, *frequency and extent of exposure of an ecological system*, *environment compartment*, and *(specific) (human) population (or people)*. Depending on the source of the definitions, the agent is called *substance*, *pesticide*, *chemical*, *contaminant*, or *biochemical, chemical, or physical agent*.

As was the case for *dose–response assessment*, the definition of *exposure assessment* as a process is recognized implicitly rather than explicitly (only in two definitions). The selection or grouping of factors points to shifts in perspectives on what may appear eventually to be a common understanding of the essence of the concept.

One of the comments received clarifies the issue and helps distinguish between the different technical fields that use specific interpretations of *exposure assessment*:

> Most of the literature on health deals with exposure assessment as measurement or modeling of concentrations of the agent in ambient media, which, when combined with information on amount of medium to which the organism is exposed, will yield a measure of applied dose. This reflects the fact that health scientists are usually seeking to develop harm criteria and then compare real exposure with the exposure just avoiding harm. However, engineering risk assessors are more concerned with how the agent reached the medium, i.e. the sources of exposure. For this purpose, source-release assessments are combined with information on dispersion patterns, etc. in order to yield a prediction of exposure (the exposure assessment). Both of these relate to individual risk to a hypothetical person. When the exposure assessment is linked to a geographical area, and hence to the populations contained within that area, the risk estimates can be associated with societal (or population) risks. **Definitions are required which differentiate between exposure assessments** for: **[1]** determination (by measurement or modeling) of the amounts of an agent (substance, physical agent or biological agent) likely to be present in a medium to which an individual or a population may be exposed; **[2]** the assessment of the sources and sizes of releases and the dispersion patterns within the different media for an agent; or **[3]** assessment of the sources and sizes of releases and the dispersion patterns for an agent in relation to the geographic areas (and hence the populations within the geographic area) surrounding the resources. **[Emphasis added]**

The three proposed definitions are said to differentiate between *exposure assessments.* In fact, they differ by the emphasis they put on one particular subset of features or another, from among those that had been identified as representative of the concept.

As indicated, the first one displays a health concern and the second one focuses on engineering issues. Admittedly, they both refer to people, but hypothetical people. The last proposal is more concerned with possible effects on a real population. We could therefore have the semantic representation as follows: {*process*} {*for quantitatively and qualitatively analysing*} {*amount*} of {*agent*} in {*medium*} AND {*inferring consequences*} that [may] affect a {*population*}, where {*quantitatively and qualitatively analysing*} refers to the wide range of analytical techniques, such as actual measurement, modelling, extrapolation, etc.; {*amount*} applies to a series of relevant variables, such as emissions, rates of movement, concentration or intensity, environmental levels, duration, frequency, and extent, as appropriate for the intended purpose; {*agent*} is a general term for *substance* (chemical, physical, or biological agent), pesticide, contaminant, etc., not only as such, but also considered in its potential derivatives ("*transformation and degradation of an agent*," also referred to as "*fate*"); {*medium*} is the relevant environment that matters for a particular concern: soil, air, water, sea, environmental compartment, or ecological system; {*inferring consequences*} refers to the second component of *assessment*, as previously identified; and {*population*} actually means either an organism/individual person or a group of them, considered as a hypothetical or as a true entity. Related to *exposure assessment* are *exposure scenario*, *margin of exposure*, and *fate.*

Exposure scenario

The only two definitions proposed in the survey were selected by 58.4% and 36.8% of respondents, respectively. Comments were scarce and mostly of an editorial nature, except to say that one is worded more in the spirit of health risk assessment and the second one is more suited to environmental risk assessment. Essentially, they both contain a list of parameters that may be taken into account in order to carry out exposure assessment.

Fate

Only three definitions were proposed: Definition 1 gathered some 52.6% of the preferences; Definitions 2 and 3 were identical except for one word, together collecting 41.6% of the preferences. The last two are explicitly concerned with environmental compartments, a reason that some commentators put forward to justify their preference for Definition 1.

Guidance value

The two proposed definitions are almost identical. Thirteen per cent of the respondents rejected them as imprecise, unknown, etc. It was also suggested that the definition should be kept short and that the reference to *tolerable intake* should be replaced with *reference dose*. A number of synonyms were mentioned, including *tolerance*, *guideline level*, *maximum residue limit*, *maximum acceptable concentration*, *threshold limit value*, and *protection factor*. Since those terms were not included in the initial survey, the available information does not permit conclusions to be drawn on a generic definition for this particular term. It was suggested that the term could be deleted from the list of generic terms and be taken up in future work on technical terms.

Harm

Of the five proposed definitions, Definition 3 collected 76% of the votes. There is a large consensus in the expressed opinions that harm is a "simpler" word for *adverse effect*. In view of the numerous general language connotations for the word, it was proposed that it be deleted from the final list.

Hazard

Hazard and *risk* are two major nodes in the terminology of risk assessors. They enter into a number of word combinations, where they denote concepts in their own rights: *hazard assessment*, *hazard characterization*, *hazard evaluation*, *hazard identification*, *risk analysis*, *risk assessment*, *risk communication*, *risk management*, etc. They also enter into a number of definitions, with a tendency to circular definitions. Furthermore, technical usage is often influenced, willingly or not, by the common language meaning. This explains the confusion surrounding the terms *hazard* and *risk* and their collocates or related terms.

The references used for the present study include 18 definitions of the term *hazard* alone. Four of those definitions were preferred by at least 5% of the respondents, aggregating 65.6% of the total responses.

The vast majority of definitions, including the preferred ones, refer to an inherent property (of a natural phenomenon, a chemical, a pesticide, a substance, a mixture of substances, a process involving substances, a source of energy, a situation or event) capable of causing adverse effects (called variably *harm*, *undesirable consequences*, *human injury*, *damage to property*, *damage to the environment*).

Comments pointed to the confusion deriving from reference to a *likelihood* [1, 2, 9, 10, 16], which points to *risk* rather than *hazard*. Similarly, *under certain conditions* (as in *under the conditions of its production, use and disposal* [2, 3, 9, 16], *depending on the degree of exposure* [4, 6]) would enter into the definition of *risk* rather than *hazard*.

From the available data, it appears that the following elements should be included in the definition: {*inherent property*} of {*entity to be specified*} with {*potential*} of {*adverse effects*}. Applied, for instance, to a given pesticide, the *hazard* associated with pesticide X could be defined as "*the inherent properties* (due to the nature of chemicals entering in its formula) *of pesticide X that may* (i.e., as a potentiality that will materialize **only** if a target organism is actually exposed to it) *cause* (definitely, *causality* must be there) *cancer* (as a qualified negative consequence resulting from the actual exposure)"; this is exemplified in Definition 18, which reads: "*The capacity* <for a particular substance> *to produce a particular type of adverse health or environmental effect*, e.g. one *hazard* associated with benzene is leukaemia," with *capacity* conveying the meaning of *potentiality*, the word *produce* expressing the idea of causality, the wording *a particular type* standing for a range of consequences associated specifically with any given substance, and *adverse health or environmental effect* indicating the particular kind of consequence in which the author is interested.

The above reasoning will not be repeated in such detail for all definitions. It is considered that in multidisciplinary environments, harmonization is possible only if confined to a certain level of generality and commonality of meaningful elements. In this way, several wordings may be found acceptable to convey a single meaning in languages that are more familiar to individual user groups. As a corollary, additional (often discipline-specific) information may be added without jeopardizing the baseline generality of the initial statement, thus preserving at the same time harmonization and technical specificity.

Hazard assessment

Six [1, 3, 4, 5, 9, 12] of the 15 listed definitions were selected by at least 5% of the respondents. Together, they represented 64.8% of all responses.

Preferred definitions point to a variety of factors and variables that have to be taken into account. Not surprisingly, they are concerned with *adverse effects*, a semantic feature included in *hazard* itself. More specifically, however, they point to parameters that help characterize those adverse effects: *incidence*, *severity*, *actual or predicted exposure*, *mechanisms of toxicity*, *dose–effect relationship, worst-case exposure level*, *dose–effect and dose–response relationships*, *variations in target susceptibility*, *mechanisms of toxicity*. Definition 12 is more process-oriented (i.e., uses more action collocates than the others) and lists various steps to be integrated: *hazard identification*, *hazard characterization*, *exposure assessment, estimation.* In addition, Definition 3 provides a clear link to risk-related terminology ("*this is the prelude to risk assessment*").

There is strong rejection among respondents of all of the proposed definitions for the term (none of the above = 16.6%), and comments further indicated strong rejection of the term itself: "*not a good term*," "*confusing term*," "*not a necessary term*," etc. There were explicit

comments pointing to a confusion between *hazard* and *risk*. A number of synonyms were mentioned: *risk estimation*, *effects assessment*, *hazard characterization*, *hazard evaluation*, *hazard identification*, *dose–response assessment*, *hazard analysis*, *risk characterization*, and *risk assessment*.

Respondents who chose one of the preferred definitions also provided synonyms, in whole or in part: *risk assessment*, *hazard evaluation*, *hazard characterization*, *risk characterization*, and *hazard identification*.

One comment provided useful insight into the confusing picture: "The use of *hazard*, *risk*, *hazard assessment*, *risk assessment* and their definitions should have some logic, some coherence." This is indeed much needed if one is to reconcile statements from the quoted definitions, such as "*this is the prelude to risk assessment*" [3] vs. "*the final phase of the risk-assessment process*" [10]. In essence, the concept may be described as follows: {*process*} to determine {*factors*} for controlling the {*possible adverse effects of a substance*} on {*target systems*}.

Hazard characterization

Only two definitions were provided in the survey. Slightly more than half the respondents (51.2%) preferred Definition 2. Substantive comments, on either Definition 1 or Definition 2, were scarce, pointing at the qualitative ("*characterization of mechanisms of action*," "*biological extrapolation of experimental data*") rather than the quantitative ("*dose–response assessment*") aspects of the notion. Rejecters mostly alleged excessive specificity for food or confusion with other terms listed as synonyms. One commentator considered *hazard characterization* to be a combination of *hazard identification* and *dose–response assessment*. Another one suggested eliminating "*evaluation*" from the definitions, as it confuses the issue with *hazard evaluation* as a term *per se*.

The synonyms mentioned by the respondents included *hazard assessment*, *hazard evaluation*, *hazard identification*, *risk characterization*, *hazard analysis*, and *effect assessment*. The variety of proposed synonyms emphasizes, as is the case with *hazard identification*, the difficulty users face in dealing with changeable terminology. It seems that a number of users simply do not need to analyse the process in such great detail for the purpose of their everyday activities. Building a consensus for a multidisciplinary activity, however, calls for a closer look at all options in the general perspective of an entire concept system. It should be noted that the proposed definition includes, in the context of *hazard assessment*, a dose–response assessment element, which, in relation to *risk assessment*, is considered a discrete step in an otherwise similar process.

Hazard evaluation

The distribution of responses (about one-third of responses each for Definition 1, Definition 2, and None of the below) does not allow final conclusions to be drawn based on preferences. Comments were very scarce. Two respondents preferring Definition 2 re-emphasized the relation between *hazard* and *benefit*. Most rejecters of all of the proposed definitions mentioned other terms that they considered synonymous: *hazard assessment*, *hazard*

characterization, *hazard identification*, *hazard analysis*, *risk evaluation*, *risk assessment*, and *effect assessment*.

Allusions to risk collocates are dealt with under *hazard* and *risk*. As to the proposed synonyms, they again reflect the view that, for a majority of respondents, a fine distinction between possible subcomponents of *hazard assessment* is not relevant to their usual practice. In the majority of cases, *hazard assessment* would suffice. Wherever analytically sufficient, *hazard assessment* could be used to represent a superordinate concept for a process, the output of which is then used as an input in another subsequent process of *risk assessment*.

Following the analysis of the survey results, it was decided not to include the term *hazard evaluation* in the list of generic terms.

Hazard identification

Seven out of 14 definitions collected more than 5% each of the total responses for the term, with Definition 2 (with more than 38% of the preferences) standing out.

As a matter of fact, Definitions 2, 4, and 14 being exactly identical, the preference for that particular wording represents altogether almost 52% of the responses. Its usefulness, however, may be questioned on semantic grounds.

Comments confirmed the need to ensure consistency of the definition with that of *hazard*. Beyond that, several comments stressed the importance of including indications on "*identification of target populations and conditions of exposure*," "*pathways and target populations*," "*examination of science data and data needs, policy and regulatory issues and site-specific factors to define the feasibility, scope and objectives for the risk assessment*," and "*studies conducted under specific conditions*," thus emphasizing the need to consider *hazard identification* also in the broader context of the entire process of *risk assessment.*

Synonyms mentioned by the respondents included *effect assessment*, *hazard assessment*, *hazard characterization*, *hazard evaluation*, and *problem formulation*.

The variety of alternative names highlights the difficulty encountered: some terms are perceived as synonymous by those who adopt a broader view on the subject, while they are considered sub-entities by others attempting to pursue the analysis further. By comparison with the accepted terminological cluster around *risk assessment* (displaying an analytical sequence including *hazard identification*, *dose–response relationship*, *exposure assessment*, and *risk characterization*), it follows logically that the *hazard assessment* cluster can be further analysed and that consequently the terms considered synonymous to *hazard identification* are actually used as equivalent terms by many. Furthermore, following the semantic analysis deriving from both the definitions and the related comments, it appears that *hazard identification* is used in relation to *hazard* and *risk* with two different meanings. In the context of hazard assessment, it is very specific and limited in scope as the first of the three steps that characterize that process. In the area of *risk assessment*, it is again used as an equivalent.

Margin of exposure

This term is recommended as a synonym for *margin of safety* by the majority of respondents.

Note: In the case of environmental risk assessment, predicted environmental concentration (PEC) is often used instead of estimated exposure concentration (EEC).

Margin of safety

From among the six definitions proposed in the survey, two [1, 6] together have the preference of more than 50% of the respondents (22.7% and 28.0%, respectively).

The majority of definitions include a reference to NOAEL and are presented as ratios. The fact that more than 17% of the respondents did not choose any of the definitions casts some doubts on the general acceptability of the term. Rejecters tended to concur that the term is obsolete, particularly due to a possibly misleading reference to safety (see *Safety*).

Measurement end-point

The only definition for the term was approved by more than 77% of the respondents, with next to no comments.

Rejecters claimed that they either do not use the term or are not familiar with its meaning. Others emphasize its use in very specific areas, such as ecological risk assessment. In view of these comments, the Working Group suggested that the only proposed definition be kept as it is, but that it could be set aside for possible inclusion in future work on technical terms. After subsequent peer review, however, it was included in the generic terms.

Reference dose

The key semantic features include an {*amount*} (also "*exposure dose*") of a {*substance*} (occasionally specified as "*chemical*," "*food additive*," "*pesticide*") that a person can {*ingest*} (or "be exposed to") on a {*daily basis*}, even {*over a lifetime*}. It is reportedly expressed in mg/kg body weight per day.

Commentators insisted that any definition should be generalized for any exposure route. *Reference dose* is used in certain legal frameworks to mean *acceptable daily intake*. An examination of the definition arrived at for that term shows that *reference dose* contains the same semantic components.

Indications that the *reference dose* is derived from the NOAEL and lowest-observed-adverse-effect level (LOAEL) and other specific details of technical relevance may be reserved for subject field-specific definitions, rather than for generic definitions.

Response

Response shifts the emphasis onto the recipient system rather than the causative agent (cf. *effect* above). The constitutive elements of the concept can be expressed as follows: {*change*} {*developed by*} {*a system*} {*as a consequence*} of exposure to an {*agent*}. The IPCS/OECD Terminology Planning Working Group agreed to add this term after the original survey had been conducted.

Risk

The survey included 22 different definitions. The highest scores go to Definitions 3 and 22, with 11.3% and 12.3%, respectively. The number of definitions available in the literature as well as the spread of choices among them seem to indicate a somewhat delicate, if not controversial, concept. In spite of the wide choice, it should also be noted that close to 10% of the respondents were not happy with any of the proposed definitions. As well, definitions emanating from international sources (the Food and Agriculture Organization of the United Nations [FAO], WHO) were not chosen by any of the respondents.

All definitions start with an expression of the nature and quantification of the event under investigation, albeit in different ways. The nature of the event in point is called variably *damage*, *deleterious effect*, *undesirable effect*, *harmful event*, *adverse effect*, and *adverse outcome*. The method for quantifying the subject of study is sometimes called *expected frequency* [1, 4, 8, 14], *chance* [19], *likelihood* [13, 15], or *possibility* [2, 7]; mostly it is referred to as a *probability* [3, 5, 6, 9, 10, 11, 12, 16, 17, 18, 20, 21, 22]. Probability is qualified in Definition 20 as *quantitative probability*.

There is also a wide range of causative agents, including *toxicant*, *pesticide*, *chemical/physical agent*, *substance*, *exposure to a hazard*, *chemical*, *mixture*, *risk factor*, and *known or potential environmental concentration of material*.

The object to which *risk* applies is quoted as *man*, *the environment*, or *a biological or other system*. Comments emphasized the absolute need to distinguish between *hazard* and *risk*, which, it is said, are often erroneously interchanged. The essential elements that should appear in the definition include: {*probability*} of {*adverse effect*} {*caused by*} {*agent*} in {*system*}, where {*probability*} refers to a mathematical or statistical quantification of a phenomenon; if no measurable data are available, estimates may be used; {*adverse effect*} is a generic term, the essence and scope of which are discussed elsewhere; {*agent*} represents any chemical, physical, or biological entity that may act on a system under study and result in various effects, including adverse ones that are of more particular concern to the risk assessors; clearly, it points to an interaction with the system rather than at an intrinsic property of the agent; {*system*} represents any set of interrelated elements that, from a particular viewpoint, function as a whole; it may be realized as an organism, a person, a population, an ecological system, etc.; {*caused by*} specifies the kind of relationship between the agent and the system in question. The detailed mechanisms of causation are varied. They are determined by the intrinsic characteristics of the agent, the nature of the system under study and its capacity to react or adapt, and the situation in which the exposure to the agent occurred. For the sake of generality, it is preferable not to attempt to list the kinds of systems

concerned in an exhaustive manner, nor to generalize the features of, and conditions applicable to, the agents.

Risk analysis

Only 14.0% of the respondents preferred Definition 1. Some 65% selected Definition 2 or 3, which are identical, but from different sources.

On the basis of the preferred definitions, the following structure may be used as a guide:

This situation is, however, confusing to many users. A number of rejecters of the term considered that *risk analysis* is obsolete, actually means *risk assessment*, or should not be used at all. To one respondent, *communication* cannot possibly be part of *analysis*; to another, *management* is subsequent to *analysis*, not part of it. Such comments are in line with our previous discussions of action collocates, such as *analysis* and *assessment* (see also Annex 4). Since we have seen that {*assessment*} includes {*analysis*} AND {*inference*}, then {*analysis*} cannot include, e.g., {*assessment*} in the same system of concepts. The only way to resolve the apparent contradiction is by defining two different perspectives, one with scientific objectives, the other with decision-making objectives comprising the sequentially related concepts of *risk assessment*, *risk management*, and *risk communication*.

