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

30-Oct-2003

English - Or. English

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

DESCRIPTIONS OF SELECTED KEY GENERIC TERMS USED IN CHEMICAL HAZARD/RISK ASSESSMENT

OECD SERIES ON TESTING AND ASSESSMENT
Number 44

JT00152557

ENV/JM/MONO(2003)15
Unclassified

English - Or. English

OECD Environment, Health and Safety Publications

Series on Testing and Assessment

No.44

DESCRIPTIONS OF SELECTED KEY GENERIC TERMS USED IN CHEMICAL HAZARD/RISK ASSESSMENT

Joint Project with IPCS
on the Harmonisation of Hazard/Risk Assessment Terminology

October 2003

Also published in the Series on Testing and Assessment:

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

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

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

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

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

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

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

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

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

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

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

No. 12, *Detailed Review Document on Classification Systems for Germ Cell Mutagenicity in OECD Member Countries (1998)*

No. 13, *Detailed Review Document on Classification Systems for Sensitising Substances in OECD Member Countries 1998)*

No. 14, *Detailed Review Document on Classification Systems for Eye Irritation/Corrosion in OECD Member Countries (1998)*

No. 15, *Detailed Review Document on Classification Systems for Reproductive Toxicity in OECD Member Countries (1998)*

No. 16, *Detailed Review Document on Classification Systems for Skin Irritation/Corrosion in OECD Member Countries (1998)*

No. 17, *Environmental Exposure Assessment Strategies for Existing Industrial Chemicals in OECD Member Countries (1999)*

No. 18, *Report of the OECD Workshop on Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals (2000)*

No. 19, *Draft Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals used in Safety Evaluation (1999)*

No. 20, *Revised Draft Guidance Document for Neurotoxicity Testing (in preparation)*

No. 21, *Detailed Review Paper: Appraisal of Test Methods for Sex Hormone Disrupting Chemicals (2000)*

No. 22, *Guidance Document for the Performance of Out-door Monolith Lysimeter Studies (2000)*

No. 23, *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (2000)*

No. 24, *Guidance Document on Acute Oral Toxicity Testing (2001)*

No. 25, *Detailed Review Document on Hazard Classification Systems for Specifics Target Organ Systemic Toxicity Repeated Exposure in OECD Member Countries (2001)*

No. 26, *Revised Analysis of Responses Received from Member Countries to the Questionnaire on Regulatory Acute Toxicity Data Needs (2001)*

No 27, *Guidance Document on the Use of the Harmonised System for the Classification of Chemicals Which are Hazardous for the Aquatic Environment (2001)*

No 28, *Guidance Document for the Conduct of Skin Absorption Studies (2004)*

No 29, *Draft Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media (2001)*

No 30, *Detailed Review Document on Hazard Classification Systems for Mixtures (2001)*

No 31, *Detailed Review Paper on Non-Genotoxic Carcinogens Detection: The Performance of In-Vitro Cell Transformation Assays(draft)*

No. 32, *Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies (2000)*

No. 33, *Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures(2001)*

No. 34, *Guidance Document on the Development, Validation and Regulatory Acceptance of New and Updated Internationally Acceptable Test Methods in Hazard Assessment (in preparation)*

No. 35, *Guidance notes for analysis and evaluation of chronic toxicity and carcinogenicity studies (2002)*

No. 36, *Report of the OECD/UNEP Workshop on the use of Multimedia Models for estimating overall Environmental Presistence and long range Transport in the context of PBTS/POPS Assessment (2002)*

No. 37, *Detailed Review Document on Classification Systems for Substances Which Pose an Aspiration Hazard (2002)*

No. 38, *Detailed Background Review of the Uterotrophic Assay Summary of the Available Literature in Support of the Project of the OECD Task Force on Endocrine Disrupters Testing and Assessment (EDTA) to Standardise and Validate the Uterotrophic Assay (2003)*

No. 39, *Guidance Document on Acute Inhalation Toxicity Testing (in preparation)*

No. 40, *Detailed Review Document on Classification in OECD Member Countries of Substances and Mixtures Which Cause Respiratory Tract Irritation and Corrosion (2003)*

No. 41, *Detailed Review Document on Classification in OECD Member Countries of Substances and Mixtures which in Contact with Water Release Toxic Gases (2003)*

No. 42, *Draft Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure (in preparation)*

No. 43, *Draft Guidance Document on Reproductive Toxicity Testing and Assessment (in preparation)*

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised Committees and subsidiary groups composed of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

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

More information about the Environment, Health and Safety Programme and its publications (including the Test Guidelines) is available on the OECD's World Wide Web site http://www.oecd.org/ehs/.

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

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

TABLE OF CONTENTS

BACKGROUND

1. Over the past decades OECD and IPCS, as well as many other international organisations and Programmes, have been faced with the problem of misunderstandings concerning terms used in environmental health. The main reason for this problem is the interdisciplinary character of environmental health, and the fact that each of the disciplines developed within their own frameworks a specific "language culture". Due to the lack of an internationally agreed upon glossary of environmental health terms, almost every single programme/project has developed for practical reasons its own "working terminology".

2. 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 OECD, IPCS and others), inconsistencies in the definitions and use of many of these terms still exist. For example, inconsistencies were recognised 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 an developmental toxicity, carcinogenicity). IPCS, through its various activities and, in particular, through its project on Harmonisation Approaches to the Assessment of Risk from Exposure to Chemicals, has also identified the development and consistent use of terminology as a priority area.

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

OBJECTIVE

4. The objective of this joint OECD/IPCS project is to develop internationally harmonised 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.

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

CONTEXT

6. This project was focused on the harmonisation of terms used in the hazard/risk assessment of chemicals (including pesticides) to be used in the context of chemicals management (i.e. notification, registration, classification, etc.)

SCOPE

7. The project covers two categories of terms:

Generic Terms: general terms used in the process of determining hazard and risk. This publication 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 tumors and other pathological lesions and technical terms used in hazard characterisation (e.g. teratogenicity). Technical terms are published separately, as they are developed.