Risk assessment

Risk assessment is the first of three components of *risk analysis*. Six definitions attracted at least 5% of the responses each and together accounted for 73.7% of all responses. A stronger preference was marked for Definition 1 (38.1%) than for Definition 2 (11.3%). The other four scored between 5% and 10%.

All preferred definitions include a narrative; most of them also include a further breakdown into four constituent parts. The designations of the sub-elements vary.

One respondent equated *dose–response assessment* with *hazard characterization*, which, combined with *hazard identification*, should constitute *hazard assessment*. Several comments pointed to the need to include specifically the notion of "judgement" in order to remain consistent with the previously debated definition for *assessment*. Synonyms mentioned for *risk assessment* included *risk analysis*, *risk characterization*, *risk estimation*, and *risk evaluation*.

The semantics of *assessment*, as discussed above, as well as the close examination of the semantics behind the narrative text of the definitions support the view that *risk assessment* describes a process rather than a product. In particular, it is clear that the elements that are

reported to be part of *risk assessment* are indeed steps, i.e., they occur in a logical sequence of events.

There is a clear emphasis on the need to exert a judgement, on the basis of scientific evidence, on a *risk* that specific agents may represent for human health or the environment. As a result, *risk assessment* may be said to be a process for measuring, quantitatively and qualitatively, the risk that a particular agent represents for a specific target system.

Analytically, and in order to ensure a close monitoring of a process that is intended to protect individuals and populations against serious health risks, the process may be subdivided into four smaller parts. In conclusion, the concept definition could read: {*process*} {*for measuring*} {*a specific risk*}, where {*process*} is a four-step sequence of actions, {*measuring*} is meant in a quantitative as well as qualitative manner, and {*specific risk*} means the risk associated with a specific agent.

From the analysis of the various steps involved, it appears that the risk measured in the process is closely related to the intrinsic potential of the agent in point to have adverse effects on something. As the definition of hazard indicates, this goes back to the inherent properties of the agent, which are best determined with scientific knowledge. The various definitions of the term display consensus on the first step, referred to as *hazard identification*. There also seems to be wide-ranging agreement on the ultimate goal of the process, namely *risk characterization*, as well as on the necessity for the two intermediate steps to deal with dose–response and exposure. Terms to designate those steps tend to vary, however. The first intermediate step is referred to as *dose–response assessment*, *effects assessment*, *hazard characterization*, and *risk characterization*; the second is mostly referred to as *exposure assessment*.

Risk characterization

Eight of the 16 listed definitions collected at least 5% of the responses each. Together, they represented 78.7% of all responses. Moreover, four of the preferred definitions stood out, with around 13% each.

A number of definitions, including two of the top-ranking preferred ones, and quite a number of comments from rejecters recognize the fact that *risk characterization* is one step (often the last one) of *risk assessment.* This is consistent with the analysis of *risk assessment.*

Additional elements include a clear reference to a process that should take into account a number of parameters, including *dose–response assessment* and *exposure assessment*, and integrate those with an estimation of the risk (see definition of "*risk estimation*") and the "*strengths and weaknesses of those estimates*" (also called "*attendant uncertainties*").

Some commentators pointed again to the obvious confusion between *hazard* and *risk.* More confusion arises from the different presentations of related terms, such as *risk estimation*, *risk analysis*, etc. *Risk estimation* is sometimes considered a preliminary step to *risk characterization*, but is also considered an integral (although facultative) part of it: "*it may include risk estimation*."

The assertion in Definition 1 that *risk characterization* is "*a summary and description of the results of a risk analysis*" is in contradiction with the agreed definition that it is the last step in *risk assessment*, which is itself the first step in *risk analysis*.

Proposed synonyms include *risk assessment*, *risk evaluation*, *risk estimation*, *risk analysis*, *risk identification*, *hazard assessment*, and *hazard characterization*.

Taking into account the key elements included in the preferred definitions and the suggestions made by commentators, the following semantic construct may be proposed: {*integration of* {{*hazard identification*}, {*dose–response assessment*}, *and* {*exposure assessment*} *data*} *with* {*estimation* {*including attendant uncertainties*} *of a risk*} for {*system of concern*}.

Risk communication

In essence, all four definitions listed in the survey contain the same information. The differences in the wording are of an editorial rather than substantive nature. Confronting the language with comments received shows only one area of minor disagreement — namely, on the interactive nature of the exchange of information, which a few respondents question. No strong argument was offered, however, either in favour of or against it. It was suggested that the interactivity be included explicitly, as it is an intrinsic component of exchange.

Risk estimation

It was suggested that *risk estimation* be considered a part of *risk characterization.* To assess the validity of the suggestion, responses specifically related to the term are discussed here.

Each of the six proposed definitions gathered more than 5% of the responses for this term. There was, however, a strong preference for Definition 1 (35.1%) and Definition 2 (17.3%). In spite of different wordings, the definitions all contain the same semantic features: {*quantification of probability, including uncertainties*} of {*effects of exposure*} based on {*hazard identification*}, {*dose–response assessment*}, and {*exposure assessment*} in a {*population*}. Quoted synonyms include (part of) *risk assessment*, (part of) *risk characterization*, and *last step of risk assessment*.

Risk evaluation

Only two proposed definitions collected 45.7% and 28.6% of the responses, respectively, together representing almost 75% of the total. Rejecters represented more than 25% of the respondents, which may indicate the difficulty some experts face with the term, because of the reference to a risk–benefit relationship.

To some, integrating risk–benefit considerations suggests that the term relates more to *risk management*. Others, more numerous, supported the view that the term is in fact synonymous with a series of more familiar terms: *risk assessment*, *risk characterization*, *risk estimation*, and *risk management*. Supporters of either Definition 1 or Definition 2 also mentioned the

same synonyms, but to a much lesser extent: *risk assessment*, *risk–benefit analysis*, *risk estimation*, and *risk characterization*.

In the previous analysis of *risk assessment*, there was no mention of a risk–benefit relationship. Since the vast majority of respondents considered that the risk–benefit relationship is indeed part of the *risk evaluation*, the synonymy with *risk assessment* must be rejected. On the other hand, the only way to bring it closer to *risk management* is to consider it an intermediary step after *risk assessment* in the *risk analysis* process. A logical link would also thus be established with such terms as *acceptable risk*.

Risk identification

Some 65% of the respondents selected the only definition proposed in the survey. They made no comments and cited no synonyms. Rejecters recommended the use of *hazard identification*. For lack of evidence, it is suggested that the term be left aside for the present purpose.

Risk management

Of the 16 definitions collected for the survey, only 6 were selected by at least 5% of the respondents, with a strong preference for Definition 5 (28.6%).

In their majority, the preferred definitions refer to *risk management* as a decision-making process that takes into account political, social, economic, and engineering information on the one hand and risk assessment information (sometimes loosely called "risk-related information" or "assessed risks") associated with a hazard on the other hand, in order to weigh policy alternatives in response to the hazard.

Occasionally, policy alternatives are detailed in different ways, such as the development, analysis, and comparison of regulatory options (coupled with non-regulatory ones, in one case) and the selection of appropriate (in two cases "optimum") responses for safety, followed by implementation measures.

These elements are confirmed by the vast majority of commentators.

Furthermore, the process is broken down into three sub-elements — namely, *risk evaluation*, *emission and exposure control*, and *risk monitoring*. There was little controversy about this division in the comments received.

Risk monitoring

Definition 1 (of 2) was preferred by almost 70% of the respondents. Comments were very scarce on either definition. Rejecters concurred that they found the term unnecessary or unknown to them. Considering the prevailing view expressed regarding the definition of *risk management*, it was considered logical to keep the term in the list.

Safety

Six out of eight proposed definitions for *safety* found the agreement of at least 5% of the respondents, with a clear preference for Definition 4 (29.7%) and, to a lesser extent, Definitions 1 and 3 (16.9% and 15.4%, respectively).

The preferred definitions point to a number of semantic elements that relate, reciprocally, to *risk*. The event is designated as *adverse effect* (or *injury*) caused by an *agent* (*material* [1], *substance* [2, 5], *chemical substance* [6, 8]) under certain circumstances. As pointed out in the comments, the adverse effects need not be limited to health effects. It was also suggested that, in the absence of a more explicit context, the definition is close to that of the general language dictionary: the Oxford English Dictionary defines *safety* as "*Exemption from hurt or injury*."

Most comments (almost exclusively from rejecters) stressed the difficulty of using the term in practice. It was claimed that in absolute value, *safety* corresponds to a zero probability of a risk, a situation seldom encountered in real life. In that sense, it was recommended that the term be abandoned altogether. This is impossible, however, as it combines with other terms to express concepts relevant to the practice of risk assessment, including *safety factor* and *margin of safety*, and is also related to other concepts, such as *uncertainty*, *uncertainty factor*, *acceptable risk*, *tolerable risk*, and *acceptable daily intake*.

Safety factor

All five options (four proposed definitions and none of the below) collected a fair number of votes. In essence, a *safety factor* is considered a modifier of measured or estimated values in toxicological assessment practice. Comments indicated that the term is largely considered obsolete and should be replaced by *uncertainty factor*, not the least to prevent the assumption that the application of a corrective factor to real measurements or estimates in the course of extrapolation, for instance, will ensure absolute safety.

Occasional reference is made to *no-observed-effect level (NOEL)* [1, 4] or *no-effect level* [2], a concept that has not been mentioned anywhere else in the proposed list of generic terms. It was recommended that the possibility of deleting the term from the list of generic terms in favour of subject-specific lists, if necessary, should be considered. Indications that the *safety factor* enters into the calculation of the *acceptable daily intake* should also be taken into account in this respect.

Synonyms were mentioned as follows: *uncertainty factor*, *assessment factor*, *application factor*, *extrapolation factor*, *margin of safety*, *margin of exposure*, and *modifying factor*. In spite of those opinions, Definition 2 indicates that "*it therefore differs from assessment or application factors*": this contradiction should be resolved by technical experts.

Threshold

From the five listed definitions, four were selected by more than 10% of respondents. Scores for those ranged between 13.3% [4] and 34.7% [1]. They all display the same semantic

structure: {*dose*} (also called "exposure concentration," "exposure") below which an {*effect*} is {*not expected to occur*}.

Contrary to the usual, i.e., general language, definition, which defines a point beyond which a given physiological or psychological phenomenon will occur, the present concept operates from the opposite perspective, as a limit beyond which it will not occur.

The preferred definitions vary as to the designation of the event that is expected to occur or not to occur: {*effect*} is called simply *effect*, but is also called *adverse effect*, *significant adverse effect*, or *specified measurable effect*. From the comments, there is a suggestion that the effect could also be beneficial, which is incompatible with *adverse effect*. Finally, one respondent suggested that {*not expected to occur*} should be replaced by {*not be observed*}, which is consistent with the wording of Definition 5.

Tolerable daily intake

Note: "Tolerable daily intake" is broadly related to "acceptable daily intake."

Preference for four out of five listed definitions ranged from 14.0% to 21.5%. All definitions were rejected by more than 22% of the respondents.

The term *tolerable daily intake* has been coined by the European Commission Scientific Committee on Food as a regulatory equivalent for *acceptable daily intake*. As noted in Definition 3, TDI is expressed, unlike the ADI, in mg/person, assuming a body weight of 60 kg.

Commentators emphasized that the term is in essence synonymous to *acceptable daily intake* for European Commission regulatory purposes. It tends to be used for contaminants rather than substances that might be deliberately added.

Tolerable intake

The only available definition was found suitable by 77.6% of the respondents.

Many comments suggested that *tolerable daily intake* or *tolerable weekly intake* be used instead. Other synonyms mentioned included *acceptable daily intake* and *reference dose*. In essence, two views were expressed: the term is considered either not relevant (or used) or not appropriate where time limits are required; these may refer to a daily or to a weekly intake, to the explicit exclusion of a lifetime period. It was recommended that for the sake of generality, the only definition could be slightly modified to remove the indication of time, in order to keep the options open in practice for more specificity.

Toxicity

Out of 13 different definitions, Definitions 2, 3, and 4 are clear and simple and canvassed more than 60% of the votes. Definition 6, which was somewhat more complex, collected another 9% of the votes. In the spirit of the present project, i.e., the production of simple,

clear definitions of a generic nature, the Working Group proposed that the simplest definition be kept, with *chemical* replaced with *substance*, for consistency reasons.

Toxicity assessment

No clear opinion comes out of the responses to the survey. Until further evidence is collected, it was suggested that the term be left out of the glossary of generic terms.

Uncertainty

As mentioned in the analysis of *safety*, reference to *uncertainty* is preferred by many respondents, in order to prevent the abusive assumption that *safety* could mean *absolute safety*.

Definition 1 by itself was found suitable by more than 45% of the respondents. Comments were scarce and mostly recommended the use of a general language definition. It seems that the term cannot be excluded from the list of generic terms, due to the specific preference expressed by the commentators on *safety*.

Uncertainty factor

Definition 1 is a paraphrase more than a definition, a terminologically unacceptable practice, as it provides no explanation or definition. However, it was selected by more than 40% of the respondents.

Rejecters claimed that the proposed definitions were too specific in certain respects. This is confirmed where definitions start with an indication of the domain ("*in assay methodology*," "*in toxicology*").

A number of synonyms were mentioned in the comments, including *safety factor* and *assessment factor*. In view of the preference for *uncertainty factor* instead of *safety factor*, it was suggested that the definition arrived at under *safety factor* (see *Safety factor*) be used as a starting point for a generic definition, to be qualified as required for use in more specific subject fields.

Validation

Almost 75% of the respondents adopted Definition 1 (out of two). However, in 1996, the concept of validation was discussed extensively in the context of new and revised methods for hazard characterization/identification. This newer description is preferred.

ANNEX 1
LIST OF HIGH-PRIORITY GENERIC TERMS INCLUDED IN THE NOVEMBER 1996 IPCS/OECD SURVEY[1]

A
acceptable daily intake
acceptable risk
adverse effect
assessment
assessment end-point
assessment factor

C
concentration–effect relationship

D
dose–effect relationship
dose-related effect
dose–response
dose–response assessment
dose–response curve
dose–response relationship

E
ecological risk assessment
effect assessment
expert judgement
exposure assessment
exposure scenario

F
fate

G
guidance value

H
harm
hazard
hazard assessment
hazard characterization
hazard evaluation
hazard identification

M
margin of exposure
margin of safety
measurement end-point

R
reference dose
risk
risk analysis
risk assessment
risk characterization
risk communication
risk estimation
risk evaluation
risk identification
risk management
risk monitoring

S
safety
safety factor

T
threshold
tolerable daily intake
tolerable intake
toxicity
toxicity assessment

U
uncertainty
uncertainty factor

V
validation

[1] Following the survey, deliberations of the IPCS/OECD Terminology Planning Working Group and subsequent expert review resulted in the addition of the terms "analysis," "concentration," "dose," "effect," "exposure," and "response" and deletion of the terms "ecological risk assessment," "harm," "hazard evaluation," "risk identification," and "toxicity assessment."

ANNEX 2
REFERENCES AND OTHER SOURCE DOCUMENTS OF DESCRIPTIONS OF HIGH-PRIORITY TERMS

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ANNEX 3
ORIGINAL SURVEY RESULTS

Summary of respondents

Table A.1 summarizes the areas of expertise of the respondents, as well as the region of the world in which they live. It should be noted that there are some respondents who did not complete the personal profile survey. The collection of the necessary information on these respondents will be attempted in the near future. For the purposes of this report, their selections have been included in Table A.1 under the headings "None"/"None listed" and in the summaries in the "None reported" category.

Table A.1: Summary of respondents by expertise and country

Expertise	*All*	*None*	*Asia*	*Africa*	*Europe*	*North America*	*Latin America/ Caribbean*	*Australia/New Zealand*
Biochemistry								
Biology								
Chemistry	1				1			
Drugs/pharmaceuticals	3	1			2			
Ecological science (general)								
Ecological science (aquatic)	2		1		1			
Ecological science (terrestrial)								
Environmental science	10			1	6	1		2
Epidemiology	3				2	1		
Food safety								
Laboratory research								
Mathematical sciences								
Occupational health	4	2			1	1		
Office research								
Pesticides	7				4		1	2
Risk assessment (general)	3		2		1			
Risk assessment (environmental)	25				17	7	1	
Risk assessment (human health)	71		6		40	17	2	6
Risk assessment methodology	1					1		
Risk management								
Toxicology	8		1	2	4	1		
Other	27	2	2	1	15	2	4	1
None listed	18	3	1		5	8	1	
TOTALS	183	8	13	4	99	39	9	11

Acceptable daily intake

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	12	6.1									2	3		1	2	4
1	44	22.4		1		4	1	1			3	15	1	1	9	8
2	12	6.1			1	1			1	1	1	5			1	1
3	39	19.9			1	2	2		2	1	6	13		1	3	8
4	19	9.7						1	2	1	2	3		1	5	4
5	1	0.5										1				
6	3	1.5										1		1		1
7	12	6.1						1	1		1	5		1	2	1
8	54	27.6	1	2		3		1	1		8	21		2	3	12

Definition

0 None of the below.

1 Estimate of the amount of a substance in food or drinking water, expressed on a body mass basis (usually mg/kgbw), which can be ingested over a lifetime by humans without appreciable health risk. (van Leeuwen & Hermens 1996)

2 Estimate of the amount of a pesticide in food and drinking water which can be ingested daily over a lifetime by humans without appreciable health risk. It is usually expressed in milligrams per kilogram of body weight. (Holland 1996)

3 An estimate of the daily exposure dose that is likely to be without deleterious effect even if continued exposure occurs over a lifetime. (US EPA 1992a)

4 Estimate of the largest amount of a substance (e.g., a chemical) to which a person can be exposed on a daily basis that is not anticipated to result in adverse effects. Usually expressed in milligrams per kilogram per day (mg/kg/day). (Cohrssen & Covello 1989)

5 The maximum amount of a chemical whose total daily intake during lifetime. [*sic*] (source unknown)

6 The amount of a food additive, expressed on a body weight basis, that can be taken daily in the diet, even over a lifetime, without risk. (WHO 1979)

7 The acceptable daily intake of a chemical is the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time when a toxicological assessment is carried out. It is expressed in milligrams of the chemical per kilogram of body weight. (Vettorazzi 1980)

8 The daily intake of a chemical which, during a lifetime, appears to be without appreciable risk, on the basis of all the facts known at the time. It is expressed in milligrams per kilogram of body weight per day (mg/kg/day). (IPCS 1996)

Acceptable risk

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	93	58.1				4	1	3	1		9	40		2	9	24
1	67	41.9	1	1	1	5	2	1	4	1	8	16		5	13	9

Definition

0 None of the below.

1 A risk, perhaps in the region of 1 in a million of a seriously adverse occurrence, where the conduct of life is not affected provided that we are in fact satisfied that reasonable precautions are in place. (Le Guen 1995)

Adverse effect

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	21	10.3				1					1	10		1	1	7
1	58	28.4		1	1	3	1	1	1		11	17	1	1	7	13
2	42	20.6	1	1		2	1	1	3	1	4	15		4	2	7
3	5	2.9								1	1	2			1	
4	77	37.7		1		4	1	1	3	1	9	27		2	14	14