APPROACH OF THE WORK

8. The project is being carried out in a step-wise fashion beginning with the generic terms as described below:

Generic Terms:

9. OECD and IPCS, in consultation with other organisations from the Inter-Organization for the Sound Management of Chemicals (IOMC), first developed a list of terms and identified "key documents and sources" from which definitions were extracted. Note that in this context, "key documents /sources" were those that have regulatory implications (e.g. European Community Directives, US EPA documents) or are widely used and cited. The terms have been divided into "higher" and "lower" priority.

10. Next, 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 organisations) for review and preference. Responders 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

11. The comments and suggestions received were subsequently critically analysed by an OECD/IPCS Terminology Planning Working Group.

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

13. The OECD/IPCS Terminolgy Planning Group and WHO terminology experts critically analysed the survey results during two successive meetings in Carshalton, UK 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 Group are described in Annex 4. After several commenting rounds the OECD and IPCS secretariats jointly edited the most recent proposal of the Terminology Planning 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 Planning Group's proposal to improve consistency,

comprehensibility and coherence of the description of related terms. This version was submitted to the OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology for final review and declassification, and also to the Core Group of the IPCS Harmonisation Steering Committee for final review. A number of small, 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.

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

15. The alphabetical list of selected generic terms in hazard and risk assessment and their descriptions are provided in the table below, followed by a compilation of remarks and background notes to each of the terms included in this overview.

Technical Terms:

16. Once the work on the generic terms was well underway, work on the technical terms was also initiated. OECD and IPCS have started to identify:

- those areas which should be included (divide technical terms into broad areas such as reproductive toxicity, genetic toxicity, etc.)
- other key organizations that should be involved (e.g. academia, government, and industry).

17. Considering the amount of work involved in this exercise, and its high priority, the initial focus is on the harmonisation of terms used in human health hazard/risk assessment. Input is sought from international scientific societies to assist with the technical description of technical terms.

ALPHABETICAL LIST OF SELECTED 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 an individual in a (sub) population may be exposed daily over its lifetime 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 on 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 Endpoint	Qualitative/Quantitative 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.
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	Total amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population.
Dose-Effect Relationship	Relationship between the total amount of an agent administered to, taken up 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 or absorbed by that organism, system or (sub) population.
Dose Response	Relationship between the amount of an agent administered to, taken up 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 Term: *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 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 Characterisation, 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 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 Term: *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.
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	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	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	A set of conditions or assumptions about sources, exposure pathways, amount 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, which 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.
Hazard Characterization	The qualitative and, wherever possible, quantitative description of the inherent properties 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 Characterisation is the second stage in the process of Hazard Assessment, and the second step 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 as inherent capacity to cause in an organism, system or (sub) population. Hazard identification is the first stage in hazard assessment and the first step in the process of 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 the Margin of Safety has the same meaning as the Margin of Exposure, while for others, the Margin of Safety means the margin between the reference dose and the actual exposure dose or concentration. Related term: *Margin of Exposure*
Measurement Endpoint	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.
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 characterisation (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 Characterisation 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. It 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; 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.
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 that 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 which 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.

REMARKS AND BACKGROUND INFORMATION TO THE GENERIC TERMS

14. 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 analysis of survey responses.

Acceptable Daily Intake:

15. All definitions start with some expression of quantification; variants include *estimate of the amount* [1, 2], *estimate of the largest amount*, *estimate of the daily exposure dose*, *amount*, *maximum amount*. Definitions 7 and 8 focus on "*acceptable*" rather than the full term. The quantification is occasionally qualified by the use of such adjectives a *maximum, largest*.

16. 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 refers to *diet*.

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

18. The time factor is accounted for on a daily basis in all definitions except, with reference to accumulation during the lifetime of the person, except in Definition: (*over a lifetime*), *during lifetime*, and *during an entire lifetime*.

19. 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*.

20. Two respondents suggested to include reference to a *maximum* amount; two others indicated the need for the possible use of other time scales 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 exposures assessment mechanisms was essentially wrong. For those other exposures, another term had been coined as *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:

21. The only definition provided was rejected by the majority of respondents (58.1%). The relevance of the inclusion of the terms in the consensus list may even be questioned as only one definition was found in the 76 reference sources.

22. The main difficulty encountered by respondents focuses on the interpretation of "*acceptable*", which is considered more of socio-political than scientific significance, i.e. they "*relate more to risk management than to risk assessment*". Given the variety of socio-political environments in the world, a number of respondents suggest the term should be deleted from the scope of the hazard/risk assessment

terminology, either because it is not in use (varies regionally/internationally in meaning), not adequate for scientific work (too subjective), or too vague/broad in its formulation, except with reference to specific sets of regulatory instruments. Others suggest that the definition should be generalized to cover the field of socio-politics. It is found inappropriate in relation to environmental sciences.

23. 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:

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

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

26. Suggestions include the need to add specific references to "functions", "organ system", "lifestyles", "reproduction". Some indicate that it 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.*

27. 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:

28. 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 in its constituent parts, to capture their determinants and to characterize them as accurately as possible and necessary, in order to understand their relations. As suggests, it is essentially based on facts and figures (*quantified calculation*) and excludes judgement or interpretation ("*without taking any judgement*"...).

Assessment:

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

30. Definition 2 is selected only by three respondents. Many others comment 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.

31. *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.

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

33. 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; *{inference}* refers to conclusions that logically follow from the consideration of facts, at least from one particular view point. Respondents have suggested a number of synonyms: *analysis, calculation, evaluation, estimation, judgement*.

34. *Analysis* is not a valid synonym as it does not take into account of 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 Endpoint:

35. Only one definition is 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 choose the definition, and only 50% of the human health risk assessors. Other categories show a similar trend, only in smaller numbers.

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

37. Additional comments from respondents selecting the definition include essentially proposals for rewording or synonyms. Rewording proposals include *"[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." "A quantitative or quantifiable expression of the environmental value considered to be a risk in a risk assessment."*

38. Suggested synonyms: evaluation endpoint, estimation endpoint, assessment objective, critical effect, measurement endpoint, assessment calculation, effect parameter, test endpoint, response, 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:

39. Seventy percent of the respondents approve definition 1. Very few substantive comments are made by those who accept the definition. Synonyms are mentioned, which include, *safety factor, uncertainty factor, applicable factor, application factor, extrapolation factor, environmental assessment factor, adjustment factor, modifying factor, evaluation factor* and *estimation factor*.

40. Comments suggest that *assessment factor* could be a term specific to ecotoxicology, equivalent to *uncertainty factor* in toxicology. There are also several suggestions that the proposed definition as it stands is too restricted to environment and that some adjustment is require to ensure a more general applicability. In view of the many suggestions to ignore the term because it is unclear, it is suggested to keep it 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 which accommodates the observations made in the comments received.

Concentration:

41. 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; {*substance*} is used generically to designate anything which may be quantified in the context of a particular study and may therefore be considered as a chemical substance, or a compound, or biological or physical agent; {*given medium*} refers to the nature of the system in point, be it the human body, or air in the atmosphere.

42. 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.

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

Concentration-Effect Relationship:

44. Six definitions were collected for this term, and 46.7% of the respondents preferred Definition 1. The other five definitions refer to *dose* instead of *concentration* as the first factor in the relationship, which is a reason for rejection explicitly given by some respondents. Comments include: "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 include *dose-response relationship, dose-effect relationship, exposure-response relationship* and *concentration-response relationship*.

45. It should also be noted that some comments refer explicitly to "*concentration* <of a chemical> in the environment" (also called "*external concentration*"), other to "*biological tissue concentration* "(also called "*internal concentration*") to which an organism may be exposed. "*Exposure concentration*" is 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.

46. 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, taken 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:

47. 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 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.

48. One of the clearest definitions of *dose* reads "*total amount of a substance administered to, taken or absorbed by an organism*." (Duffus, 1993) In order to facilitate the comparison with the definition of compound terms, 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 measured the amount may be measured in g, mg or µg, or in mL or µL, and or in Bq), {*substance*} is used generically to designate anything which may be quantified in the context of a particular study and may therefore be considered as a chemical substance, or a compound, or a biological or physical agent. The {*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.

49. 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.

Dose-Effect Relationship:

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

51. Six definitions were listed in the survey. Four of those have been 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, 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.

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

Dose-Related Effect:

53. As *effect* has been 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.

54. In the survey, only one definition is proposed. It meets with the agreement of 89.4% of the respondents.

55. As pointed out by some rejecters, the wording in that definition is in contradiction with 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 note that the definition of the term itself should not necessarily refer to the magnitude of the effect or change, nor that the change need be of a biological nature, but could also be for instance a behaviourial change. Others, however, are of the opposite opinion.

56. From the comments, the following (quasi)-synonyms have been noted: *dose-response relationship* (5 cases), *dose-response* (7 cases), *compound-related effect* (1 case), *concentration-effect relationship* (1 case), *concentration-related effect* (1 case), *dose-effect relationship* (1 case), emphasizing once again the confusion between *dose* and *concentration*, on the one hand, and also between *effect*, *response*, and *relationship*.

Dose Response:

57. Only three definitions were found. Almost 47% of the respondents were pleased with Definition 1, and almost 28% with Definition 2. Rejecters of any of the listed definitions were quite numerous, with about 18% of the total.

58. The vast majority of the respondents who submitted comments suggest various wordings for new definitions that would include some reference to "relationship". Many claim 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, dose-response evaluation*.

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

60. *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 emphasised 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*").

61. Integrating the considerations on *effect* vs. *response*, 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 a dose of a chemical and the toxic effects produced by the chemical*" (Definition 3) keeps the perspective attached to the chemical rather than the target system.

62. 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:

63. Among the 10 definitions included in the survey, preferences can be aggregated in four groups, namely <5% (3 cases), 5-15% (4 cases) and more than 15% (3 cases) [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*. This had already been noted and

discussed under the respective head words. 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) would for instance prevent listing of synonyms built on the *dose-effect* base word.

64. 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 indicate that the concept "may involve extrapolation outside the experimental data range."

65. Finally, none of the three preferred definitions refers 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 except in two definitions chosen by the majority of respondents.

66. The following terms are cited as synonyms: *dose-response, effect assessment, effects assessment, toxicity assessment, dose-effect assessment, effects characterization, dose-response evaluation, dose-response estimation, toxicity test, 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, taken 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:

67. In the light of the conclusions drawn after analyzing the semantic elements of the base concepts involved, namely *dose* and *response*, equating "*degree of exposure to a substance*" with *dose*, confuses the issue, as it brings the additional concept *of exposure* into play. Also, the preferred definition 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 entering 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.

68. 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:

69. Preferences are quite uniformly distributed among the five definitions, ranging from almost 10% to 23.7%. Comments are 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*, which confirm the analysis given earlier.

70. 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, taken 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:

71. Rejecters of any of the proposed two definitions represent only 6% of the reference group. The remaining 94% are almost equally divided in two groups. Few substantive comments are 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 the ecology. In order to preserve the general applicability of the present term list, it is proposed to transfer the term to a more subject-specific section on the environment.

Effect:

72. The concept appears in the present study in contrast to *response*. Both are common language terms which enter into a series of combinations with other terms (collocates). Essentially, *effect* is analysed as follows: {*change*} {*caused by*} {*agent*} in {*a 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, or an organism, or an ecological system, for instance; {*change*} is any departure from previous state, condition or situation taken as reference; {*caused by*} stresses the causative link between the agent and the change.An *effect* therefore is an intrinsic capability of a causative agent which may affect a target system if and only if the potential materializes. This is noted by one of the contributors 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).*" (Leeuwen)

73. 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*".

Effect Assessment:

74. From the 9 definitions collected, [1, 3] stand out representing 40% of the preferences. Many respondents limit themselves to indicating synonyms: *dose-response, dose-response assessment, dose-effect assessment, toxicity assessment, hazard assessment, hazard characterization, hazard evaluation* and *hazard identification.*

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

Expert Judgement:

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

Exposure Assessment:

77. Ten out of 15 listed definitions for this term were selected by at least 5% of the respondents, ranging between 6.1% and 15.3%.