Definition

0 None of the below.

1 Change in morphology, physiology, growth, development or life span of an organism which results in impairment of its functional capacity or impairment of its capacity to compensate for additional stress or increased susceptibility to the harmful effects of other environmental influences. (van Leeuwen & Hermens 1996)

2 Change in morphology, physiology, growth, development or life span of an organism which results in impairment of functional capacity or which increases susceptibility to the harmful effects of other environmental influences. (WHO 1978; Holland 1996)

3 Change in morphology, physiology, growth, development or life span of an organism which results.… (Jager & Visser 1994)

4 Change in morphology, physiology, growth, development or life span of an organism which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to the harmful effects of other environmental influences. (IPCS 1994, 1996)

Assessment

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	66	36.3		2		5	1	1	1		6	26	1	2	5	16
1	113	62.1	1	1	2	5	1	3	6	3	15	32		4	19	21
2	3	1.6									1	1			1	

Definition

0 None of the below.

1 The combination of analysis with policy-related activities such as identification of issues and comparison of risks and benefits (as in risk assessment and impact assessment). (van Leeuwen & Hermens 1996)

2 In the asbestos-in-schools program, the evaluation of the physical condition and potential for damage of all friable asbestos containing materials and thermal insulation systems. (US EPA 1993)

Assessment end-point

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	63	40.4		2		3	1	2	2		5	27	1	2	4	14
1	93	59.6	1			5	1	1	4	2	14	26		4	15	20

Definition

0 None of the below.

1 An explicit expression of the environmental value that is to be protected. (US EPA 1992a)

Assessment factor

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	47	29.6		1		2		1			5	17	1	1	5	14
1	112	70.4	1	1	1	7	1	1	5	2	18	33		4	18	20

Definition

0 None of the below.

1 Numerical adjustment that can be used as tools to extrapolate from experimentally-determined effects endpoints to estimate an environmental concern level, i.e. that concentration of a substance at and above which ecosystems could be adversely affected. Note: They can be used to extrapolate from acute to chronic effects, from laboratory to field conditions, from a few species to many, etc. (It should be noted that concern levels are not "safe" levels. They merely indicate that further assessment or information may be required.) (OECD 1995)

Concentration–effect relationship

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	24	12.1		1		1					5	8		1	1	7
1	93	46.7		1	2	7	1	1	5		8	28	1	2	16	21
2	13	6.5								1	5	4			1	2
3	31	15.6	1	1		1	1	1		1	5	11		2	3	4
4	9	4.5							1		1	4		1	1	1
5	10	5.0				1		1				4		1		3
6	19	9.5						1		1	2	10			2	3

Definition

0 None of the below.

1 Association between exposure concentration and the magnitude of the resultant continuously graded change, either in an individual or in a population. (Duffus 1993)

2 Association between the dose and the magnitude of a continuously graded effect in an individual or a population. Source After IUPAC Glossary. (Last 1995)

3 The relationship between dose and severity of effect. (Beaglehole et al. 1993)
4 Graded relationship between the dose of the pesticide to which the organism is exposed and the magnitude of a defined biological effect, either in an individual organism or in a population. (Duffus 1993; Holland 1996)
5 Association between dose and the magnitude of a continuously graded effect, either in an individual or in a population or in experimental animals. (Duffus 1993)
6 The relationship between the administered or absorbed dose and the magnitude of the biological change in an animal or human subject. (WHO 1979)

Dose–effect relationship

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	16	8.2									1	7		1	1	6
1	57	29.1		1	2	5			3		7	19		2	9	9
2	40	20.4	1	2		2	1	1		2	4	12	1	2	5	7
3	15	7.7						1	1		4	5		1	2	1
4	34	17.3				3	1	1	2		2	11		2	3	9
5	30	15.3						1		1	4	14			3	7
6	4	2.0							1						1	2

Definition

0 None of the below.
1 Association between the dose and the magnitude of a continuously graded effect in an individual or a population. (WHO 1979; Last 1995)
2 The relationship between dose and severity of effect. (Beaglehole et al. 1993)
3 Graded relationship between the dose of the pesticide to which the organism is exposed and the magnitude of a defined biological effect, either in an individual organism or in a population. (Duffus 1993; Holland 1996)
4 Association between dose and the magnitude of a continuously graded effect, either in an individual or in a population or in experimental animals. (Duffus 1993)
5 The relationship between the administered or absorbed dose and the magnitude of the biological change in an animal or human subject. (WHO 1979)
6 Association between exposure concentration and the magnitude of the resultant continuously graded change, either in an individual or in a population. (Duffus 1993)

Dose-related effect

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	19	10.6				1		1			3	6			4	4
1	161	89.4	1	2	2	9	3	2	7	3	19	58	1	6	19	29

Definition

0 None of the below.

1 Situation in which the magnitude of a biological change is related to the dose. (Duffus 1993)

Dose–response

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	35	17.9		1		2					2	16			4	10
1	91	46.7		2	2	4	1	1	5	1	11	30		4	10	20
2	15	7.7				3			1	1	4	2		2	1	1
3	54	27.7				1	1	3	1	1	5	20	1	2	8	11

Definition

0 None of the below.

1 A quantitative relationship between the dose of a substance (e.g., a chemical) and an effect caused by the substance. (Cohrssen & Covello 1989)

2 How a biological organism's response to a toxic substance quantitatively shifts as its overall exposure to the substance changes (e.g., a small dose of carbon monoxide may cause drowsiness; a large dose can be fatal). (US EPA 1993)

3 The relationship between the dose of a chemical and the extent of the toxic effect produced by the chemical in a biological system. (IPCS 1996)

Dose–response assessment

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	11	5.7										2	1			8
1	43	22.2		1	1	1		1	3		5	20		1	4	6
2	21	10.8			1	3	1				1	8			3	4
3	12	6.2	1			2			1		1	2		1	2	2
4	12	6.2		1		2	1				2	1		1	3	1
5	31	16.0							1	1	1	13		3	4	8
6	39	20.1		1		1		2	1	2	5	14		1	7	5
7	2	1.0										1				1
8	2	1.0									1					1
9	2	1.0									1			1		
10	19	9.8				1	1	1	1		6	5				4

Definition

0 None of the below.

1 The estimation of the relationship between dose or concentration and the incidence and/or severity of an effect. (OECD 1995)

2 The process of characterizing the relationship between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations. (van Leeuwen & Hermens 1996)

3 The estimation of the relationship between dose or concentration and the incidence and severity of an effect in a particular group of test organisms and, through extrapolation, in a whole population or ecosystem. (Jager & Visser 1994)

4 A component of risk assessment that describes the quantitative relationship between the amount of exposure to a substance and the extent of injury or disease. (Cohrssen & Covello 1989)

5 The determination of the relationship between the magnitude of exposure and the magnitude and/or frequency of adverse effects. (WHO 1995)

6 The determination of the relationship between the magnitude of administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population. (US EPA 1992a)

7 The identification and quantification of the potential adverse effects of a substance and therefore includes hazard identification and dose–response assessment. (OECD 1995)

8 The component of an environmental risk analysis concerned with quantifying the manner in which the frequency and intensity of effects increase with increasing

exposure to a contaminant or other source of stress. (van Leeuwen & Hermens 1996)

9 Characterization of the toxicological properties and effects of a substance (e.g., a chemical) including all aspects of its absorption, metabolism, excretion, and mechanism of action, with special emphasis on establishment of dose–response characteristics. (Cohrssen & Covello 1989)

10 The estimation of the relationship between dose, or level of exposure to a substance, and the incidence and severity of an effect. (EC 1993)

Dose–response curve

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	16	8.2					1			1	6				2	6
1	9	4.6				1					2	3			1	2
2	30	15.4				2			2			17		1	4	4
3	140	71.8	1	3	2	7	2	4	5	3	20	41	1	7	17	27

Definition

0 None of the below.

1 Similar to concentration–response curve except that the exposure dose (i.e., the quantity) of the chemical administered (e.g., by injection) to the organisms is known. (Rand 1995)

2 Graph of the relation between dose and the proportion of individuals in a population responding with an all-or-none effect. (Duffus 1993)

3 A graphical presentation of the relationship between degree of exposure to a substance (dose) and observed biological effect or response. (Cohrssen & Covello 1989)

Dose–response relationship

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	20	10.3		1			2				1	6		1	1	8
1	19	9.8				2					2	4			3	8
2	35	18.0			1	3		1	2		5	14		2	3	4

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
3	33	17.0	1	1		1				2	6	10	1	2	5	4
4	41	21.1			1	3		3	2		3	14		2	6	7
5	46	23.7		1					3	1	5	21		1	6	8

Definition

0 None of the below.

1 A relationship that occurs when changes in the level of a possible cause are associated with changes in the prevalence or incidence of the effect. (Beaglehole et al. 1993)

2 Association between dose and the incidence of a defined biological effect in an exposed population. (Duffus 1993; Holland 1996)

3 A relationship between the amount of an agent (either administered, absorbed, or believed to be effective) and changes in certain aspects of the biological system (usually toxic effects), apparently in response to that agent. (US EPA 1992a)

4 Association between dose and the incidence of a defined biological effect in an exposed population. (Duffus 1993)

5 The relationship between administered dose or exposure and the biological change in organisms. It may be expressed as the severity of an effect in one organism (or part of an organism) or as the proportion of a population exposed to a chemical that shows a specific reaction. Synonym(s) include dose–response relationship, exposure–response relationship. (WHO 1979)

Ecological risk assessment

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	12	6.4						1	1	1	3	1			1	4
1	83	44.4	1		1	3			2	2	13	25	1	3	16	16
2	92	49.2		1	3	5	3	2	4		8	33		5	8	20

Definition

0 None of the below.

1 The application of a formal framework, analytical process, or model to estimate the effects of human action(s) on a natural resource and to interpret the significance of

those effects in light of the uncertainties identified in each component of the assessment process. Such analysis includes initial hazard identification, exposure and dose–response assessments, and risk characterization. (US EPA 1993)

2 The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. (US EPA 1992a)

Effect assessment

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	21	11.1				1	1					8	1	1	3	6
1	44	23.2	1	2	1	1	1		1		6	16			8	7
2	14	7.4				1					4	4		1	2	2
3	36	18.9		1	1	1	1	3		1	2	12		2	1	11
4	6	3.2							1			4				1
5	20	10.5				3		1	1		6	5		1	1	2
6	5	2.6							1			1		1		2
7	18	9.5				2			1		1	6			3	5
8	11	5.8							1	2	2	4		1		1
9	15	7.9				1			1			5			4	4

Definition

0 None of the below.

1 The identification and quantification of the potential adverse effects of a substance and therefore includes hazard identification and dose–response assessment. (OECD 1995)

2 The component of an environmental risk analysis concerned with quantifying the manner in which the frequency and intensity of effects increase with increasing exposure to a contaminant or other source of stress. (van Leeuwen & Hermens 1996)

3 The estimation of the relationship between dose or concentration and the incidence and/or severity of an effect. (OECD 1995)

4 The process of characterizing the relationship between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations. (van Leeuwen & Hermens 1996)

5 The estimation of the relationship between dose or concentration and the incidence and severity of an effect in a particular group of test organisms and, through extrapolation, in a whole population or ecosystem. (Jager & Visser 1994)

6 A component of risk assessment that describes the quantitative relationship between the amount of exposure to a substance and the extent of injury or disease. (Cohrssen & Covello 1989)

7 The determination of the relationship between the magnitude of exposure and the magnitude and/or frequency of adverse effects. (WHO 1995)

8 The determination of the relationship between the magnitude of administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population. (US EPA 1992b)

9 Characterization of the toxicological properties and effects of a substance (e.g. a chemical) including all aspects of its absorption, metabolism, excretion, and mechanism of action, with special emphasis on establishment of dose–response characteristics. (Cohrssen & Covello 1989)

Expert judgement

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	53	30.6				5	1	1	1		3	14	1	2	8	17
1	120	69.4	1	1	2	5	1	2	5	3	18	43		5	14	20

Definition

0 None of the below.

1 Opinions of persons well informed in an area that are incorporated into probability estimates. (Cohrssen & Covello 1989)

Exposure assessment

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	14	7.1									3	2	1	1	1	6
1	13	6.6	1	2	1		1	1				4			2	1
2	12	6.1						1			2	3		1	2	3
3	30	15.3			1	1		1	1	1	6	8		1	4	6
4	20	10.2				2			1		2	8		1	2	4
5	1	0.5										1				
6	16	8.2				2			2		2	5		1	1	3

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
7	17	8.7				1	1				3	4			4	4
8	13	6.6				1		1	1			6				4
9	5	2.6				1						2			1	1
10	1	0.5										1				
11	4	2.0										1		1	2	
12	0	0.0														
13	2	1.0										2				
14	21	10.7				1				2	2	10			2	4
15	12	6.1							1		4	4			1	2
16	15	7.7		1		1					1	7		2	1	2

Definition

0 None of the below.

1 The quantification of exposure (dose) in a specific population based on measurements of emissions, environmental levels, biological monitoring, etc. (WHOTERM)

2 Process of estimating concentration or intensity, duration and frequency of exposure to an agent that can affect health. (Last 1995)

3 The determination of the emissions, pathways and rates of movement of a substance in the environment, and its transformation or degradation, in order to estimate the concentrations/doses to which ecological systems and populations are or may be exposed. (OECD 1995)

4 The component of an environmental or human health risk analysis that estimates the emissions, pathways and rates of movement of a chemical in the environment, and its transformation or degradation, in order to estimate the concentrations/doses to which ecological systems and populations are or may be exposed. (van Leeuwen & Hermens 1996)

5 Process of measuring or estimating concentration, duration and frequency of exposures to pesticide present in environment or, if estimating hypothetical exposures, that might arise from the release of the pesticide into the environment. (Duffus 1993; Holland 1996)

6 Process of measuring or estimating concentration (or intensity), duration and frequency of exposures to an agent present in the environment or, if estimating hypothetical exposures, that might arise from the release of a substance, or radionuclide, into the environment. (Duffus 1993)

7 The determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation in order to estimate the concentrations/doses to which human populations or ecological systems and populations are or may be exposed. (Jager & Visser 1994)

8 The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, route, and extent (number of people) of exposure to a substance. (Cohrssen & Covello 1989)

9 The qualitative and/or quantitative evaluation of the degree of intake likely to occur. (WHO 1995)

10 The quantification of exposure in a specific population based on measurements of emissions, environmental levels, biological monitoring, etc. (WHO 1989)

11 The qualitative and/or quantitative evaluation of the likely intake of biochemical, chemical, and physical agents via food as well as exposures from relevant sources if relevant. (Codex 1995)

12 A scientific evaluation of the intake of a hazardous agent through food, taking into account exposure from other sources if relevant. It includes a quantitative and/or qualitative estimation of exposure and attendant uncertainties. (WHOTERM)

13 The quantification of the amount of exposure to a hazard for an individual or group. (WHO 1979)

14 The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure. (US EPA 1992b)

15 The determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation in order to estimate the concentrations/doses to which human populations or environment compartments are or may be exposed. (EC 1993)

16 The estimation (qualitative or quantitative) of the magnitude, frequency, duration, route and extent (for example, number of organisms) of exposure to a chemical substance or contaminants. (IPCS 1996)

Exposure scenario

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	9	4.9										1			1	7
1	108	58.4			2	7	1	3	4		12	42		5	13	19
2	68	36.8	1	3		3	1	1	2	3	12	19	1	2	8	12

Definition

0 None of the below.

1 A set of conditions or assumptions about sources, exposure pathways, concentrations of toxic chemicals, and populations (numbers, characteristics, and habits) that aid the investigator in evaluating and quantifying exposure in a given situation. (Cohrssen & Covello 1989)

2 A set of assumptions concerning how an exposure may take place, including assumptions about the exposure setting, stressor characteristics, and activities that may lead to exposure. (US EPA 1992a)

Fate

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	11	5.8				2	1				1	2			3	2
1	100	52.6	1	3		3	2	1	4	3	15	33	1	3	13	18
2	58	30.5			2	3		1	1		7	20		2	6	16
3	21	11.1				1			1		2	10		3	2	2

Definition

0 None of the below.

1 The pattern of distribution of a substance in the environment, or in organisms, and its changes with time (in concentration, chemical form, etc.). (OECD 1995)

2 Disposition of a material in various environmental compartments (e.g. soil or sediment, water, air, biota) as a result of transport, partitioning, transformation, and degradation. (van Leeuwen & Hermens 1996)

3 Disposition of a material in various environmental compartments (e.g. soil or sediment, water, air, biota) as a result of transport, transformation, and degradation. (Holland 1996)

Guidance value

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	21	12.7									2	9		1	2	7
1	27	16.4	1		1	4	1				1	13			4	2
2	117	70.9		2	1	5	1	2	6	3	15	40		5	14	23

Definition

0 None of the below.

1 Value, such as concentrations in air or water, which is derived after appropriate allocation of the TI among the different possible media of exposure. Note: Combined exposures from all media at the guidance values over a lifetime would be expected to be without appreciable health risk. The aim of the guidance value is to provide quantitative information from risk assessment for risk managers to enable them to make decisions concerning the protection of human health. (IPCS 1994)

2 Values, such as concentrations in air or water, which are derived after appropriate allocation of the tolerable intake among the different possible media of exposure. Note: Combined exposures from all media at the guidance values over a lifetime would be expected to be without appreciable health risk. The aim of the guidance value is to provide quantitative information from risk assessment for risk managers to enable them to make decisions concerning the protection of human health. (IPCS 1996)

Harm

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	10	5.1				1			1		1	3			1	3
1	4	2.0								1	1	2				
2	0	0.0														
3	149	76.0		3	2	8	2	2	6	1	21	52	1	6	20	25
4	18	9.2						2			1	6			2	7
5	15	7.7	1							1	1	5		1	2	4

Definition

0 None of the below.

1 A loss to a species or individual as a result of damage. (van Leeuwen & Hermens 1996)

2 A function of the concentration to which an organism is exposed and the time of exposure. (van Leeuwen & Hermens 1996)

3 Damage or adverse effect to a population, species, individual organism, organ, tissue or cell. (Duffus 1993)

4 Physical injury and/or damage to health or property. (ISO 1990)

5 Refers to injury which requires repair or cure, or which may be irreparable. (Le Guen 1995)

Hazard

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	17	8.4				1					2	6	1		1	6
1	4	2.0									1	1				2
2	7	3.4			1						1	1			2	2
3	8	3.9							1		2	2			2	1
4	31	15.3		1		1			2	1	4	12		3	2	5
5	65	32.0		1		3	1	1	1	1	9	23		4	5	16
6	17	8.4			1	2		1			2	7			1	3
7	3	1.5										2		1		
8	1	0.5													1	
9	0	0.0														
10	6	3.0							1	1	1	2			1	
11	6	3.0				1			1			3			1	
12	0	0.0														
13	20	9.9		1		1	1	1			1	5			6	4
14	3	1.5									1				1	1
15	5	2.5									1	4				
16	0	0.0														
17	2	1.0	1												1	
18	8	3.9				1			1			3			1	2