78. From the text of the definitions as well as from the rather scarce comments, a number of factors are 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, (specific) (human) population (or people)*. Depending on the source of the definitions, the agent is called *substance; pesticide; chemical; biochemical, chemical or physical agent; contaminant*.

79. 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 at shifts in perspectives on what may appear eventually to be a common understanding of the essence of the concept.

80. 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: 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; the assessment of the sources and sizes of releases and the dispersion patterns within the different media for an agent; or 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)*

81. 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 which had been identified as representative of the concept.

82. As indicated, the first one displays a health concern and the second one focuses in on engineering issues. Admittedly, they both refer to people, but a hypothetical one. 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} which [may] affect a {population}]*where *{quantitatively and qualitatively analysing}* refers to the wide range of analytical techniques such as actual measurement, modeling, 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, ecological system; *{inferring consequences}* refers to the second component of *assessment* as previously identified; *{population}* actually means either an organism or an individual person, or a group of them, considered as a hypothetical or as a true entity. Related to this term are *exposure scenario, margin of exposure* and *fate.*

Exposure Scenario:

83. The only two definitions proposed in the survey collected 58.4% and 36.8%, respectively. Comments are 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 more suited for environmental risk assessment.Essentially, they both contain a list of parameters which may be taken into account in order to carry out exposure assessment.

Fate:

84. Only three definitions were proposed: Definition 1 gathers some 52.6% of the preferences, Definitions 2 and 3 being similar except for one word collecting together 41.6%. 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:

85. The two proposed definitions are almost identical. 12% of the respondents reject them as imprecise, unknown, etc. It is also suggested to keep it short and replace the reference to *tolerable intake* with *reference dose*. A number of synonyms are mentioned, including *tolerance, guideline level, maximum residue limit, maximum acceptable concentration, threshold limit value, 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. Possibly, the term should be deleted from the list of generic terms, and be taken up in more specific subsets of the risk assessment terminology.

Harm:

86. Of the five proposed definitions, [3] collects 75% of the votes. There is a large consensus in the expressed opinions that it is a "simpler" word for ***adverse effect***. In view of the numerous general language connotations for the word, it is proposed to delete it from the final list.

Hazard:

87. *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 in 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.

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

89. 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*).

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

91. 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 No. 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 leukemia", 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 the author is interested in.

92. 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 base line generality of the initial statement, thus preserving at the same time harmonization and technical specificity.

Hazard Assessment:

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

94. Preferred definitions point at a variety of factors and variables which 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 at 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 and exposure assessment, estimation.*. In addition, Definition 3 provides a clear link to risk-related terminology ("*this is the prelude to risk assessment*").

95. There is strong rejection among respondents of any of the proposed definitions for the term (none of the above = 16.5%), and comments further indicate strong rejection of the term itself: "*not a good term*", "*confusing term*", "*not a necessary term*", etc. There are explicit comments pointing at a confusion between *hazard* and *risk*. A number of synonyms are mentioned: *risk estimation, effects assessment, hazard characterization, hazard evaluation, hazard identification, dose-response assessment, hazard analysis, risk characterization, risk assessment*.

96. Comments from respondents who chose one of the preferred definitions also give synonyms, in whole or in part: *risk assessment, hazard evaluation, hazard characterization, risk characterization and hazard identification*.

97. One comment provides useful insight in 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*" vs. "*the final phase of the risk-assessment process*". 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:

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

99. The synonyms mentioned by the respondents include *hazard assessment, hazard evaluation, hazard identification, risk characterization, hazard analysis, effect assessment and hazard evolution*. The variety of proposed synonyms emphasizes, as was already the case with *hazard identification,* the difficulty users face in dealing with unstable 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. This is visualized graphically on the conceptual graphs for hazard assessment and the entire system. It should be noted that the proposed concept 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:

100. The distribution of responses (about one third of responses each for Definition 1, Definition 2 and None-of-the-above) does not allow to draw final conclusions based on preferences. Comments are very scarce. Two respondents preferring Definition 2 re-emphasize the relation between hazard and benefit. Most rejecters of any of the proposed definitions mention other terms which they consider synonymous: *hazard assessment, hazard characterization, hazard identification, hazard analysis, risk evaluation, risk assessment and effect assessment*.

101. 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*.

Hazard Identification:

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

103. 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. Keeping in mind the concept definition of hazard, the preferred definition as it stands is circular.

104. Comments confirm the need to ensure consistency of the definition with that of *hazard*. Beyond that, several comments stress 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*", "*studies concluded under specific conditions*", thus emphasizing the need to consider *hazard identification* also in the broader context of the entire process of *risk assessment.*

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

106. 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 risk characterization*), it follows logically that the *hazard assessment* cluster can be further analyzed, 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:

107. 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 used instead of EEC.

Margin of Safety:

108. From among the six definitions proposed in the survey, two (Definitions 1 and 6) have the preference of 50% of the respondents (22.7% and 28%, respectively).

109. The majority of definitions include a reference to no-observed-adverse-effect level (NOAEL), and are mostly presented as formulae. 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 tend to concur that the term is obsolete, particularly due to a possible misleading reference to safety (see safety).

110. In view of the technical (i.e. more mathematical than discursive) nature of most definitions for this term, it is suggested to use it as a subject-field specific term rather than a generic term. **Note**: "margin of exposure" has the same meaning as "margin of safety", margin of exposure is preferred.

Measurement Endpoint:

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

112. Rejecters claim 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, it appears that the only proposed definition may be kept as it is but that the term could be set aside for subject-specific developments of the glossary.

Reference Dose:

113. 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/day.

114. Commentators insist that any definition should be generalized for any exposure route. It is used in certain legal frameworks to mean *acceptable daily intake*. Looking at the definition arrived at for that term, *reference dose* contains the same semantic components.

115. Indications that the *reference dose* is derived from the NOAEL and LOAEL and other specific details of technical relevance may be reserved for subject-field specific definitions, rather than for generic definitions.