Definition

0 None of the below.

1 Likelihood of an adverse natural phenomenon. (WHO 1992)

2 Likelihood that exposure to a chemical will cause an injury or adverse effect under the conditions of its production, use, or disposal. (Holland 1996)

3 Set of inherent properties of a pesticide which gives potential for adverse effects to man or the environment under conditions of its production, use or disposal, and depending on the degree of exposure. (Duffus 1993; Holland 1996)

4 Set of inherent properties of a substance, mixture of substances or a process involving substances that, under production, usage or disposal conditions, make it capable of causing adverse effects to organisms or the environment, depending on the degree of exposure; in other words, it is a source of danger. (Duffus 1993)

5 An inherent property of a substance, agent, source of energy or situation having the potential of causing undesirable consequences. (OECD 1992)

6 The potential of a substance to cause adverse effects at a particular degree of exposure. (Jager & Visser 1994)

7 A source of risk that does not necessarily imply potential for occurrence. (Cohrssen & Covello 1989)

8 A physical situation with a potential for human injury, damage to property, damage to the environment or some combination of these. (Jones 1992)

9 The likelihood that a pesticide will cause an adverse effect (injury) under the conditions in which it is used. (FAO 1990)

10 The likelihood that a chemical will cause adverse health effects under the conditions under which it is produced or used. (WHO 1979)

11 A biological, chemical, or physical agent in or property of food that may have an adverse health effect. (WHO 1995)

12 Chemical or physical agent or property that may cause a food to be unsafe for human consumption, or a defect generally considered objectionable. (FAO 1995)

13 A potential source of harm. (ISO 1990)

14 The disposition of a thing, a condition or a situation to produce injury. (Le Guen 1995)

15 A source of danger; a qualitative term expressing the potential that an environmental agent can harm health. (IPCS 1989)

16 The likelihood that a chemical will cause adverse health effects (injury) under the conditions under which it is produced or used. (source unknown)

17 A source of danger. (WHO 1988)

18 The capacity to produce a particular type of adverse health or environmental effect. e.g. one hazard associated with benzene is leukaemia. (IPCS 1996)

Hazard assessment

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	32	16.6					1				4	13	1	1	1	11
1	36	18.7			2	3			1	1	6	10		1	4	8
2	5	2.6									2	1		1	1	
3	19	9.8		1		1			2		1	8		2		4
4	23	11.9				1		1	1		4	8			3	5
5	20	10.4						1		1	2	7		1	4	4
6	5	2.6									1	1			3	
7	1	0.5						1								
8	6	3.1	1			1					1	2				1
9	10	5.2				1					2	4			2	1
10	3	1.6									1	1				1
11	3	1.6				1					1				1	
12	17	8.8		1		1		1			1	6		2	1	4

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
13	2	1.0								1					1	
14	7	3.6					1					4			2	
15	4	2.1							1			1			1	1

Definition

0 None of the below.

1 The estimation of the incidence and severity of the adverse effects likely to occur in an environmental compartment due to actual or predicted exposure to a substance, i.e. integration of the effects and exposure assessments. (OECD 1995)

2 Comparison of the intrinsic ability to cause harm (see hazard) and expected environmental concentration, often a comparison of PEC and PNEC. (van Leeuwen & Hermens 1996)

3 Determination of factors controlling the likely effects of a hazard such as mechanism of toxicity, dose–effect relationships and worst case exposure levels. This is the prelude to risk assessment. (US EPA 1992a; Holland 1996)

4 Determination of factors controlling the likely effects of a hazard such as the dose–effect and dose–response relationships, variations in target susceptibility, and mechanism of toxicity. (Duffus 1993)

5 The process designed to estimate the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure. (Jager & Visser 1994)

6 The estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartments due to actual or predicted exposure to a substance. This may include risk estimation, i.e. quantification of that likelihood. It also serves as a summary and description of the results of a risk analysis for a risk manager or the public and other interested parties. (van Leeuwen & Hermens 1996)

7 Outcome of hazard identification and risk estimation applied to a specific use of a substance or occurrence of an environmental health hazard: the assessment requires quantitative data on the exposure of organisms or people at risk in the specific situation. The end product is a quantitative statement about the proportion of organisms or people affected in a target population. (Duffus 1993)

8 The description of the nature and often the magnitude of human or non-human risk, including attendant uncertainty. (US EPA 1992b)

9 The process designed to estimate the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure. (Jager & Visser 1994)

10 The final phase of the risk-assessment process that involves integration of the data and analysis involved in hazard identification, source/release assessment, exposure

assessment, and dose–response assessment to estimate the nature and likelihood of adverse effects. (Cohrssen & Covello 1989)

11 A phase of ecological risk assessment that integrates the results of the exposure and ecological effects analyses to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. The ecological significance of the adverse effects is discussed, including consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery. (US EPA 1992)[1]

12 Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties. (WHO 1995)

13 Integration of the above steps into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainty. (FAO 1995)

14 The description of the different potential health effects of the hazard and quantification of dose–effect and dose–response relationships in a general scientific sense. (WHO 1989)

15 A summary, integration, and evaluation of the major scientific evidence, reasoning and conclusions of a risk assessment. It is a concise description of the estimates of potential risk and the strengths and weaknesses of those estimates. (US EPA 1993)

Hazard characterization

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	48	27.9		1		2	2	1			7	20	1	1	3	10
1	36	20.9				3			3	2	3	11		1	4	9
2	88	51.2	1	1	2	5		3	4	1	9	30		4	15	13

Definition

0 None of the below.

1 The qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents which may be present in food. For chemical agents, a dose–response assessment should be performed. For biological or physical agents, a dose–response assessment should be performed if the data is obtainable. (WHO 1995)

2 The quantitative and/or qualitative evaluation of the nature of the adverse effects, and may include a dose–response assessment. (FAO 1995)

[1] It is unknown whether this is referring to US EPA 1992a or 1992b.

Hazard evaluation

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	56	33.5		1		1	2	1	1		9	25	1	1	6	8
1	56	33.5	1		1	5		2	2		7	19		1	5	13
2	55	32.9		2		4		1	2	3	6	15		4	10	8

Definition

0 None of the below.

1 Identification and assessment of the potential adverse effects that could result from manufacture, use, and disposal of a material in a specified quantity and manner. (Rand 1995)

2 Establishment of a qualitative or quantitative relationship between hazard and benefit, involving the complex process of determining the significance of the identified hazard and balancing this against identifiable benefit: this may subsequently be developed into a risk evaluation. (Duffus 1993)

Hazard identification

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	17	8.9				1					1	3	1		3	8
1	3	1.6				1		1								1
2	73	38.2	1	2	1	3		2	4	2	10	26		1	6	15
3	15	7.9			1						4	3		1	3	3
4	15	7.9		1		1	1				5	5		1	1	
5	5	2.6										2			3	
6	15	7.9					1		2			10			1	1
7	0	0.0														
8	9	4.7				2						1		1	4	1
9	5	2.6					1					3				1
10	2	1.0									1	1				
11	1	0.5						1								

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
12	10	5.2				1					1	3		1		4
13	10	5.2								1	1	5		1	1	1
14	11	5.8							1		1	5		1		3

Definition

0 None of the below.

1 The first stage in risk assessment to establish qualitatively whether a carcinogenic hazard exists. (ECETOC 1982)

2 The identification of the adverse effects which a substance has an inherent capacity to cause. (OECD 1995)

3 Determination of substances of concern, their adverse effects, target populations, and conditions of exposure, taking into account toxicity data and knowledge of effects on human health, other organisms and their environment. (Duffus 1993)

4 The identification of the adverse effects which a substance has an inherent capacity to cause. (Jager & Visser 1994)

5 A component of risk assessment that involves gathering and evaluating data on the types of injury or disease (for example, cancer) that may be produced by a substance and on the conditions of exposure under which injury or disease is produced. (Cohrssen & Covello 1989)

6 The identification of known or potential health effects associated with a particular agent. (WHO 1995)

7 The qualitative indication that a hazard(s) could be present in a particular food. (FAO 1995)

8 Identification of the adverse effects which a substance has an inherent capacity to cause, or in certain cases, the assessment of a particular effect. It also includes the identification of target populations and conditions of exposure. (WHOTERM)

9 The identification of the environmental agent of concern, its adverse effects, target populations and conditions of exposure. (WHO 1989)

10 The identification of known or potential adverse health effects in humans produced by biological, chemical, and physical agents which may be present in a particular food or group of foods. (Codex 1995)

11 The confirmation of the existence of a hazard in food, based on its known or potential health effects in humans, on its known or potential levels of the agent in food and on any other relevant information available. (WHOTERM)

12 The identification of the substance of concern, its adverse effects, target populations, and conditions of exposure. (WHO 1988)

13 A description of the potential health effects attributable to a specific chemical or physical agent. For carcinogen assessments, the hazard identification phase of the risk

assessment is also used to determine whether a particular agent or chemical is, or is not, causally linked to cancer in humans. (US EPA 1992b)

14 The identification of the adverse effects which a substance has the inherent capacity to cause. (EC 1993)

Margin of exposure

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	21	12.4					1				1	8	1	1	1	8
1	45	26.6	1		1	2		1	3	2	3	16		2	7	7
2	63	37.3		2		2		1	2	1	8	22		3	9	13
3	21	12.4		1		2		1			2	12		1		2
4	7	4.1				1					1	2			2	1
5	3	1.8										1			2	
6	9	5.3						1				2			2	4

Definition

0 None of the below.

1 The ratio of the no-observed-adverse-effect level (NOAEL) to the estimated exposure dose (EED). (US EPA 1992a)

2 Ratio of the no-observed-adverse-effect level (NOAEL) to the theoretical or estimated exposure dose (EED) or concentration (EEC). (Duffus 1993)

3 The ratio of the no-observed-adverse-effect level (NOAEL) to the estimated exposure intake or dose. (van Leeuwen & Hermens 1996)

4 Ratio of the highest estimated or actual level of exposure to a pesticide and the toxic threshold level (usually the NOEC or NOEL). (US EPA 1992a; Holland 1996)

5 The ratio of the estimated daily intake of man to the NOAEL(mammal, non-carcinogens) or NEL(man, genotoxic carcinogens). (Jager & Visser 1994)

6 The maximum amount of exposure producing no measurable effect in animals (or studied humans) divided by the actual amount of human exposure in a population. (Cohrssen & Covello 1989)

Margin of safety

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	26	17.3		1							4	8	1		3	9
1	34	22.7			1					1	2	16		1	3	10
2	10	6.7				1				1	4	3				1
3	6	4.0				1		1				2			1	1
4	10	6.7				1		2				2		1	3	1
5	22	14.7				2			1		2	7		2	4	4
6	42	28.0				1			2	1	5	17		3	5	8

Definition

0 None of the below.

1 The ratio of the no-observed-adverse-effect level (NOAEL) to the estimated exposure intake or dose. (van Leeuwen & Hermens 1996)

2 Ratio of the highest estimated or actual level of exposure to a pesticide and the toxic threshold level (usually the NOEC or NOEL). (US EPA 1992a; Holland 1996)

3 The ratio of the estimated daily intake of man to the NOAEL(mammal, non-carcinogens) or NEL(man, genotoxic carcinogens). (Jager & Visser 1994)

4 The maximum amount of exposure producing no measurable effect in animals (or studied humans) divided by the actual amount of human exposure in a population. (Cohrssen & Covello 1989)

5 The ratio of the no-observed-adverse-effect level (NOAEL) to the estimated exposure dose (EED). (US EPA 1992a)

6 Ratio of the no-observed-adverse-effect level (NOAEL) to the theoretical or estimated exposure dose (EED) or concentration (EEC). (Duffus 1993)

Measurement end-point

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	29	22.7				2				1	1	16			2	7
1	99	77.3		2	2	7	1	2	3	2	20	23		4	15	18

Definition

0 None of the below.

1 A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint. (US EPA 1992a)

Reference dose

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	23	13.8		1		1	1		1		1	9	1	1	2	5
1	16	9.6				1			1	1	1	4		1	3	4
2	6	3.6							1			1			1	3
3	59	35.3	1	1		4		1	2	1	4	23		2	8	12
4	12	7.2				1		1			1	3			1	5
5	4	2.4									2	1		1		
6	0	0.0														
7	5	3.0				1		1				2			1	
8	42	25.1						1		1	5	21		2	5	7

Definition

0 None of the below.

1 Estimate of the amount of a substance in food or drinking water, expressed on a body mass basis (usually mg/kgbw), which can be ingested over a lifetime by humans without appreciable health risk. (van Leeuwen & Hermens 1996)

2 Estimate of the amount of a pesticide in food and drinking water which can be ingested daily over a lifetime by humans without appreciable health risk. It is usually expressed in milligrams per kilogram of body weight. (Holland 1996)

3 An estimate of the daily exposure dose that is likely to be without deleterious effect even if continued exposure occurs over a lifetime. (US EPA 1992a)

4 Estimate of the largest amount of a substance (e.g. a chemical) to which a person can be exposed on a daily basis that is not anticipated to result in adverse effects. Usually expressed in milligrams per kilogram per day (mg/kg/day). (Cohrssen & Covello 1989)

5 The maximum amount of a chemical whose total daily intake during lifetime. [*sic*] (IRPTC 1994)

6 The amount of a food additive, expressed on a body weight basis, that can be taken daily in the diet, even over a lifetime, without risk. (WHO 1979)

7 The acceptable daily intake of a chemical is the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time when a toxicological assessment is carried out.

It is expressed in milligrams of the chemical per kilogram of body weight. (Vettorazzi 1980)

8 An estimate (with uncertainty factors spanning perhaps an order of magnitude) of the daily exposure (mg/kg/day) to the general human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime of exposure. It is derived from the NOAEL or the LOAEL by application of uncertainty factors that reflect various types of data used to estimate RfD and an additional modifying factor, which is based on professional judgement of the entire database of the chemical. (IRIS 1992; IPCS 1996)

Risk

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	20	9.8									1	3		2	6	8
1	19	9.3		2		2	1				3	4		1	1	5
2	12	5.9		1		1		1			1	4	1			3
3	23	11.3			1		1	1			6	6			3	5
4	13	6.4				2			1		2	6			1	1
5	11	5.4				1			2		1	6			1	
6	9	4.4				1				1		6				1
7	8	3.9				2			1		1	1			1	2
8	4	2.0										2		2		
9	14	6.9						1			1	6				6
10	8	3.9			1						1	4		1		1
11	14	6.9								2	2	4		1	2	3
12	3	1.5	1									1				1
13	2	1.0										1			1	
14	0	0.0														
15	2	1.0										1				1
16	3	1.5										3				
17	0	0.0														
18	5	2.5						1			2	1			1	
19	5	2.5				1					1	1			2	
20	0	0.0														
21	4	2.0					1					2			1	
22	25	12.3							3		3	6		1	6	6

Definition

0 None of the below.

1 Statistical concept defined as the expected frequency of undesirable effects arising from exposure to a given hazard.

2 The possibility that a harmful event (death, injury, loss, etc.) arising from exposure to a physical or chemical agent may occur under specific conditions. (Last 1995)

3 The probability of an adverse effect on man or the environment resulting from a given exposure to a chemical or mixture. It is the likelihood of a harmful effect or effects occurring due to exposure to a risk factor (usually some chemical, physical or biological agent). (van Leeuwen & Hermens 1996)

4 A statistical concept defined as the expected frequency or probability of undesirable effects resulting from a specified exposure to known or potential environmental concentrations of a material. (Holland 1996)

5 Probability of any defined hazard occurring from exposure to a pesticide under specific conditions. Risk is a function of the likelihood of exposure and the likelihood to harm biological or other systems. (Holland 1996)

6 The probability of injury, disease, or death under specific circumstances. In quantitative terms, risk is expressed in values ranging from zero (representing the certainty that harm will not occur) to one (representing the certainty that harm will occur). (US EPA 1992a)

7 Possibility that a harmful event (death, injury or loss) arising from exposure to a chemical or physical agent may occur under specific conditions. (Duffus 1993)

8 Expected frequency of occurrence of a harmful event (death, injury or loss) arising from exposure to a chemical or physical agent under specific conditions. (WHOTERM)

9 The combination of a consequence and the probability of its occurrence. (OECD 1992)

10 The probability of a substance to cause adverse effects. (Jager & Visser 1994)

11 A measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard. (US EPA 1993)

12 In risk assessment, the probability that something will cause injury, combined with the potential severity of that injury. (Cohrssen & Covello 1989)

13 The likelihood of a specified undesired event occurring within a specified period or in specified circumstances. (Jones 1992)

14 The expected frequency of undesirable effects of exposure to the pesticide. (FAO 1990)

15 The likelihood of suffering a harmful effect or effects resulting from exposure to a risk factor (usually some chemical, physical, or biological agent). (WHO 1979)

16 A function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food. (WHO 1995)

17 A function of the probability of an adverse event and the magnitude of that event, consequential to a hazard(s) in food. (FAO 1995)

18 The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm. (ISO 1990)

19 The chance of something adverse happening. (WHO 1995)

20 A quantitative probability that a health effect will occur after a specified “amount” of a hazard has exposed an individual. (WHO 1989)

21 The probability of deleterious health or environmental effects. (US EPA 1992b)

22 The probability that an adverse outcome will occur in a person, a group, or an ecological system that is exposed to a particular dose or concentration of a hazardous agent, i.e. it depends on both the level of toxicity of hazardous agent and the level of exposure. It is expressed in values ranging from zero (certainty that an effect will not occur) to one (certainty that an effect will occur). (IPCS 1996)

Risk analysis

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	36	21.1				1	1	1			4	11		3	4	11
1	24	14.0				2		1	2		3	9		1	3	3
2	106	62.0		3		4	1	2	3	2	11	37	1	3	18	21
3	5	2.9				1					1	2		1		

Definition

0 None of the below.

1 An imprecise term which infers the quantified calculation of probabilities and risks without taking any judgements about their relevance. (Jones 1992)

2 A process consisting of three components: risk assessment, risk management and risk communication. (WHO 1995)

3 A process consisting of three components: risk assessment, risk management and risk communication. (FAO 1995)

Risk assessment

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	15	7.7									2	7		1	1	4
1	74	38.1	1	2	2	1	2	1	4	2	9	22		4	7	17
2	22	11.3				1	1	1			3	5	1		4	6
3	4	2.1							1		1	1				1
4	13	6.7				1		1		1	2	5			2	1
5	5	2.6				1						1		1	1	1

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
6	7	3.6		1		1						3				2
7	8	4.1				1					2	3		1		1
8	12	6.2				2					2	5			1	2
9	3	1.5										1			2	
10	0	0.0														
11	12	6.2				1			1			6			3	1
12	10	5.2						1			2	3			2	2
13	7	3.6							1		1	3				2
14	2	1.0										1			1	
15	0	0.0														

Definition

0 None of the below.

1 The determination of the relationship between the predicted exposure and adverse effects in four major steps: hazard identification, dose–response assessment, exposure assessment and risk characterization. (OECD 1995)

2 A process which entails some or all of the following elements: hazard identification, effects assessment, exposure assessment and risk characterization. It is the identification and quantification of the risk resulting from a specific use or occurrence of a chemical compound including the determination of dose–response relationships and the identification of target populations. When little or no quantitative data is available on dose–response relationships for different types of populations, including sensitive groups, such considerations may have to be expressed in more qualitative terms. (van Leeuwen & Hermens 1996)

3 Process of defining the risk associated with a specified use pattern for a pesticide, usually expressed as a numerical probability or as a margin of safety. (Holland 1996)

4 The determination of the kind and degree of hazard posed by an agent, the extent to which a particular group of people have been or may be exposed to the agent, and the present or potential health risk that exists due to the agent. (US EPA 1992a)

5 Identification and quantification of the risk resulting from a specific use or occurrence of a chemical or physical agent, taking into account possible harmful effects on individual people or society of using the chemical or physical agent in the amount and manner proposed and all the possible routes of exposure. Quantification ideally requires the establishment of dose–effect and dose–response relationships in likely target individuals and populations. (Duffus 1993)

6 The value judgment of the significance of the risk, identified by a risk analysis taking into account any relevant criteria. (OECD 1992)

7 Determination of the relation between the predicted exposure and adverse effects in four major steps: hazard identification, dose–response assessment, exposure assessment and risk characterization. (Jager & Visser 1994)

8 Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants. (US EPA 1993)

9 The quantitative evaluation of the likelihood of undesired events and the likelihood of harm or damage being caused together with the value judgements made concerning the significance of the results. (Jones 1992)

10 The assessment of the risk encountered by populations or groups of human individuals exposed to the agent under consideration. (WHO 1979)

11 The scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties. (WHO 1995)

12 A scientific process of identifying hazards, and estimating risk in quantitative or qualitative terms. This involves four analytical steps: hazard identification, hazard characterization, exposure characterization and risk characterization. (FAO 1995)

13 A risk assessment depends on an identification of hazards and dangers, and consists of an estimation of the risks arising from them with a view to their control, avoidance, or to a comparison of risks. Included in a risk assessment is the intention to accept risks while defining and limiting one's exposure to them, or to avoid risks which are too high. (WHO 1995)

14 Hazard identification + risk characterization + exposure assessment + risk estimation. (WHO 1989)

15 A global term for the whole activity from hazard identification to risk monitoring. (WHO 1989)

Risk characterization

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	15	7.9		1							2	6		1		5
1	24	12.6			1	1	1				4	9	1	1	3	3
2	9	4.7							1		1	2			2	3
3	25	13.1				3		2			1	8			3	8
4	17	8.9				1				1	1	8		1	2	3
5	10	5.2							1		1	6				2
6	5	2.6						1		1	1	1				1

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
7	24	12.6		1		1			2		1	11		1	3	4
8	1	0.5													1	
9	2	1.0										2				
10	24	12.6				2	1	1			5	4		2	5	4
11	11	5.8	1								1	5		1		3
12	1	0.5									1					
13	3	1.6		1	1				1							
14	2	1.0													1	1
15	3	1.6										1			1	1
16	15	7.9							2	1	4	4			2	2

Definition

0 None of the below.

1 The estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartments due to actual or predicted exposure to a substance. This may include risk estimation, i.e. quantification of that likelihood. It also serves as a summary and description of the results of a risk analysis for a risk manager or the public and other interested parties. (van Leeuwen & Hermens 1996)

2 Outcome of hazard identification and risk estimation applied to a specific use of a substance or occurrence of an environmental health hazard: the assessment requires quantitative data on the exposure of organisms or people at risk in the specific situation. The end product is a quantitative statement about the proportion of organisms or people affected in a target population. (Duffus 1993)

3 The description of the nature and often the magnitude of human or non-human risk, including attendant uncertainty. (US EPA 1992b)

4 The process designed to estimate the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure. (Jager & Visser 1994)

5 The final phase of the risk-assessment process that involves integration of the data and analysis involved in hazard identification, source/release assessment, exposure assessment, and dose–response assessment to estimate the nature and likelihood of adverse effects. (Cohrssen & Covello 1989)

6 A phase of ecological risk assessment that integrates the results of the exposure and ecological effects analyses to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. The ecological significance of the adverse effects is discussed, including consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery. (US EPA 1992a)

7 Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties. (WHO 1995)

8 Integration of the above steps into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainty. (FAO 1995)

9 The description of the different potential health effects of the hazard and quantification of dose–effect and dose–response relationships in a general scientific sense. (WHO 1989)

10 A summary, integration, and evaluation of the major scientific evidence, reasoning and conclusions of a risk assessment. It is a concise description of the estimates of potential risk and the strengths and weaknesses of those estimates. (US EPA 1993)

11 The estimation of the incidence and severity of the adverse effects likely to occur in an environmental compartment due to actual or predicted exposure to a substance, i.e. integration of the effects and exposure assessments. (OECD 1995)

12 Comparison of the intrinsic ability to cause harm (see hazard) and expected environmental concentration, often a comparison of PEC and PNEC. (van Leeuwen & Hermens 1996)

13 Determination of factors controlling the likely effects of a hazard such as mechanism of toxicity, dose–effect relationships and worst case exposure levels. This is the prelude to risk assessment. (US EPA 1992a; Holland 1996)

14 Determination of factors controlling the likely effects of a hazard such as the dose–effect and dose–response relationships, variations in target susceptibility, and mechanism of toxicity. (Duffus 1993)

15 The process designed to estimate the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure. (Jager & Visser 1994)

16 The estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance, and may include risk estimation, i.e. the quantification of that likelihood. (EC 1993)

Risk communication

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	8	4.0									1				2	5
1	47	23.6		1		3	1	2	1		5	14		1	7	12
2	69	34.7			1	5	1	1		3	9	26	1	2	7	13
3	62	31.2	1	2	1	2	1		3		7	24		4	8	9
4	13	6.5						1	3		2	4		1	1	1

Definition

0 None of the below.

1 Interpretation and communication of risk assessments in terms that are comprehensible to the general public or to others without specialist knowledge. (Duffus 1993)

2 The exchange of information about health or environmental risks among risk assessors and managers, the general public, news media, interest groups, etc. (US EPA 1993)

3 An interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties. (WHO 1995)

4 An interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and stakeholders. (FAO 1995)

Risk estimation

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	27	14.6				1		1	1		3	10		1	1	9
1	65	35.1	1	1	2	2	1		4	2	13	20		2	6	11
2	32	17.3				2		1			1	11		3	8	6
3	23	12.4		1		2	1	1			4	5			5	4
4	10	5.4							1		1	3			2	3
5	18	9.7				1			1	1		8	1		3	3
6	10	5.4						1				5		1		3

Definition

0 None of the below.

1 The quantification of the likelihood (i.e. probability) that adverse effects will occur in an environmental compartment due to actual or predicted exposure to a substance. (OECD 1995)

2 Assessment, with or without mathematical modelling, of the probability and nature of effects of exposure to a substance based on quantification of dose–effect and dose–response relationships for that substance and the population(s) and environmental components likely to be exposed and on assessment of the levels of potential exposure of people, organisms and environment at risk. (Duffus 1993)

3 The quantitative estimation of probabilities of clearly described effects by including uncertainty analysis; the risk assessment is complete when the risk characterization includes "risk estimation." (Jager & Visser 1994)

4 Estimated risks where a degree of precision can be claimed. (Le Guen 1995)

5 The process of combining the risk characterization, dose–response relationships and exposure estimated to quantify the risk in a specific population. The end product is a

qualitative and quantitative statement about the type of health effects expected and the proportion and number of affected people in a target population, including estimates of the uncertainties involved. The size of the population exposed needs to be known. (WHO 1989)

6 The quantification of dose–effect and dose–response relationships for a given environmental agent, showing the probability and nature of the health effects of exposure to the agent. (WHO 1988)

Risk evaluation

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	45	25.7		1			1		1		6	16	1		6	13
1	80	45.7		1	1	4		2	4	1	9	26		5	12	15
2	50	28.6	1			3		1	1	2	3	23		2	6	8

Definition

0 None of the below.

1 Establishment of a qualitative or quantitative relationship between risks and benefits, involving the complex process of determining the significance of the identified hazards and estimated risks to those organisms or people concerned with or affected by them. (Duffus 1993)

2 Comparing calculated risks or public health impact of the exposure to the environmental agent with risks caused by other agents or societal factors and with the benefits associated with the agent, as a basis for a decision about "acceptable risk." (WHO 1989)

Risk identification

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	51	35.4		1		1	1	1	1	1	5	26	1	1	2	10
1	93	64.6				7	1	3	4	2	8	25		5	17	21

Definition

0 None of the below.

1 Recognition of a potential hazard and definition of the factors required to assess the probability of exposure of organisms or people to that hazard and of harm resulting from such exposure. (Duffus 1993)

Risk management

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	12	6.0										1		2	3	6
1	9	4.5				1			1			4			1	2
2	5	2.5		1		1						1		2		
3	7	3.5						1		1		3				2
4	12	6.0				1		1				3			2	5
5	57	28.6		1	1	2	2				9	22		3	4	13
6	7	3.5				1			1		1	3				1
7	16	8.0				1		1		2	3	7			1	1
8	15	7.5				1						4			7	3
9	1	0.5										1				
10	16	8.0			1				1		3	8			2	1
11	7	3.5									1	2		1	1	2
12	0	0.0														
13	20	10.1	1	1		2			3		3	7			1	2
14	2	1.0										1	1			
15	9	4.5							1		3	1			2	2
16	4	2.0						1			1	2				

Definition

0 None of the below.

1 The managerial, decision-making and active hazard control process to deal with those environmental agents for which the risk evaluation has indicated that the risk is too high. (WHOTERM)

2 This term covers (1) risk evaluation, (2) exposure control, and (3) risk monitoring. (WHOTERM)

3 Interventions to control environmental factors which adversely affect health and to prevent or limit environmental damage. (WHO 1994)

4 The practical application and implementation of the risk assessment to meet specific goals and achieve safe use of a substance. (IPCS 1989)

5 A decision making process that entails the consideration of political, social, economic and engineering information together with risk-related information in order to develop, analyze and compare the regulatory options and select the appropriate regulatory response to a potential health or environmental hazard. (van Leeuwen & Hermens 1996)

6 Decision-making process and procedures used by regulators and others to limit potential risks from use of pesticides. This involves risk assessment, emission control, exposure control and evaluation of the success of the risk mitigation efforts. (Holland 1996)

7 A decision-making process that entails considerations of political, social, economic, and engineering information with risk-related information to develop, analyse, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard. (US EPA 1992a)

8 Decision-making process involving considerations of political, social, economic, and engineering factors with relevant risk assessments relating to a potential hazard so as to develop, analyse, and compare regulatory options and to select the optimal regulatory response for safety from that hazard. Essentially risk management is the combination of three steps: risk evaluation; emission and exposure control; risk monitoring. (Duffus 1993)

9 Actions taken to achieve or improve the safety of an installation and its operation. (OECD 1992)

10 Decision-making process involving considerations of political, social, economic, and engineering factors with relevant risk assessments relating to a potential hazard so as to develop, analyse, and compare regulatory options and to select the optimal regulatory response for safety from that hazard. (Jager & Visser 1994)

11 The process of evaluating and selecting alternative regulatory and non-regulatory responses to risk. (US EPA 1993)

12 The actions one may take, given the quantification of the risks posed by the technological system under consideration. (WHO 1979)

13 The process of weighing policy alternatives to accept, minimize or reduce assessed risks and to select and implement appropriate options. (WHO 1995)

14 The process of weighing policy alternatives, selecting an appropriate regulatory option, and implementing that option. (FAO 1995)

15 The application of a set of measures relevant to a particular set of significant risks and intended to restrict and maintain risks within tolerable limits at proportionate cost. (WHO 1995)

16 Risk evaluation + exposure control + risk monitoring. The managerial, decision-making and active hazard control process to deal with those environmental agents for which the risk evaluation has indicated that the risk is too high. (WHO 1989)

Risk monitoring

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	19	10.3									1	11		1	1	5
1	126	68.1	1	2	1	3	2	3	4	2	15	45		2	20	26
2	40	21.6		1	1	5	1	1	3	1	6	7	1	5	3	5

Definition

0 None of the below.

1 Process of following up the decisions and actions within risk management in order to check whether the aims of reduced exposure and risk are achieved. (Duffus 1993)

2 The process of measuring the reduction in risk after exposure control actions have been taken, in order to make decisions concerning a re-assessment of the risk and further control actions. (WHO 1989)

Safety

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	17	8.7				1			1			5		2	2	6
1	33	16.9			1	1	1		1		5	13	1	1	6	3
2	14	7.2				1					2	6			3	2
3	30	15.4		2		3				2	6	7		1	2	7
4	58	29.7	1		1	2		1	4		8	14		3	8	16
5	13	6.7				1				1		8			2	1
6	5	2.6						1				2				2
7	19	9.7		1				1	1		2	9		1	1	3
8	6	3.1						1				4			1	

Definition

0 None of the below.

1 The practical certainty that adverse effects or injury will not result from exposure to a material when used in the quantity and the manner proposed for its use. (Rand 1995)

2 Reciprocal of risk: practical certainty that injury will not result from a hazard under defined conditions: 1. Safety of a drug or other substance in the context of human health: the extent to which a substance may be used in the amount necessary for the intended purpose with a minimum risk of adverse health effects. 2. Safety (toxicological): The high probability that injury will not result from exposure to a substance under defined conditions of quantity and manner of use, ideally controlled to minimise exposure. (Duffus 1993)

3 A situation without unacceptable risks. For purposes of this text, "safety" embraces health, safety and environmental protection, including protection of property. (OECD 1992)

4 Reciprocal of risk: practical certainty that injury will not result from a hazard under defined conditions. (Jager & Visser 1994)

5 Practical certainty that a substance will not cause injury under carefully defined circumstances of use. (Cohrssen & Covello 1989)

6 The extent to which a chemical substance may be used in the necessary amount for intended purposes with a minimum risk of adverse health effects. (WHO 1979)

7 Freedom from unacceptable risk of harm. (ISO 1990)

8 The extent to which a chemical substance may be used in the amounts necessary for intended purposes with a minimum risk of adverse health effects. (WHO 1979)

Safety factor

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	31	16.4		1		1			1		3	12		1	5	7
1	21	11.1				2		1	1		1	7		2	2	5
2	47	24.9	1	1		2	1	2	3	1	7	11		1	4	13
3	51	27.0		1	1	2			1	1	11	17	1	2	5	9
4	39	20.6			1	2	1	1	1	1	1	19		2	6	4

Definition

0 None of the below.

1 A factor applied to reduce the no-observed-effect level (NOEL) to derive an acceptable daily intake. (Last 1995)

2 A number which accounts for the uncertainty or variability in an estimate of a no effect level by adding an extra margin of safety and therefore differs from assessment or application factors. (OECD 1995)

3 A factor applied to an observed or estimated toxic concentration or dose to arrive at a criterion or standard that is considered safe. Safety factor and uncertainty factor are often used synonymously. (van Leeuwen & Hermens 1996)

4 A factor applied to the no-observed-effect level to derive acceptable daily intake (ADI) (the no-observed-effect level is divided by the safety factor to calculate the ADI). The value of the safety factor depends on the nature of the toxic effect, the size and type of population to be protected, and the quality of the toxicological information available. (IPCS 1987)

Threshold

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	11	5.6				1						2		1	3	4
1	68	34.7			2	2	1	1	1		9	31		1	6	14
2	7	3.6							1		2	3				1
3	49	25.0	1	1		1			2	2	5	18	1	3	7	8
4	26	13.3				3		1	1	1	2	5		3	4	6
5	35	17.9		2		2	2	2	2		5	10			5	5

Definition

0 None of the below.

1 Dose or exposure concentration below which an effect is not expected to occur. (van Leeuwen & Hermens 1996)

2 Concentration of a pesticide in an organism or environmental compartment below which an adverse effect is not expected. (Holland 1996)

3 The dose or exposure below which a significant adverse effect is not expected. (US EPA 1992a)

4 Dose or exposure concentration below which an effect is not expected. (Duffus 1993)

5 The lowest dose of a substance (e.g. a chemical) at which a specified measurable effect is observed and below which it is not observed. (Cohrssen & Covello 1989)

Tolerable daily intake

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	39	22.7				1	1	1	2		5	13		1	4	11

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
1	12	7.0	1			4			1		1	5				
2	27	15.7				1			1	1	2	13		2	2	5
3	24	14.0		1				1		1	3	8		1	1	8
4	37	21.5				1				1	6	14		2	8	5
5	33	19.2		1	1	2		1	2			13			8	5

Definition

0 None of the below.

1 Regulatory value equivalent to the acceptable daily intake established by the European Commission Scientific Committee on Food. (van Leeuwen & Hermens 1996)

2 Term preferred by the European Commission for acceptable daily intake of environmental contaminants. ADI is reserved for pesticides and food additives where extensive toxicological test data is available. (Holland 1996)

3 Regulatory value equivalent to the acceptable daily intake established by the European Commission Scientific Committee on Food. Unlike the ADI, the TDI is expressed in mg/person, assuming a body weight of 60 kg. TDI is normally used for food contaminants. (Duffus 1993)

4 Regulatory value equivalent to the acceptable daily intake and nominally used for food contaminants. (Jager & Visser 1994)

5 An estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis (mg/kg or µg/kg of body weight), that can be ingested daily over a lifetime without appreciable health risk. (WHOTERM)

Tolerable intake

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	32	22.4				1	1	1		1	4	12		2	3	7
1	111	77.6		1		6		1	4	2	12	42		3	19	21

Definition

0 None of the below.

1 An estimate of the intake of a substance which can occur over a lifetime without appreciable health risk. (IPCS 1994)

Toxicity

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	11	5.6							1			3		1	3	3
1	3	1.5						1	1						1	
2	68	34.3	1	2	1	3	1	3	1	1	8	27		2	5	13
3	21	10.6			1	1	1				5	6		1	1	5
4	31	15.7		1		3			1	1	5	7		1	4	8
5	15	7.6				1					3	5			4	2
6	18	9.1				1			1	1	2	6		1	2	4
7	1	0.5										1				
8	4	2.0									1	2				1
9	1	0.5														1
10	8	4.0							1			4		1	2	
11	6	3.0										4				2
12	1	0.5													1	
13	10	5.0					1		1			4	1	1	1	1

Definition

0 None of the below.

1 The general term applied to adverse biological effects in man resulting from pollutants. (Pfafflin 1976)

2 The inherent property of a chemical to cause an adverse biological effect. (ECETOC 1982)

3 The inherent potential or capacity of a substance to cause adverse effects on a living organism, seriously damaging structure or function or producing death. (van Leeuwen & Hermens 1996)

4 The inherent potential or capacity of an agent or material to cause adverse effects in a living organism when the organism is exposed to it. (Holland 1996)

5 Capacity to cause injury to a living organism defined with reference to the quantity of substance administered or absorbed, the way in which the substance is administered (inhalation, ingestion, topical application, injection) and distributed in time (single or repeated doses), the type and severity of injury, the time needed to produce the injury, the nature of the organism(s) affected and other relevant conditions. (Duffus 1993)