Response:

116. *Response*, on the contrary, shifts the emphasis on the recipient system rather than the causative agent. The constitutive elements of the concept can be expressed as follows:{*change*} {*developed by*} {*a system*} {*as a consequence*} of {*agent*}.

Risk:

117. The survey included 22 different definitions. The highest score for any definition goes to definitions 3 and 22, with 12% each. The number of definitions available in the literature as well as the spread of choices among them seems 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. It should also be noted that definitions emanating from international sources (FAO, ALINORM and WHO/PEP) have not been chosen at all by any of the respondents.

118. 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]; *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 [20] as *quantitative probability*.

119. 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*.

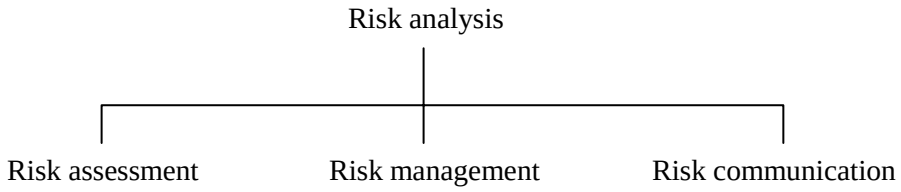
120. The object to which *risk* applies is quoted as *man*, *the environment*, *a biological or other system*. Comments emphasize the absolute need to distinguish between *hazard* and *risk* which, it is said, are often

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 is 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 which are of more particular concern to the risk assessors; clearly it points at an interaction on the system rather than at an intrinsic property of the agent; {*system*} represents any set of interrelated elements that, from a particular view point, function as a whole. It may be realized as an organism, a person, a population, an ecological system, etc.; {*cause*} 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 system concerned in an exhaustive manner, nor to generalize the features of, and conditions applicable to, agents.

Risk Analysis:

121. Only 14.5% of the respondents prefer Definition 1. Some 67% do select Definitions 2 or 3, which are identical but from different sources.

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



123. This situation, however, is confusing to many users. A numbers of rejecters of the term consider 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 earlier discussions of action collocates such as *analysis* and *assessment*. Since we have seen that *{assessment}* includes *{analysis} + {inference}*, then *{analysis}* cannot include, i.e., *{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 one with decision-making objectives comprising the sequentially related concept of *risk assessment*, *risk management*, and *risk communication*.

Risk Assessment:

124. *Risk assessment* is the first of three components of *risk analysis*. Six definitions have attracted at least 5% of the responses each, and account together for 73.7% of all responses. A stronger preference is marked for Definition 1 (38.1%) and to a lesser extent Definition 2 (11.3%). The other four score between 5% and 10%.

125. 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. Some of them also appear in the less chosen definitions, as well as in comments.

126. One respondent equates *dose-response assessment* with *hazard characterization* which, combined with *hazard identification*, should constitute *hazard assessment*. Several comments point at 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* includes *risk analysis, risk characterization, risk estimation* and *risk evaluation*.

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

128. 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.

129. Analytically, and in order to ensure a close monitoring of a process which is intended to protect individuals and populations against serious health risks, the process may be subdivided into four smaller parts, as tabulated above. 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, *{specific risk}* means the risk associated with a specific agent.

130. From the analysis of the various steps involved, it appears that the risk measured in the process is closely related to the intrinsic properties for 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 above table displays 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*, *risk characterization*, the second is mostly referred to as *exposure assessment*.

Risk Characterization:

131. Eight of the 16 listed definitions have collected at least 5% of the responses each. Together they represent 73.7% of all responses. Moreover, four of the preferred definitions stand out with around 13% each.

132. In 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*.

133. 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 *"risk estimation"*) and the "*strengths and weaknesses of those estimates*" (also called "*attendant uncertainties*").

134. Some commentators point again at 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*"*.

135. 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*.

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

137. 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:

138. 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 is offered, however, either in favour or against it. It is suggested to include the interactivity explicitly, as it is an intrinsic component of exchange.

Risk Estimation:

139. 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.

140. Each of the six proposed definitions has gathered more than 5% of the responses for this term. There is however a strong prevalence for Definition 1 (35.1%) and Definition 2 (17.3%). In spite of different wordings, they 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:

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

142. To some, integrating risk-benefit considerations suggests that the term relates more to *risk management*. Others, more numerous, support the view that the term is in fact synonymous to a series of more familiar terms: *risk assessment, risk characterization, risk estimation, risk management*. Supporters of either Definition 1 or 2 also mention the same synonyms, but to a much lesser extent: *risk assessment, risk-benefit analysis, risk estimation, risk characterization.*

143. In the previous analysis of *risk assessment*, there was no mention of a risk-benefit relationship. Since the vast majority of respondents do consider 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 consider it an intermediary step after *risk assessment* in the *risk analysis* process. A logical link would thus be established also with such term as *acceptable risk.*

Risk Identification:

144. Some 65% of the respondents selected the only definition proposed in the survey. They make no comment, cite no synonyms. Rejecters recommend to use *hazard identification*. As it is, the term is almost not used in the comments concerning the entire concept system. For lack of evidence, it is suggested to leave the term aside for the present purpose.

Risk Management:

145. Of the 16 definitions collected for the survey, only six have been selected by at least 5% of the respondents, with a strong lead for Definition 5 (28.6%).

146. 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, in order to weigh policy alternatives in response to it.

147. 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.

148. 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 is little controversy about that in the comments received.

Risk Monitoring:

149. Definition 1 (of 2) was preferred by almost 70% of the respondents. Comments are very scarce on either definition. Rejecters concur to find the term unnecessary or unknown to them. Considering the prevailing view expressed regarding the definition of *risk management*, it is logical to keep the term in the list as defined in the preferred definition.

Safety:

150. Six out of eight proposed definitions for *safety* have 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).

151. The preferred definitions point at a number of semantic elements which relate, reciprocally, to *risk*. The event is designated as *adverse effect* (or *injury*) caused by an *agent* (*material* [1], *substance* [2], *chemical substance* [3,6,8] under certain circumstances. As pointed out in the comments, the adverse effects need not be limited to health effects. It is 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*".