6 Adverse effects of a substance on a living organism defined with reference to the quantity of substance administered or absorbed, the way in which the substance is

administered (inhalation, ingestion, topical application, injection) and distributed in time (single or repeated doses), the type and severity of injury, the time needed to produce the injury, the nature of the organism(s) affected, and other relevant conditions. (WHOTERM)

7 Measure of incompatibility of a substance with life: this quantity may be expressed as the reciprocal of the absolute value of median lethal dose (l/LD50) or concentration (1/LC50). (WHOTERM)

8 The quality or degree of being poisonous or harmful to plant, animal, or human life. (Cohrssen & Covello 1989)

9 The relative power of a toxic material to cause harm. (Jones 1992)

10 A physiological or biological property which determines the capacity of a chemical to do harm or produce injury to a living organism by other than mechanical means. (FAO 1990)

11 The capacity to cause injury to a living organism. (WHO 1979)

12 (Of a substance) The capacity to cause injury to a living organism. (WHO 1978)

13 The quality or degree of being poisonous or harmful to plant, animal or human life. (IPCS 1996)

Toxicity assessment

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	21	11.1									2	8	1	1	3	6
1	49	25.9		1		4	1		2		3	20			12	6
2	20	10.6			1	1		1			4	4			1	8
3	11	5.8						1	1		3	4			1	1
4	10	5.3				1			1		1	2		1	2	2
5	8	4.2		1							1	3		1		2
6	24	12.7		1		1		1		1	4	6		3	2	5
7	13	6.9							1	2	1	7			1	1
8	29	15.3	1		1	1		1	1		3	14		2	2	3
9	4	2.1									1				1	2

Definition

0 None of the below.

1 Characterization of the toxicological properties and effects of a substance (e.g. a chemical) including all aspects of its absorption, metabolism, excretion, and mechanism of action, with special emphasis on establishment of dose–response characteristics. (Cohrssen & Covello 1989)

2 The estimation of the relationship between dose or concentration and the incidence and/or severity of an effect. (OECD 1995)

3 The process of characterizing the relationship between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations. (van Leeuwen & Hermens 1996)

4 The estimation of the relationship between dose or concentration and the incidence and severity of an effect in a particular group of test organisms and, through extrapolation, in a whole population or ecosystem. (Jager & Visser 1994)

5 A component of risk assessment that describes the quantitative relationship between the amount of exposure to a substance and the extent of injury or disease. (Cohrssen & Covello 1989)

6 The determination of the relationship between the magnitude of exposure and the magnitude and/or frequency of adverse effects. (WHO 1995)

7 The determination of the relationship between the magnitude of administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population. (US EPA 1992b)

8 The identification and quantification of the potential adverse effects of a substance and therefore includes hazard identification and dose–response assessment. (OECD 1995)

9 The component of an environmental risk analysis concerned with quantifying the manner in which the frequency and intensity of effects increase with increasing exposure to a contaminant or other source of stress. (van Leeuwen & Hermens 1996)

Uncertainty

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	28	14.5				2			1		1	13	1	1	3	6
1	88	45.6		3	2	6	1	2	2		10	26		2	14	20
2	29	15.0						1	2	1	5	10		2	3	5
3	20	10.4							2	1	4	6			1	6
4	28	14.5				1	1	1	1	1	5	8		1	4	5

Definition

0 None of the below.

1 Imperfect knowledge concerning the present or future state of the system under consideration. A component of risk resulting from an imperfect understanding of the degree of hazard or of its spatial and temporal pattern of expression. (van Leeuwen & Hermens 1996)

2 Uncertainty with respect to parameter values and model formulations of processes. (Jager & Visser 1994)

3 A felt state of imperfect knowledge where one may seek to increase the chances of successful action by improving available information. (Le Guen 1995)

4 Felt deficiency in knowledge relevant to forthcoming decisions of critical importance. (Le Guen 1995)

Uncertainty factor

Definition	All respondents	Percentage	Chemistry	Pharmaceuticals	Ecological – Aquatic	Environmental science	Epidemiology	Occupational health	Pesticides	Risk assessment – General	Risk assessment – Environmental	Risk assessment – Human health	Risk assessment – Methodology	Toxicology	Other	None reported
0	23	12.4		1							3	9			3	7
1	75	40.5			2	4	1	3	3		14	20	1	2	6	19
2	16	8.6							1	1	2	6		1	3	2
3	23	12.4		1					2	2	3	7			3	5
4	8	4.3	1	1		2					1			1	2	
5	31	16.8							1			18		3	5	4
6	9	4.9				1	1				1	4				2

Definition

0 None of the below.

1 A factor applied to an exposure or effect concentration or dose to correct for identified sources of uncertainty. (van Leeuwen & Hermens 1996)

2 Factor in toxicological assessment for extrapolation of data from experimental animals to man (assuming that man may be more sensitive) or from selected individuals to the general population. For example an uncertainty factor is generally applied to the no-observed-effect level to derive an acceptable daily intake. (Holland 1996)

3 One of several, generally 10-fold factors, used in operationally deriving the Reference Dose (RfD) from experimental data. UFs are intended to account for (1) the variation in sensitivity among the members of the human population; (2) the uncertainty in extrapolating animal data to the case of humans; (3) the uncertainty in extrapolating from data obtained in a study that is of less-than-lifetime exposure; and (4) the uncertainty in using LOAEL data rather than NOAEL data. (US EPA 1992a)

4 In assay methodology, confidence interval or fiducial limit used to assess the probable precision of an estimate. (Duffus 1993)

5 In toxicology, value used in extrapolation from experimental animals to man (assuming that man may be more sensitive) or from selected individuals to the general population: for example, a value applied to the no-observed-effect level (NOEL) or no-observed-adverse-effect level (NOAEL) to derive an acceptable daily intake or reference dose (RfD) (the NOEL or NOAEL is divided by the value to calculate the

acceptable daily intake or RfD). The value depends on the nature of the toxic effect, the size and type of population to be protected, and the quality of the toxicological information available. (WHOTERM)

6 A product of several single factors by which the NOAEL or LOAEL of the critical effect is divided to derive a TI. (IPCS 1994)

Validation

Definition	*All respondents*	*Percentage*	*Chemistry*	*Pharmaceuticals*	*Ecological – Aquatic*	*Environmental science*	*Epidemiology*	*Occupational health*	*Pesticides*	*Risk assessment – General*	*Risk assessment – Environmental*	*Risk assessment – Human health*	*Risk assessment – Methodology*	*Toxicology*	*Other*	*None reported*
0	35	17.7				1					1	15	1	1	3	13
1	144	72.7	1	3	2	7	2	4	2	3	22	43		7	19	29
2	19	9.6				1			4		2	8		1	2	1

Definition

0 None of the below.

1 The process of assessing whether the predictions or conclusions reached in a risk assessment are correct. (OECD 1995)

2 In pesticide analysis, the process for establishing that an analytical method or equipment will provide reliable and reproducible results. (Holland 1996)

ANNEX 4
DETAILS OF THE PROCESS OF WORK INVOLVED IN THE DEVELOPMENT OF HARMONIZED DESCRIPTIONS OF GENERIC TERMS IN HAZARD AND RISK ASSESSMENT

The below is a reproduction of material that appeared in the draft report that was released by the International Programme on Chemical Safety (IPCS) and the Organisation for Economic Co-operation and Development (OECD) for final expert peer review. This provides more detailed information on the approach taken by the Terminology Planning Working Group. Readers will need to turn to the section of the report entitled "Approach to the work" for information on the process employed in finalizing the draft report.

Introduction

The overall objective of this project is to harmonize the definitions of generic terms used in chemical hazard/risk assessment. This will help to facilitate the mutual use and acceptance of the assessments of chemicals between countries, saving resources for both governments and industry. This project has been initiated as a direct response to requests from governments to harmonize the use of such terms and, therefore, increase the understanding and communication of risks associated with exposure to chemicals. Specifically, it addresses and responds to the need for "Harmonized Approaches for Performing and Reporting Health and Environmental Risk Assessments" (requested by the 1st Intergovernmental Forum on Chemical Safety [IFCS] in 1994). It will facilitate meeting the objectives set forth by the IFCS regarding Programme Area A of Chapter 19, Agenda 21. Further, the goals and objectives of this project are instrumental in addressing the needs and objectives outlined in the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures and Agreement on Technical Barriers to Trade. It should be noted that this project is complementary to other activities being undertaken by IPCS and OECD to harmonize technical terms used in chemical hazard/risk assessment.

The current focus is on the harmonization of terms used by risk assessors in the hazard/risk assessment of chemicals (including pesticides) in the context of chemicals management (i.e., notification, registration, classification, etc.). Although work has been done previously on the development of internationally agreed upon definitions for terms used in chemical hazard/risk assessment (e.g., by IPCS, OECD, and others), inconsistencies in the definitions and use of many of these terms still exist. Such inconsistencies have been highlighted in a number of forums, including the work of the IPCS project to harmonize risk assessment approaches and the OECD Pilot Project to Compare Pesticide Data Reviews. Through such efforts, inconsistency in the usage of terminology was found in all test areas, but was particularly prevalent for certain aspects related to human health.

Inconsistencies in the use of terminology can become an impediment to the harmonization of risk assessment approaches by hindering the mutual understanding of the different approaches currently in use. The barriers created by these inconsistencies in terminology reduce the possibility for the sharing and use of assessments between countries.

Methodology

The principles of good practice in international terminology work have been a subject of study for many decades by many individual scientists and researchers as well as a wide range of national and international bodies. Although the principles have evolved and continue to be dynamically adapted to meet new requirements and take advantage of new technologies, they have reached a fair level of overall stability. The methodology of terminology data management adopted in the present project follows international standards. Standardization of the content of definitions started from existing materials, on which expert opinions were sought using a modified Delphi technique.

Scope

The scope of this joint activity covers the general category of terms referred to as **generic**. **Generic terms** are defined as general terms used in the process of determining risks from exposure to chemicals, regardless of the subject-specific fields. Examples of such terms include hazard identification, risk characterization, and risk assessment.

Terms

The IPCS and OECD, in consultation with the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), identified generic terms that were considered to be problematic from the standpoint of understanding and communication. It was agreed that in this initial stage, the list of terms considered be kept to a minimum. It was recognized that the set of terms must be considered as a total package so that no terms used in a definition were themselves left undefined. Thus, it was agreed that the list considered be limited to 50 terms.

Definition

The secretariats compiled a database with the definitions used for each of the terms in key sources. “Key” sources were identified as those that are widely cited or used (i.e., IUPAC) or those that have regulatory implications in countries or organizations (i.e., EU Technical Guidance Documents or national guidelines). From a total of 5000 terms and 15 000 definitions collected from the key sources, the 50 initial terms featured a total of over 300 definitions.

Survey

These terms and definitions were compiled into a survey. The survey was circulated widely among IPCS, OECD, and IOMC contact points. It was also posted on the World Wide Web for response electronically. Respondents were asked to

a) identify or provide their preferred definition for each term,
b) identify terms considered as synonyms, and
c) indicate whether any important key documents/sources were omitted.

Additional information on the individuals responding was requested, such as their area of expertise, years of experience with risk assessment, affiliation, etc. Responses were received from 186 respondents from different countries, institutions, and scientific disciplines.

Terminology Planning Working Group

A Terminology Planning Working Group was established by the secretariats to provide advice and guidance in coming to agreement on the use and definition of the terms and towards developing a glossary of chemical hazard/risk assessment terms as used by hazard/risk assessors. The Working Group is composed of individual experts in the areas of terminology and hazard/risk assessment. The list of Working Group members is provided below.

The Working Group met in March 1998 to review the preliminary survey results and to make recommendations on the use and further analysis of the data collected by developing an action plan to work towards harmonizing this first set of generic terms.

Members of the Terminology Planning Working Group

Dr J.H. Duffus
Director, The Edinburgh Centre for Toxicology
43 Mansionhouse Road
Edinburgh EH9 2JD
Scotland, United Kingdom

Dr R. Fielder
Head, Chemical Toxicology Unit
Department of Health
HEF Division
Skipton House
80 London Road
London SE1 6LW
England, United Kingdom

Mr C. Galinski
Director, International Information Centre for Terminology (INFOTERM)
Simmeringer Haupstrasse 24
A-1110 Vienna
Austria

Dr N. Grandy
Environmental Directorate
OECD
2 rue André Pascal
F-75775 Paris Cedex 16
France

Dr K. Gutschmidt
International Programme on Chemical Safety
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

Mr Bjorn Hansen
European Chemicals Bureau
Joint Research Centre
Ispra Site 020
I21020 Ispra (VA) Italy

Dr H. Koepp
The Federal Biological Research Centre for Agriculture and Forestry
Messeweg 11/12
D-383104 Braunschweig
Germany

Mr P. Lewalle
Computer Assisted Translation and Terminology
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

Ms C. Sonich-Mullin
Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals
International Programme on Chemical Safety
World Health Organization
7788 Bennington Drive
Cincinnati, OH 45241
USA

Critical analysis of results

The Terminology Planning Working Group agreed upon a mechanism for reaching consensus on the definitions. Using a "concept-driven" approach, a detailed semantic analysis was conducted for each term based on the most frequently chosen definitions. Furthermore, all comments were taken into account to refine the analysis and reflect the participants' views. Eventually, a generic definition was proposed for each term as a synthesis of the participants' contributions and preferences. Through the course of the analysis, some terms were considered necessary for better understanding of the concept system. Several such terms were added. It is hoped that the definitions for all these terms will be accepted and used. If necessary, they can be modified to further elucidate the concept as related to a particular field or situation. Using this method, areas of convergence and divergence can be readily identified. It was further recognized that analysing the definitions in their semantic constituents would aid in producing appropriate translations into a variety of languages. (Such translation work is not currently within the scope of this joint project.)

Models have been developed for each of the terms based on the results of the initial survey. The Terminology Planning Working Group met in October 1998 to review the critical analysis and the resulting concept definitions. Comments have been incorporated into this analysis.

Output

It should be noted that the concepts described by the terms must not be viewed in isolation from one another. The generic terms identified have a variety of uses and applications in a number of disciplines. Thus, to be most clear and transparent, the concepts developed for each term should also be viewed in the context of their use with and relationship to the other terms. The final output of this effort will be an annotated glossary of terms reflecting the situation that emerges from the responses to the survey. However, it must be stressed that the resulting glossary will remain dynamic. It must be viewed as an agreement of the use of hazard/risk assessment terms *as they are used by hazard/risk assessors* in the chemicals area. It should not be implied that the definitions provided are the correct definitions to be used in all cases by all disciplines. The purpose is to be transparent about how they are used by risk assessors in the most basic sense, and then, with this understanding, they can be modified or enhanced as appropriate. Thus, it is hoped that these definitions will be adopted as commonly used "root definitions" that can be built upon to suit the needs of specific disciplines.

Elements of terminology

The set of generic terms under review clearly consists of two kinds of terms. Along with the expected terms referring to objects of the real world (e.g., threshold, toxicity), the list contains an unusually high number of terms referring to actions. The first group is therefore data oriented, and the second is more process or action oriented.

Data-oriented terms

Terms such as *guidance value* or *reference dose* have been marked as important concepts in the terminology under review; they represent entities that derive from superordinate concepts, either in a generic or in a partitive relation, or are associated with other concepts in a circumstantial rather than essential fashion. The term *acceptable risk* is one of two theoretical kinds of *risk* along an imaginary acceptability axis. In a set comprising all *risks*, there is a subset of *acceptable risks*, as opposed to another set, unmentioned, of *unacceptable risks*. Taking another axis, say, the nature of the risk, a number of risks of a different nature may be thought of. In the list of generic terms, only one kind is mentioned explicitly as *ecological risk*; another kind, however, exists implicitly from the definitions and the related comments, as *health risk*. The concept system around *risk* may therefore be represented as shown in Figure 1. The advantage of such a representation is that is visualizes the relations between terms and points to apparent logical inconsistencies, which have to be further addressed in the course of the detailed analysis.

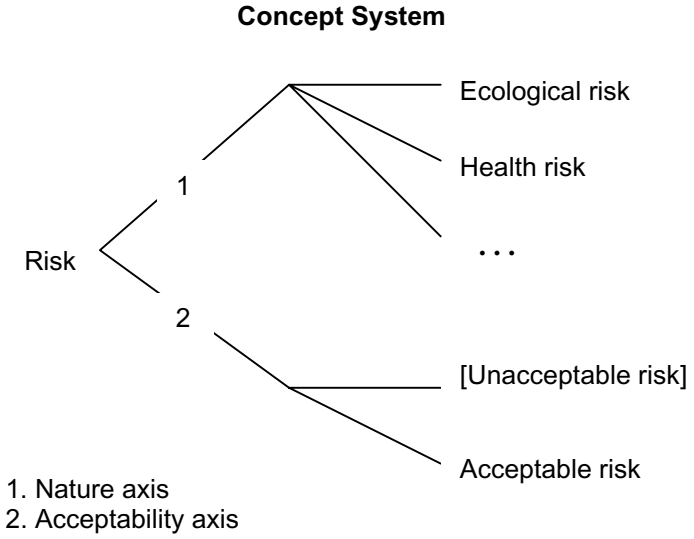

Figure 1: The concept system around risk

From the survey list, it appears that some terms are more prone to enter into multiple relations than others. We shall consider them in groups according to their natural affinity. There is, for instance, one cluster around *risk*, another somewhat smaller one around *hazard*. They both present complex and variable semantic features with stronger binding combinatorial capabilities, resulting in part from their popularity in many language areas, including the general language. Others, which are more specific to particular subject fields, have a more restricted connectivity. These include *guidance value*, *margin of exposure*, *safety factor*, *threshold*, etc.

Action-oriented terms

Action-oriented terms are used in combinations with other single-word terms, except for *assessment*, which also appears individually. For the purpose of the present analysis, we shall identify as "base" any term that is used as the anchor for a number of combinations and collocate the variable part in a set of collocations. The list of collocates to be found in various combinations with a number of bases is as follows:

ACTION COLLOCATES

Collocate		*Related action*
Analysis	=	Analyse
Assessment	=	Assess
Characterization	=	Characterize
Communication	=	Communicate
Estimation	=	Estimate
Evaluation	=	Evaluate
Identification	=	Identify
Management	=	Manage
Monitoring	=	Monitor

All the verbs used to generate the collocations are normally used transitively. The bases in the combinations therefore represent objects to which the actions expressed by the collocates apply: *risk assessment* means that the act of assessing applies to a risk, and *hazard evaluation* means that the action is to evaluate a hazard. This is essentially different from other combinations that do not involve action collocates, such as *safety factor*, etc.

The action collocates enter into combinations with a number of different bases. *Risk* is the most prolific one, as it combines with every one of the collocates. We therefore have *risk analysis*, *risk assessment*, *risk communication*, *risk estimation*, *risk evaluation*, *risk identification*, *risk management*, and *risk monitoring.* There are only four combinations based on *hazard*: *hazard assessment*, *hazard characterization*, *hazard evaluation*, and *hazard identification*.