152. Most comments (almost exclusively from rejecters) stress the difficulty to use the term in practice. It is 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 is recommended to abandon the term 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 *safety margin*, but also to other concepts such as *uncertainty*, *uncertainty factor*, and to *acceptable risk* and *tolerable risk*, as well as *acceptable daily intake*.

Safety Factor:

153. All five options (four proposed definitions and none-of-above) collect a fair number of votes. In essence, a *safety factor* is considered a modifier of measured or estimated values in toxicological assessment practice. Comments indicate 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.

154. Constant reference is made to *no-observed-effect level (NOEL)* [1, 3, 4] or *no-effect level* [2], a concept that has not been mentioned anywhere else in the proposed list of generic terms. 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 in the calculation of the *acceptable daily intake* should also be taken into account in this respect.

155 Synonyms are mentioned as follows: *uncertainty factor*, *assessment factor*, *application factor*, *extrapolation factor*, *margin of safety*, *margin or exposure*, *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:

156. From the five listed definitions, four have been selected by a larger number of respondents. Scores range for those between 13.3% (No.4) and 34.7% (No.1). They all display the same semantic structure: *{dose}* (also called "exposure concentration", "exposure") below which *{effect}* is *{not expected to occur}*.

157. 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.

158. 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 suggests that *{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".

159. Preference for four out of five listed definitions range from 14% to 21.5%. Any definition is rejected by more than 22% of the respondents.

160. The term 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.

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

Tolerable Intake:

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

163. Many comments suggest that *tolerable daily intake* be used instead, or *tolerable weekly intake*. Other synonyms mentioned include *acceptable daily intake*, *reference dose*. In essence, two views are 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. 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:

164. Out of 10 different definitions, Nos. 2, 3, 4, are clear and simple and canvass more than 60% of the votes. No. 6 collects another 10% of the votes with a somewhat more complex definition. In the spirit of the present project, i.e. the production of simple, clear definitions of a generic nature, it is proposed to keep the simplest, with *chemical* replaced with *substance*, for consistency reasons.

Toxicity Assessment:

165. No clear opinion comes out of the responses to the survey. Until further evidence is collected, it is suggested to leave the term out of the glossary of generic terms.

Uncertainty:

166. 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*.

167. Definition 1 by itself is found suitable by 45% of the respondents. Comments are scarce, and mostly recommend the use of a general language definition. It seems the term cannot be spared, due to the specific preference expressed by the commentators on *safety*.

Uncertainty Factor:

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

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

170. A number of synonyms are mentioned in the comments, including *safety factor* and *assessment factor*. In view of the preference for *uncertainty factor* instead of safety factor, it is 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:

171. Almost 75% of the respondents adopt 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 characterisation /identification. This newer description is preferred.

ANNEX 1

LIST OF HIGH PRIORITY GENERIC TERMS INCLUDED IN THE NOVEMBER 1996 OECD/IPCS SURVEY`

—A—	—F—	—S—
acceptable daily intake	fate	safety factor
acceptable risk		
adverse effect	—G—	—T—
assessment	guidance value	tolerable daily intake
assessment endpoint		tolerable intake
assessment factor	—H—	toxicity
	hazard,	toxicity assessment
—C—	hazard assessment	
concentration-effect	hazard characterization	—U—
relationship	hazard evaluation	uncertainty,
	hazard identification	uncertainty factor
—D—		
dose-effect relationship	—M—	—V—
dose-related effect	margin of exposure	validation
dose-response	margin of safety	
dose-response assessment	measurement endpoint	
dose-response curve		
dose-response relationship	—R—	
	reference dose	
—E—	risk	
ecological risk assessment	risk analysis	
effect assessment	risk assessment	
expert judgment	risk characterization	
exposure assessment	risk communication	
exposure scenario	risk estimation	
	risk evaluation	
	risk identification	
	risk management	
	risk monitoring	

Note: Following the survey, the OECD/IPCS Terminology Planning Working Group agreed to add the following terms: “analysis”, “concentration”, “dose”, and “response” and delete the terms: “ecological”, “risk assessment”, “risk identification”, and “toxicity assessment”.

ANNEX 2

REFERENCES AND OTHER SOURCE DOCUMENTS OF DESCRIPTIONS OF HIGH PRIORITY TERMS

Codex 1995: Codex Alimentarious Commission (1995). Circular letter CL 1995/40-CAC.

Cohrssen 1989: Cohrssen J., Covello V. (1989). Risk analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks. U.S. Department of Commerce, Springfield, VA.

Duffus 1993: Duffus JH. (1993). Glossary for Chemists of Terms used in Toxicology. International Union of Pure and Applied Chemistry.

EC 1993: European Commission (1993). Commission Directive 93/67/EEC.

ECETOC 1982: European Chemical Industry Ecology and Toxicology Centre (1982). Risk assessment of occupational chemical carcinogens. Brussels.

FAO 1990: Food and Agricultural Organization of the United Nations (1990). International Code of Conduct on the Distribution and Use of Pesticides. FAO Conference. Rome.

FAO 1995: Food and Agricultural Organization of the United Nations (1995). Report of the Eighth Session of the Codex Committee on Residues of Veterinary Drugs in Foods – Washington 7-10 June 1994. ALINORM 95/31. Rome.

Guen 1995: Le Guen J (1995). Generic Terms and Concepts in the Assessment and Regulation of Industrial Risks. Health and Safety Executive. London, UK.

Holland 1996: Holland P. Glossary of terms relating to Pesticides (1996). International Union of Pure and Applied Chemistry.

IRPTC 1994: International Register of Potentially Toxic Chemicals (IRPTC) (1994). English-Russian Glossary of Selected Terms in Preventive Toxicology. [Russian]. Centre for International Projects, Moscow.

IRIS 1992: IRIS. (1992). Glossary of Risk assessment-related Terms. US Environmental Protection Agency Washington DC.

ISO 1990: International Organization for Standardization. (1990). Guidelines for the inclusion of safety aspects in standards. Guide 51. Geneva.

Jones 1992: Jones DA (Editor) (1992). Nomenclature for Hazard and Risk Assessment in the Process Industries. Institute of Chemical Engineers.

Last 1995: Last. J. (1995). Dictionary of Epidemiology, 3rd Edition. Oxford University Press. New York, Oxford, Toront.

Leeuwen 1996: van Leeuwen C., Hermens J. (1996).Risk Assessment of Chemicals – An Introduction . Kluwer Academic Publishers, Doordecht, Boston, London.

OECD 1992: Organisation for Economic Co-operation and Development (1992). Guiding Principles for Chemical Accident Prevention, Preparadness and Response. Guidance for public authorities, industry, labour and others. OECD Environment Monograph No. 51. Paris.

OECD 1995: Organisation for Economic Co-operation and Development (1995).Report of the OECD Workshop on Environmental Hazard/Risk Assessment. OECD Environment Monographs No. 105. Paris.

Pfaffin 1976: Pfaffin J, Ziegler A. (1976). Encyclopedia of Environmental Science and Engineering. New York.

Rand 1995: Rand G. (1995). Fundamentals of aquatic toxicology: Effects, environmental fate, and risk assessment. Taylor & Francis. London.

US-EPA 1992a: US Environmental Protection Agency (1992). Federal Register – Guidelines for exposure assessment; Notice.

US-EPA 1992b: US Environmental Protection Agency (1992). Framework for Ecological Risk Assessment. EPA/630/R-92/001, Washington DC.

US-EPA 1993: U.S. Environmental Protection Agency (1993). Terms of Environment – Glossary, Abbreviations and Acronyms. EPA 175-B-93-001. Washington DC.

USES 1994: Jager D., Visser C. (1994). Uniform System for the Evaluation of Substances (USES), version 1.0, Series No. 11144/150. Ministry of Housing, Spatial Planing and the Environment. Hague.

Vettorazzi 1980: Vettorazzi G. (1980). Handbook of international food regulatory toxicology – Vol. 1: Evaluations. Spectrum Publications Inc. New York.

WHO 1978: World Health Organization (1978). Provisional guidelines for health program evaluation. HPC/DEP/78.1. Geneva.

WHO 1979: World Health Organization. (1979). Agreed terms on Health Effects Evaluation and Risk and Hazard Assessment of Environmental Agents. WHO unpublished document EHE/EHC/79.19.*WHO Environmental Health Criteria Programme.* Geneva.

WHO 1987: World Health Organization (1987). Principles for the Safety Assessment of Food Additives and Contaminants in Food. WHO Environmental Health Criteria No. 70. Geneva.

WHO 1988: World Health Organization. (1988). Basic terminology for risk and health impact assessment and measurement. Internal report of a Working Group, 24-25 March. Geneva.

WHO 1989: World Health Organization. (1989). Control of Environmental Hazards – Assessment and management of Environmental Health Hazards. WHO/PEP/89.6, Recommendations of Working Group. Geneva.

WHO 1992: World Health Organization. (1992). Collaborating Centre for Training and Research in District Health Systems. Environment and "Health as a Sustainable State". Rome.

WHO 1993: Beaglehole R, Bonita R, and Kjellström T. (1993). Basic Epidemiology, World Health Organization, Geneva.

WHO 1994a: World Health Organization. (1994). Assessing Human Health Risks of Chemicals: Derivation of Guidance Values for Health-Based Exposure Limits. Environmental Health Criteria No. 170. International Programme on Chemical Safety. Geneva.

WHO 1994b: World Health Organization (1994). Healthy and productive lives in harmony with nature a WHO global strategy for health and environment. WHO/EHE/94.1. Geneva.

WHO 1996: World Health Organization (1996). Principles and Methods for Assessing Direct Immunotoxicity Associated with Exposure to Chemicals. WHO Environmental Health Criteria No. 180. Geneva.

WHO/FAO 1995: World Health Organization. (1995). Application of Risk Analysis to Food Standard Issues. Series WHO/FNU/FOS/95. *Joint FAO/WHO Expert Consultation*, Geneva.

WHO/IPCS 1989: World Health Organization (1989). Glossary of terms on chemical safety for use in IPCS publications. WHO/ICS/89.27. Geneva.

WHOTER: World Health Organization. Submitted by the WHO Technical terminology Service, TER. Geneva.

ANNEX 3

ORIGINAL SURVEY RESULTS

Summary of Respondents

The following table summarizes the areas of expertise of the respondents, as well as the region of the world where they live. It should be noted that there are some respondents who did not complete the personal profile survey, and therefore can not be included in this table and the summary tables which are presented for each of the terms in the 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 the summaries, and recorded in the "None Reported" category.

Summary of Respondents by Expertise and Country

Expertise	All	None	Asia	Africa	Europe	N. Amer.	L. Amer. Carib.	Aus/NZ
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 (see comment)	27	2	2	1	15	2	4	1
None listed	21	3	1		5	8	1	
TOTALS	186	8	13	4	99	39	9	11

Acceptable Daily Intake

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 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 1989)
5. The maximum amount of a chemical whose total daily intake during lifetime. (sic) (UNEP 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. 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). (WHO 1996)

Acceptable Risk

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Guen 1995)

Adverse Effect

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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	6	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. (Leeuwen 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. (USES 1994)

Definition (continued)

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. (WHO 1994a) (WHO 1996)

Assessment

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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). (Leeuwen 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 Endpoint

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (OECD 1995)

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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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)

Definition (continued)

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. (WHO 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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

Definitions

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. (WHO, 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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

Definitions

0. None of the below.
1. Situation in which the magnitude of a biological change is related to the dose. (Duffus 1993)

Dose-Response

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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 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. (WHO 1996)

Dose-Response Assessment

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 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. (USES 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 1989)
5. The determination of the relationship between the magnitude of exposure and the magnitude and/or frequency of adverse effects. (WHO/FAO 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 reponse 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 (Leeuwen 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 1989)

Definition (continued*)*

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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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 1989)

Dose-Response Relationship

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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
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. (WHO 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. (WHO 1979). Synonym(s) dose-response relationship, exposure-response relationship