If such combination phrases are considered to be the mere sum of their individual components, they will show weaker bonds than other multiword terms in the lexicon, such as *heart failure* or *central nervous system*. If evidence shows that the definitions for *risk assessment* are semantically richer than the sum of the semantic features of both *risk* and *assessment* together, it is justified to clarify the meaning of *assessment* in order to understand the functioning of the word in combination. It also follows logically that other collocates used with the same base need to be defined as well. This has been suggested by respondents, in reaction to the observation that such collocates as *characterization*, *evaluation*, *identification*, etc. have not been initially included in the list of generic terms. The semantic analysis of *assessment* will be carried out on direct evidence from the survey. The other collocates will be analysed based on elements extracted from the collocations in which they occur as well as from general language dictionary sources.

PART 2

IPCS GLOSSARY OF KEY EXPOSURE ASSESSMENT TERMINOLOGY

PART 2: TABLE OF CONTENTS

1. INTRODUCTION

This glossary of exposure assessment terminology is intended to help facilitate communication and consistency of language used in the exposure sciences. The glossary was developed under the auspices of the International Programme on Chemical Safety (IPCS) as part of its project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals. The terminology project began in September 1999 as one of a series of planned projects to harmonize approaches and issues in risk assessment. Part 2 of this report represents the outcomes of work to harmonize technical terms used in exposure assessment.

An Exposure Assessment Terminology Working Group was assembled under the IPCS Harmonization Project Exposure Assessment Working Group. Its goal was to harmonize usage within a consistent exposure assessment framework. After an in-depth review of 57 glossaries of terms used in risk assessment, the terms presented here were selected because they describe fundamental concepts in exposure assessment and are, in most instances, in common use. In general, definitions are based on a review and refinement of the definitions in the 57 glossaries considered (see Annex 1 to Part 2). Where fundamentally different definitions existed for a particular term, the definition most commonly used in exposure science was selected and, if necessary, refined. Although we recommend a single definition for each term, which is consistent with the goal of harmonizing usage, we recognize that other definitions have been used for some of these terms.

The glossary was submitted for review to the IPCS Harmonization Project Steering Committee, the Harmonization Project Exposure Assessment Working Group, and selected reviewers in the organizations of the Exposure Assessment Terminology Working Group members (Tier 1 review). A revised glossary and a disposition of comments were completed in July 2001. This version of the glossary was sent to selected outside experts for review (Tier 2 review). In addition, the glossary was presented in platform and poster sessions at the November 2001 annual meeting of the International Society of Exposure Analysis, and comments were solicited.

The framework of exposure and dose and related definitions presented in this glossary is based on that in Zartarian et al. (1997). Although definitions presented use the terms agent and target generally, the primary focus of this glossary is the human as a target of exposure and a chemical as an agent of exposure. Some terms, such as stressor, are common to both human health and ecological assessment. Harmonizing terminology between human health and ecological assessment is important, but is outside the scope of this glossary. The intent of our definitions is that they would (1) build on previous definitions; (2) constitute a logically consistent framework (e.g., across routes of exposure); (3) be parsimonious; (4) be able to be expressed mathematically; (5) agree with common sense; and (6) be consistent with common usage (Zartarian et al. 1997).

Two of the fundamental terms in the exposure sciences that have caused confusion are exposure and dose. We define exposure as contact between an agent and a target, with contact taking place at an exposure surface over an exposure period. The existing environmental health literature contains many different definitions of exposure. Some are

specific, and some are vague or inconsistent with others. Our definitions build on a mathematical framework from the definition of exposure at a single point in space at a single instant in time. Exposure is commonly quantified as concentration integrated over time. In addition to this time-integrated exposure, we define time-averaged exposure, which can also be toxicologically important. The definitions allow us to mathematically describe spatially integrated and spatially averaged exposures (i.e., exposure mass and exposure loading, respectively) that are relevant to exposure measurement methods such as wipe samples. A dermal exposure measurement based on a skin wipe sample, expressed as a mass of residue per skin surface area, is an example of an exposure loading. The total mass on the wipe sample is the exposure mass.

Current methods are not always able to measure factors such as exposure concentration, exposure mass, and contact volume with complete accuracy. For example, the exposure concentration is calculated as the amount of agent collected in a personal air monitor (a surrogate for the exposure mass) divided by the volume of air sampled (a surrogate for the contact volume). In fact, the measured exposure concentration is not identical to the concentration inhaled. Variation in breathing rate throughout the monitoring period will affect the amount inhaled, and the personal air monitor may not retain 100% of the agent that is drawn into the air filter. Likewise for dermal exposure, the exposure mass and exposure loading that actually come into contact with the skin are usually only fractions of the amount removed from the skin by a wipe sample, because only a thin layer of agent directly in contact with the skin is capable of being absorbed. However, wipe sampling methods remove all of the agent from the skin. These discrepancies reflect limitations in the measurement methods, rather than in the definitions, and should be noted as uncertainties in the exposure assessment.

With the definition of an exposure surface, the framework inherent in our glossary emphasizes the need for exposure assessors to specify where the contact between an agent and a target occurs, to help facilitate communication and clarify the difference between exposure and dose. We define dose as the amount of agent that enters a target by crossing an exposure surface. If the exposure surface is an absorption barrier (e.g., exposure surface specified as a surface on the skin, lung, gut), the dose is an absorbed dose/uptake dose; otherwise (e.g., exposure surface specified as a conceptual surface over the nostrils and open mouth), it is an intake dose. This concise definition simplifies and is consistent with the numerous dose-related terms used in exposure-related fields. Terms such as internal dose, bioavailable dose, delivered dose, applied dose, active dose, and biologically effective dose that refer to an agent crossing an absorption barrier are consistent with our definition of an absorbed dose. Terms such as administered dose and potential dose, which refer to the amount of agent in contact with an exposure surface, are consistent with our definitions of either intake dose or exposure mass, depending on where the exposure surface is specified. While it is recognized that the term dose is often used in a way that does not refer to the crossing of an exposure surface (e.g., fields of toxicology, pharmacology), it is being defined this way here to eliminate confusion between exposure mass and dose.

Another source of confusion, as noted in the comments, is use of the terms acute exposure, chronic exposure, and subchronic exposure. One of the reasons for this confusion is that the terms themselves are not very precise. These modifiers are also used to refer to effects and

are used in more than one way. Some definitions of acute exposure refer only to the length of time of the exposure (e.g., less than 24 h), while others also require an accompanying acute effect that is seen immediately or shortly after the exposure. Chronic and subchronic exposures are used to refer specifically to the number of days of exposure in standard laboratory toxicity studies. The Exposure Assessment Terminology Working Group decided to retain the terms acute, chronic, and subchronic exposure, limiting the definitions to the timing of exposure without reference to effects, because the terms are still widely used and seem to be a source of some confusion. In an exposure assessment, more precise quantification of the exposure period is necessary.

After considering comments received during the Tier 1 and Tier 2 reviews, the Exposure Assessment Terminology Working Group identified four terms that were particularly difficult to define due to their relatively recent emergence as exposure terms. These are aggregate exposure, aggregate dose, cumulative exposure, and cumulative dose. Although reviewers generally agreed that it would be useful to have these terms in the glossary, they were divided on the definitions. In studying the literature, the Exposure Assessment Terminology Working Group found very few formal definitions of these terms. In most instances where the terms appear, "aggregate" and "cumulative" are used as adjectives to modify "exposure" or "dose" without further elaboration. Often, "aggregate" and "cumulative" seem to be used interchangeably, suggesting (1) exposures that are from multiple sources, received via multiple exposure pathways, or doses received through multiple routes; (2) exposures or doses that accumulate over time, often over a lifetime; or (3) exposures or doses from more than one chemical or stressor simultaneously or sequentially. The recent interest in "cumulative risk assessment" will soon demand that these terms be defined more precisely. The US Environmental Protection Agency, in its *Framework for Cumulative Risk Assessment* (US EPA 2002), uses "aggregate" as a term referring to the risks over time from multiple sources, pathways, and routes *for a single chemical or stressor*, reserving "cumulative" for assessments where (aggregate exposures or doses for) multiple chemicals or stressors are evaluated together. These definitions are based more on the contextual language of the 1996 *Food Quality Protection Act* than on a study of how the terms are being used worldwide, so it remains to be seen whether these particular definitions will come into general usage within the scientific community. At this time, we have chosen to postpone inclusion of these terms in the glossary, awaiting further developments in the field.

Case-studies illustrating the application of the IPCS glossary definitions to the inhalation, ingestion, and dermal routes of exposure follow the glossary (see section 4).

2. IPCS HARMONIZATION PROJECT EXPOSURE ASSESSMENT TERMINOLOGY WORKING GROUP PARTICIPANTS

Mr Michael Callahan, Region 6, US Environmental Protection Agency
Dr Michael DiNovi, US Food and Drug Administration
Dr Judith Graham, International Council of Chemical Associations
Ms Karen Hammerstrom, National Center for Environmental Assessment, US Environmental Protection Agency

Dr Roshini Jayewardene, National Industrial Chemicals Notification and Assessment Scheme, Australia
Ms Christine Norman, Pest Management Regulatory Agency, Health Canada
Dr Steve Olin, International Life Sciences Institute
Ms Cynthia Sonich-Mullin, National Center for Environmental Assessment, US Environmental Protection Agency
Dr Yiqun Wu, Chinese Institute of Preventive Medicine
Dr Valerie Zartarian, National Exposure Research Laboratory, US Environmental Protection Agency

3. ALPHABETICAL LIST OF KEY EXPOSURE ASSESSMENT TERMINOLOGY

Absorption barrier

Any exposure surface that may retard the rate of penetration of an agent into a target. Examples of absorption barriers are the skin, respiratory tract lining, and gastrointestinal tract wall (see also *Exposure surface*).

Activity pattern data

Information on human activities used in exposure assessments. These may include a description of the activity, frequency of activity, duration spent performing the activity, and the microenvironment in which the activity occurs.

Acute exposure

A contact between an agent and a target occurring over a short time, generally less than a day. (Other terms, such as “short-term exposure” and “single dose,” are also used.)

Agent

A chemical, biological, or physical entity that contacts a target.

Background level

The amount of an agent in a medium (e.g., water, soil) that is not attributed to the source(s) under investigation in an exposure assessment. Background level(s) can be naturally occurring or the result of human activities. (Note: Natural background is the concentration of an agent in a medium that occurs naturally or is not the result of human activities.)

Bioavailability

The rate and extent to which an agent can be absorbed by an organism and is available for metabolism or interaction with biologically significant receptors. Bioavailability involves both release from a medium (if present) and absorption by an organism.

Biomarker/biological marker

Indicator of changes or events in biological systems. Biological markers of exposure refer to cellular, biochemical, analytical, or molecular measures that are obtained from biological media such as tissues, cells, or fluids and are indicative of exposure to an agent.

Bounding estimate

An estimate of exposure, dose, or risk that is higher than that incurred by the person with the highest exposure, dose, or risk in the population being assessed. Bounding estimates are useful in developing statements that exposures, doses, or risks are "not greater than" the estimated value.

Chronic exposure

A continuous or intermittent long-term contact between an agent and a target. (Other terms, such as "long-term exposure," are also used.)

Contact volume

A volume containing the mass of agent that contacts the exposure surface.

Dose[1]

The amount of agent that enters a target after crossing an exposure surface. If the exposure surface is an absorption barrier, the dose is an absorbed dose/uptake dose (see uptake); otherwise, it is an intake dose (see intake). (See introductory comments.)

Dose rate

Dose per unit time.

Exposure[1]

Contact between an agent and a target. Contact takes place at an exposure surface over an exposure period.

Exposure assessment[1]

The process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and the uncertainties in the assessment.

Exposure concentration

The exposure mass divided by the contact volume or the exposure mass divided by the mass of contact volume, depending on the medium.

[1] This term is also contained in the list of IPCS/OECD key generic terms used in chemical hazard/risk assessment (see Part 1); both definitions are consistent and interchangeable, depending on user preference.

Exposure duration

The length of time over which continuous or intermittent contacts occur between an agent and a target. For example, if an individual is in contact with an agent for 10 min per day for 300 days over a 1-year time period, the exposure duration is 1 year.

Exposure event

The occurrence of continuous contact between an agent and a target.

Exposure frequency

The number of exposure events in an exposure duration.

Exposure loading

The exposure mass divided by the exposure surface area. For example, a dermal exposure measurement based on a skin wipe sample, expressed as a mass of residue per skin surface area, is an exposure loading.

Exposure mass

The amount of agent present in the contact volume. For example, the total mass of residue collected with a skin wipe sample over the entire exposure surface is an exposure mass.

Exposure model

A conceptual or mathematical representation of the exposure process.

Exposure pathway

The course an agent takes from the source to the target.

Exposure period

The time of continuous contact between an agent and a target.

Exposure route

The way in which an agent enters a target after contact (e.g., by ingestion, inhalation, or dermal absorption).

Exposure scenario[1]

A combination of facts, assumptions, and inferences that define a discrete situation where potential exposures may occur. These may include the source, the exposed population, the time frame of exposure, microenvironment(s), and activities. Scenarios are often created to aid exposure assessors in estimating exposure.

Exposure surface

A surface on a target where an agent is present. Examples of outer exposure surfaces include the exterior of an eyeball, the skin surface, and a conceptual surface over the nose and open mouth. Examples of inner exposure surfaces include the

[1] This term is also contained in the list of IPCS/OECD key generic terms used in chemical hazard/risk assessment (see Part 1); both definitions are consistent and interchangeable, depending on user preference.

gastrointestinal tract, the respiratory tract, and the urinary tract lining. As an exposure surface gets smaller, the limit is an exposure point.

Intake

The process by which an agent crosses an outer exposure surface of a target without passing an absorption barrier, i.e., through ingestion or inhalation (see *Dose*).

Medium

Material (e.g., air, water, soil, food, consumer products) surrounding or containing an agent.

Medium intake rate

The rate at which the medium crosses the outer exposure surface of a target during ingestion or inhalation.

Microenvironment

Surroundings that can be treated as homogeneous or well characterized in the concentrations of an agent (e.g., home, office, automobile, kitchen, store). This term is generally used for estimating inhalation exposures.

Pica

A behaviour characterized by deliberate ingestion of non-nutritive substances, such as soil.

Source

The origin of an agent for the purposes of an exposure assessment.

Stressor

Any entity, stimulus, or condition that can modulate normal functions of the organism or induce an adverse response (e.g., agent, lack of food, drought).

Subchronic exposure

A contact between an agent and a target of intermediate duration between acute and chronic. (Other terms, such as “less-than-lifetime exposure,” are also used.)

Target

Any biological entity that receives an exposure or a dose (e.g., a human, a human population, or a human organ).

Time-averaged exposure

The time-integrated exposure divided by the exposure duration. An example is the daily average exposure of an individual to carbon monoxide. (Also called time-weighted average exposure.)

Time-integrated exposure

The integral of instantaneous exposures over the exposure duration. An example is the area under a daily time profile of personal air monitor readings, with units of concentration multiplied by time.

Time profile

A continuous record of instantaneous values over a time period (e.g., exposure, dose, medium intake rate).

Uptake (absorption)

The process by which an agent crosses an absorption barrier (see *Dose*).

4. EXPOSURE ROUTE-SPECIFIC CASE-STUDIES ILLUSTRATING THE DEFINITIONS IN THE IPCS EXPOSURE ASSESSMENT TERMINOLOGY GLOSSARY

The following examples are intended to illustrate the application of the IPCS glossary definitions and to show that these definitions are self-consistent across agents, targets, and exposure routes. This discussion is intended to clarify important concepts that previously have been treated inconsistently in the literature. The three case-studies below are based on those published in Zartarian et al. (1997); however, they have been modified and expanded to reflect the IPCS glossary definitions. IPCS glossary terms are italicized when first used in each case-study.

4.1 Inhalation exposure to carbon monoxide

Because most studies in the exposure assessment field to date have focused on human exposure to air pollutants, our first example looks at carbon monoxide (CO) exposure. In this example, inhalation *exposure* refers to contact between an air pollutant and a human at the surface of the body. The *exposure route* is inhalation; the *agent* (also a *stressor*) of interest is carbon monoxide; the *target* is a man; the *medium* is air; and the *exposure surface* is specified as a locus of points over the entrance to the mouth and nose (shown as S1 in Figure 1). Theoretically, the *exposure concentration* is the average of the air concentrations at each point on the exposure surface. Practical necessity dictates that in actual field studies, the air in the vicinity of a person's nose is implicitly assumed to be well mixed, and a measured exposure concentration (e.g., 20 mg/m^3) is assumed to be the exposure at the person's nose (assuming that the measurement was in close proximity to the person). The *contact volume* is the theoretical volume of air available for inhalation in the *exposure period* of interest. The volume of air inhaled during the exposure period is a surrogate for the contact volume. Often a personal air monitor is used to estimate the exposure concentration of the agent in the contact volume.

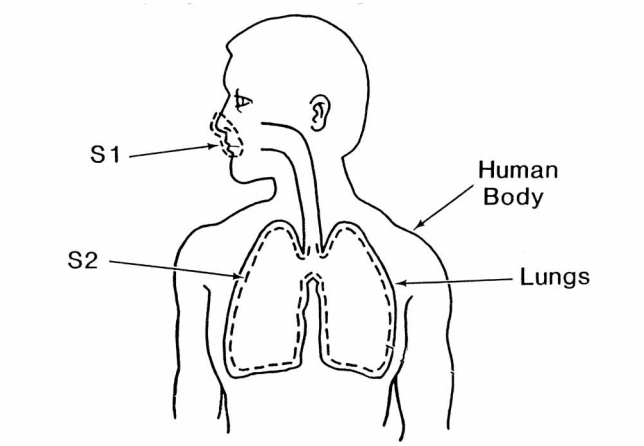

Figure 1: Inhalation exposure (from Duan et al. 1990)

Figure 2 illustrates an actual diurnal carbon monoxide profile of a 58-year-old man who worked in a public garage within about 27 m of a street (see Zartarian et al. 1997). This exposure *time profile* was plotted for one of the 450 Denver participants in the 1982–1983 Denver–Washington, DC, carbon monoxide personal exposure monitoring field study. Each point on the exposure time profile represents the instantaneous inhalation exposure to carbon monoxide and is measured by a personal exposure monitor (PEM). The man's peak exposure to carbon monoxide on the study day can be seen as approximately 39 mg/m^3. The exposure period that contains the peak exposure appears to be approximately 20 min. This high exposure is probably due to his proximity to emissions from motor vehicle tailpipes on repeated occasions during the day. The tailpipes in this *exposure scenario* are the *sources*. The physical course the carbon monoxide follows from the tailpipe through the air to the man's exposure surface is the *exposure pathway*. However, the man could also be exposed to a *background level* of carbon monoxide. The time profile in Figure 2 depicts the man's *acute exposure*, since the *exposure duration* is 1 day. Each spike on the profile represents an *exposure event*, and the *exposure frequency* appears to be 20 events per day. This exposure profile could have been estimated with an *exposure model* that combines the man's *activity pattern data* with measured or predicted concentrations in the *microenvironments* in which he spent time. If longer exposure durations are of interest, such a study could be repeated for several days (*subchronic exposure*) or several years (*chronic exposure*).

The area under the profile shown in Figure 2 is the *time-integrated exposure*. The *time-averaged exposure* over the entire day can be found by dividing the area under the curve by the total time the monitor was worn, i.e., a 24-h exposure duration. Also shown in the figure is the "moving average" 8-h exposure, which is computed from the carbon monoxide exposure profile by taking the average of the measured concentrations over the previous 8 h every hour and every time a new activity begins. The numbers at the top of the exposure profile are activity codes describing the person's microenvironments in his activity pattern data based on the diary that each person maintained. Finally, the *biomarker*, blood carboxyhaemoglobin (COHb), may be computed from the measured carbon monoxide exposure profile using a pharmacokinetic model that provides an estimate of the absorbed dose of carbon monoxide, which agrees fairly well with a blood/breath measurement of this respondent later in the day (see small dot marked "Observed COHb" on the figure, which was

derived from a breath measurement). A *dose rate* could be computed from this profile by computing the dose per unit time.

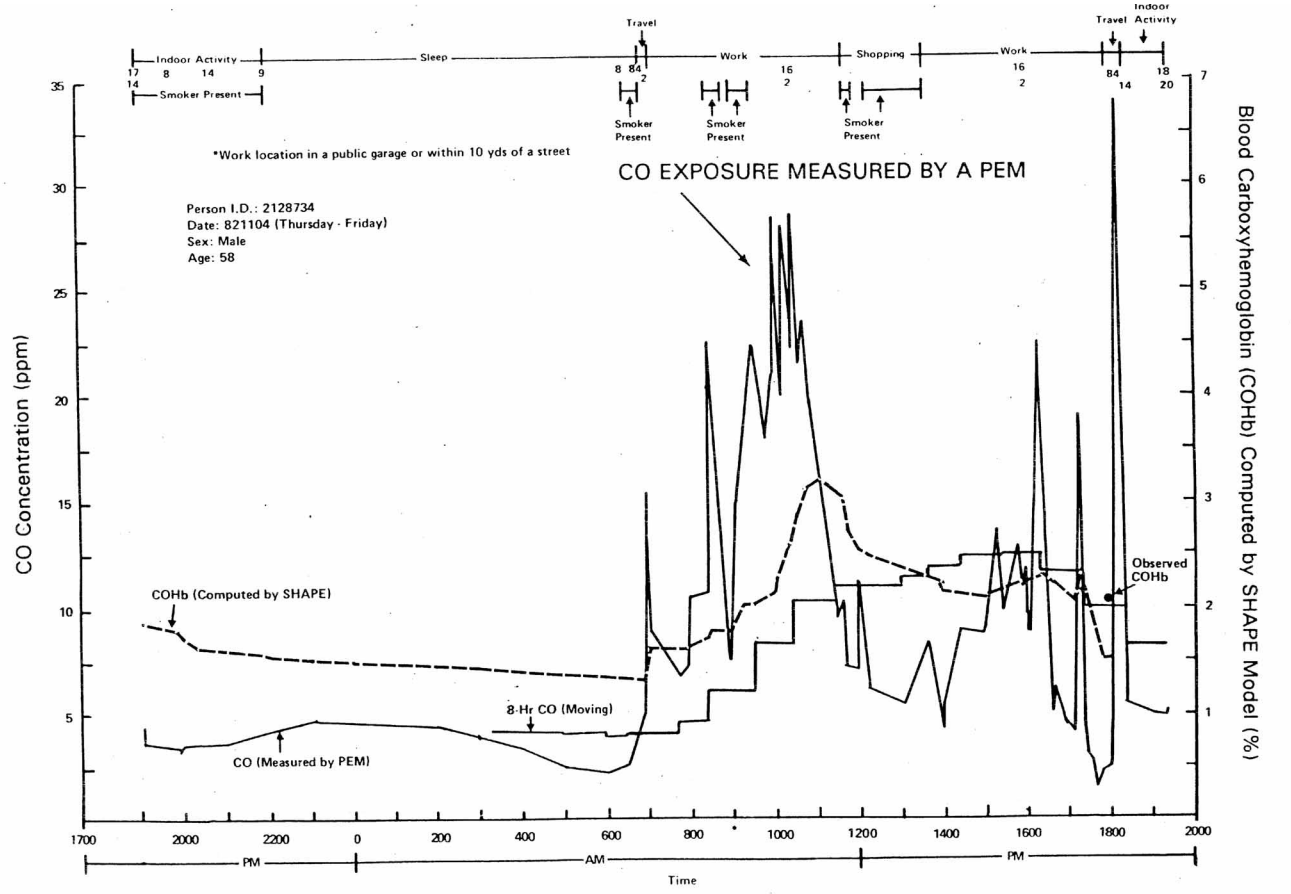

Figure 2: Inhalation exposure profile (from Zartarian et al. 1997)

A *dose* can be calculated for this exposure scenario as the product of the time-averaged exposure, the exposure duration, and the average *medium intake rate* over the exposure duration. The medium intake rate is equivalent to the man's inhalation rate, i.e., the volume of air breathed per unit time. This dose is the mass of carbon monoxide that crosses the theoretical surface at the entrance to the mouth and nose during the exposure duration. This exposure scenario is an example of *intake*, because it estimates only the amount of agent crossing the exposure surface and does not consider the amount that crosses an *absorption barrier* and is absorbed into the systemic circulation. An intake dose time profile could be obtained by multiplying each point on the exposure profile by the inhalation rate to obtain the various time formulations of inhalation dose (i.e., peak, maximum, temporally integrated, temporally averaged).

If we had defined an internal exposure surface such as the epithelial lining of the lung (S2 in Figure 1) and had defined the target to be the lung, then the definitions would still be self-consistent; the dose process in this case would be *uptake* (*absorption*) rather than intake, because the agent would pass through an absorption barrier before entering the target. The specification of the exposure surface depends on the question to be answered.

4.2 Dermal exposure to DDT

This second example focuses on a dermal *exposure scenario*; the *exposure route* is dermal absorption. Figure 3 illustrates a dermal exposure *time profile,* with the person's relevant *activity pattern data* indicated (including information about contacts with different media and surfaces). One can compute the *time-integrated exposure* and *time-averaged exposure* using Figure 3 in a way similar to that described in the inhalation example. However, it is often helpful in the case illustrated in Figure 3 to plot the *exposure loading*, rather than the *exposure concentration*, on the y-axis, since concentrations at different points on the skin surface are for different media and therefore have different units.

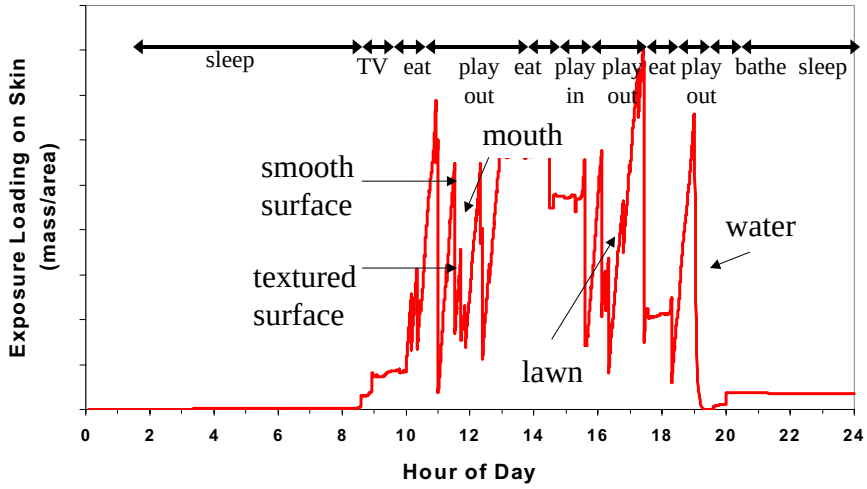

Figure 3: Hypothetical dermal exposure time profile for an individual

Dermal *exposure* is the contact between an *agent* and the external skin surface (the *exposure surface*) of a *target* (e.g., a human) (Figure 4). A point on the skin surface is considered to be exposed if chemical mass is present in the *contact volume* containing the point. Dermal exposure can occur via skin contact with a chemical in different *media*. Figure 4 illustrates the exposure of an area of a hand, during one *exposure event,* to the pesticide DDT (the agent or *stressor*) carried in air, water, and soil media. Some points are exposed to DDT on aerosols, some to aqueous-phase DDT, and some to DDT molecules in a soil matrix. The exposure surface was selected here for the purpose of illustration as a rectangular region on the surface of the stratum corneum, the outermost layer of the skin, as shown. Instantaneous exposures at points on the exposure surface in Figure 4 vary spatially because different media are in contact with the skin surface. Current dermal exposure measurement devices, including skin patches, fluorescent tracers, and skin wipes, measure dermal exposure as exposure loading.

The contact volume for the dermal route is the volume above the skin surface in which the chemical is considered to be in contact with the skin. The thickness of the contact volume (Δ_z in Figure 4) can be estimated as the height above the skin within which any molecule has a

high probability of intersecting the exposure surface during the *exposure period.* This height will vary as a function of the exposure period, since the probability of a far-away molecule intersecting the exposure surface will increase with time if diffusion is in the direction towards the skin. Zartarian et al. (1997) presented an approach for estimating the thickness of the contact volume using several well established theories of mass transfer and a range of contact times. The results yielded estimates of contact volume thickness in air, water, and soil that agree reasonably well with typical measured film thicknesses. The contact volume concept, based on sound engineering models, allows us to discuss the theory behind what we measure in practice.

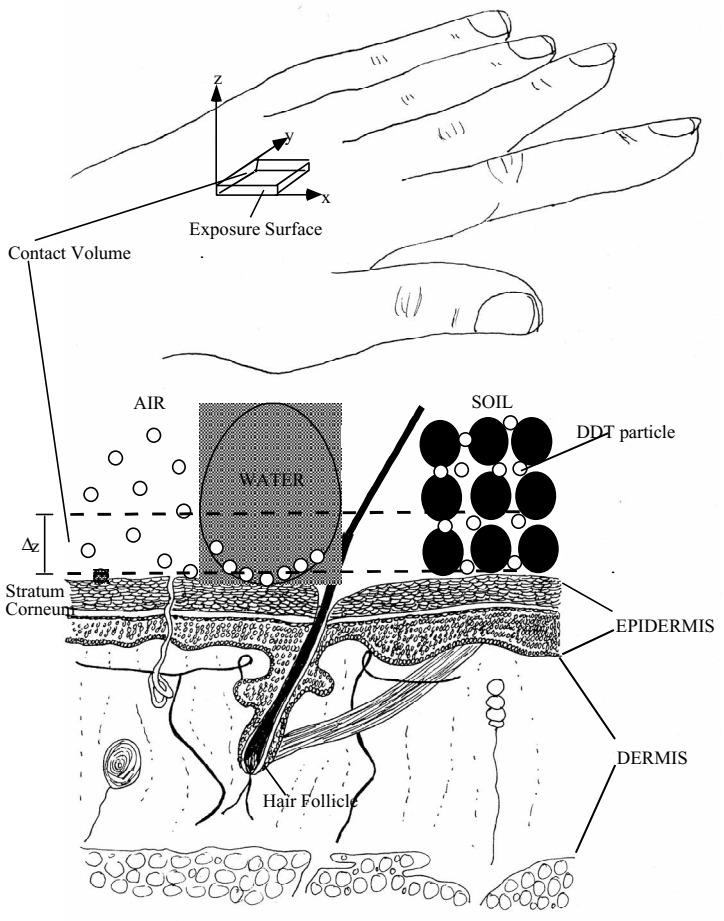

Figure 4: Dermal exposure to DDT in multiple media (from Zartarian 1996)

When the skin is immersed in a fluid medium such as water or air containing the agent (Figure 5), *uptake* (*absorption*) is usually estimated as a function of the exposure concentration, the area of the exposure surface (i.e., the immersed skin surface area, shown as S1 and S2 in Figure 5), and the exposure period using an empirical, chemical-specific permeability coefficient. The agent in the medium is assumed to be an infinite, well mixed source. While a contact volume could be defined for this exposure scenario in the same way in which it is defined for the dermal residue deposition scenario (i.e., the volume above the skin surface in which any molecule has a high probability of contacting the skin surface), the contact volume is not needed to estimate uptake for this scenario.

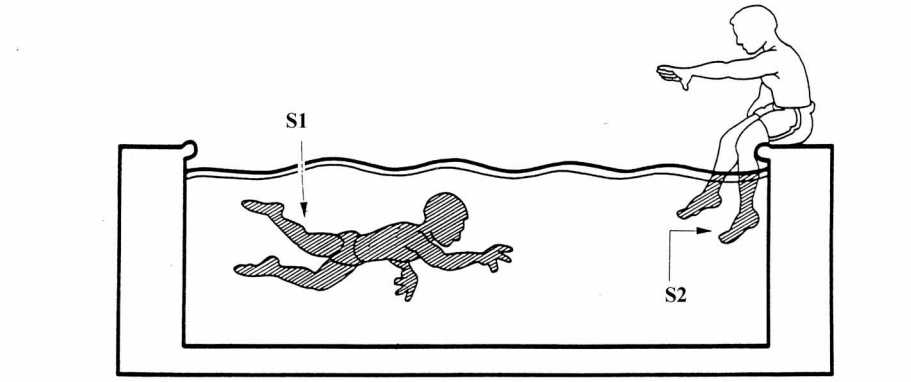

Figure 5: Illustration of dermal exposure surfaces immersed in fluid (from Duan et al. 1990)

Chemicals in media contacting the skin surface partition to the stratum corneum and then diffuse through the stratum corneum into the viable epidermis and dermis, then into general circulation in the body. Because the agent diffuses through an *absorption barrier*, the *dose* process is uptake (absorption), and dermal dose is classified as an absorbed dose. The stratum corneum provides the major barrier to chemical absorption in the skin and thus is the dermal absorption barrier. Dermal dose is complex not only because there can be multiple carrier media on a given exposure boundary, but also because the dose membrane is composed of different media. Because chemicals migrate through the stratum corneum via diffusion, the absorbed *dose rate* under steady-state conditions can be calculated using basic principles of diffusion.

4.3 Ingestion exposure to manganese in a vitamin pill

One can also speak of exposure and dose with respect to chemicals consumed in food and drinking-water. In these types of *exposure scenarios*, the *exposure route* is ingestion. Although ingestion dose may be of greater interest than ingestion exposure, we provide the following unusual examples (see also section 4.4) to illustrate that the definition of exposure is consistent across all exposure routes.

Suppose someone were interested in the total amount of manganese (Mn), the *agent*, entering the body when a person, the *target*, takes a vitamin pill containing 5 mg of manganese, a typical formulation for non-prescription multi-vitamin products. The *contact volume* in this case is the volume of the pill, i.e., 400 mm^3. If the analyst selects an *exposure surface* directly in front of the mouth (Figure 1), the same theoretical surface used above to illustrate inhalation exposure, the oral *exposure* to manganese will be zero up until the instant when the tablet first touches the exposure surface. Exposure occurs for the second that it takes for the tablet to cross the exposure surface and then drops to zero again. The *exposure mass* in this example is 5 mg, and the *exposure concentration* is 1.25×10^7 mg/m^3 (5 mg divided by the 400 mm^3 volume of the tablet). The *exposure period* is the 1 s that it takes for the pill to cross the exposure surface. The vitamin pill container in this example is the *source*, and the *exposure pathway* is the course the pill takes from the container to the person's mouth. The vitamin pill is the *medium* here, and the *medium intake rate* is 400 mm^3/s. Because the pill crosses an exposure surface that is not an *absorption barrier*, this is an example of *intake*, and

the dose is an intake *dose*. The person's oral intake dose from the tablet will be 5 mg, even though other parts of the person's body may receive a different exposure and dose later. The pill's external exposure surface is the locus of points over the mouth (similar to the external exposure surface in the inhalation case). Alternatively, an internal exposure surface could be defined as the epithelial lining of the gastrointestinal tract, and the manganese from the vitamin pill that crossed this epithelial absorption barrier would be an uptake dose.

A person who has difficulty swallowing solid pills might grind up the tablet and dissolve it in a glass of water. If the volume of liquid in the glass is 200 ml, then the concentration of the tablet when diluted in water will be 5 mg/200 ml = 25 000 mg/m^3. If the person drinks the entire contents, the values on the person's *time profile* of exposure concentrations would be zero as the glass moves towards the lips, followed by 25 000 mg/m^3 for several seconds (as it crosses the exposure surface), followed again by zero. Regardless of whether the tablet is eaten or dissolved in water and drunk, the same amount of manganese crosses the oral exposure surface, and the dose is 5 mg in both cases.

We could plot an exposure time profile as in the inhalation example. If the person takes a vitamin pill once a day every day for a year, then the *exposure frequency* is one *exposure event* per day, and the *exposure duration* is 1 year. The *time-integrated exposure* would be 25 000 mg/m^3 · 1 s · 365, and the *time-averaged exposure* would be 25 000 mg/m^3 · 1 s · 365/525 600 s. The daily time profile would illustrate the person's *acute exposure*; the 1-year time profile would illustrate the person's *chronic exposure*. The person's behaviours regarding consumption of vitamin pills would be the relevant *activity pattern data* for this example.

4.4 Ingestion exposure to lycopene in tomatoes

Additives, nutrients, and chemical residues in food items can be treated in a similar way. Consider the ingestion exposure to lycopene from consumption of a tomato. In this case, lycopene is the *agent*. The *contact volume* is the volume of the tomatoes consumed. *Exposure* occurs when the tomatoes cross the *exposure surface* in front of the mouth in the same way as it does in the vitamin pill example. As lycopene would be absorbed from the gastrointestinal tract, one could define the exposure surface of interest as the epithelium of the gastrointestinal tract, an *absorption barrier*. The concentration of lycopene at the surface of the gastrointestinal tract could be considered as a function of time (or the integrated concentration over time) at any given point. This exposure would be similar to that in the example of dermal exposure, rising from zero to a maximum, followed by a decline back to zero as a result of absorption or passage with other materials out of the gastrointestinal tract via excretion.

It is impractical to measure the concentration of lycopene as it passes through the body and is metabolized or eliminated. Typically, the concentration of lycopene in consumed foods would be measured, and the intake of those foods would be combined with the measured concentrations in each food type to estimate exposure.

There are a number of techniques for estimating exposure to ingredients such as lycopene in a tomato product, additives such as a high-intensity sweetener in a beverage, or contaminants

such as methylmercury in fish. Market basket studies and duplicate-diet studies provide information concerning the level of the substances in foods. In the duplicate-diet approach, for example, a second helping of all the food items a person eats at a given meal is prepared and submitted for laboratory analysis. Then the pollutant concentration in each food item or composites of several food items is measured, and the person's intake dose is estimated by multiplying the pollutant concentration by the quantity of each food item that the person eats. This practical method for estimating dose from ingestion is useful in many applications, and it is consistent with the Zartarian et al. (1997) conceptual framework inherent in the IPCS glossary.

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ANNEX 1
GLOSSARIES OF EXPOSURE ASSESSMENT TERMS

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