Ecological Risk Assessment

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	Toxicology	Other	None Reported
0	12	6.4						1	1	1	3	1			1	4
1	83	44.4	1	0	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 actions(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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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 (Leeuwen 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. (Leeuwen 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. (USES 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 1989)
7. The determination of the relationship between the magnitude of exposure and the magnitude and/or frequency of adverse effects. (WHO/FAO 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 reponse 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 1989)

Expert Judgment

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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 1989)

Exposure Assessment

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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
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														
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. (WHOTER)
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. (Leeuwen 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. (USES 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 1989)
9. The qualitative and/or quantitative evaluation of the degree of intake likely to occur. (WHO/FAO 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. (WHOTER)
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) or exposure to a chemical substance or contaminants. (WHO 1996)

Exposure Scenario

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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 3 exposure in a given situation. (Cohrssen 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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 are derived after appropriate allocation of the TI among the different possible media of exposure. (WHO 1994a)

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. (WHO 1994a)

2. Value, such as concentrations in air or water, which are derived after appropriate allocation of the tolerable intake among the different possible media of exposure. (WHO 1996)

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. (WHO 1996)

Harm

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	Toxicology	Other	None Reported
0	10	5.1				1			1		1	3			1	3
1	4	2.0								1	1	2				
2		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. (Leeuwen 1996)
2. A function of the concentration to which an organism is exposed and the time of exposure. (Leeuwen 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. (Guen 1995)

Hazard

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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														
10	6	3.0							1	1	1	2			1	
11	6	3.0				1			1			3			1	
12		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														
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)

Definition (continued)

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. (USES 1994)
7. A source of risk that does not necessarily imply potential for occurrence. (Cohrssen 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/FAO 1995)
12. Chemical or physical agent or property that may cause a food to be unsafe for human consumption, or a defeat 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. (Guen 1995)
15. A source of danger; a qualitative term expressing the potential that an environmental agent can harm health. (WHO/IPCS 1989)
16. The likelihood that a chemical will cause adverse health effects (injury) under the conditions under which it is produced or used.
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 leukemia (WHO 1996)

Hazard Assessment

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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
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. (Leeuwen 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 (USES 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. (Leeuwen 1996)

Definition (continued)

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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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.

Definition (continued)

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

Hazard Evaluation

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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														
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								
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. (USES 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 1989)
6. The identification of known or potential health effects associated with a particular agent. (WHO/FAO 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. (WHOTER)

Definition (continued)

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. (WHOTER)
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 carcinogens assessments, the hazard identification phase of the risk assessment is also used to determine whether a particular agent of 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 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,noncarcinogens) or NEL(man,genotoxic carcinogens. (USES 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 1989)

Margin of Safety

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 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, noncarcinogens) or NEL(man, genotoxic carcinogens). (USES 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 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 Endpoint

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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														
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. (Leeuwen 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 1989)
5. The maximum amount of a chemical whose total daily intake during lifetime. (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 sub-groups) 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 factor 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) (WHO 1996)

Risk

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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														
15	2	1.0										1				1
16	3	1.5										3				
17		0.0														
18	5	2.5						1			2	1			1	
19	5	2.5				1					1	1			2	
20		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 form exposure to a physical or chemical agent may occur under specific conditions. (Last 1995)

Definition (continued)

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). (Leeuwen 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. (WHOTER)
9. The combination of a consequence and the probability of its occurrence. (OECD 1992)
10. The probability of a substance to cause adverse effects. (USES 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 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/FAO 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. (WHO 1996)

Risk Analysis

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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/FAO 1995)
3. A process consisting of three components: risk assessment, risk management and risk communication. (FAO 1995)

Risk Assessment

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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
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														
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 characterisation. (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. (Leeuwen 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)

Definition (continued)

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 characterisation. (USES 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 characterisation, (iii) exposure assessment, and (iv) risk characterisation. The definition includes quantitative risk assessment, which emphasises reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties. (WHO/FAO 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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
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. (Leeuwen 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. (USES 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 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 characterisation and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties. (WHO/FAO 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. (Leeuwen 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 (USES 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 likelyhood. (EC 1993)

Risk Communication

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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/FAO 1995)
4. An interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and stakeholders. (FAO 1995)

Risk Estimation

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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". (USES 1994)
4. Estimated risks where a degree of precision can be claimed. (HSE 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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														
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. (WHOTER)
2. This term covers (1) risk evaluation, (2) exposure control, and (3) risk monitoring. (WHOTER)
3. Interventions to control environmental factors, which adversely affect health and to prevent or limit environmental damage. (WHO 1994b)
4. The practical application and implementation of the risk assessment to meet specific goals and achieve safe use of a substance. (WHO/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. (Leeuwen 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 potentiel 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 regu latory options and to select the optimal regulatory response for safety from that hazard. (USES 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, minimise or reduce assessed risks and to select and implement appropriate options. (WHO/FAO 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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.

Definition (continued)

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. (USES 1994)
5. Practical certainty that a substance will not cause injury under carefully defined circumstances of use. (Cohrssen 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

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 1996)

Definition (continued)

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. (WHO 1987)

Threshold

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 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 1989)

Tolerable Daily Intake

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	Toxicology	Other	None Reported
0	39	22.7				1	1	1	2		5	13		1	4	11
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. (Leeuwen 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. (USES 1994)
5. An estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis (mg/kg or ug/kg of body weight), that can be ingested daily over a lifetime without appreciable health risk. (WHOTER)

Tolerable Intake

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (WHO 1994a)

Toxicity

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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	5.1					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. (Leeuwen 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)

Definition (continued)

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. (WHOTER)
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). (WHOTER)
8. The quality or degree of being poisonous or harmful to plant, animal, or human life. (Cohrssen 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. (WHO 1996)

Toxicity Assessment

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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 1989)
2. The estimation of the relationship between dose or concentration and the incidence and/or severity of an effect. (OECD 1995)

Definition (continued)

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. (Leeuwen 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. (USES 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. (cohrseen 1989)
6. The determination of the relationship between the magnitude of exposure and the magnitude and/or frequency of adverse effects. (WHO/FAO 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 reponse 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 (Leeuwen 1996)

Uncertainty

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 1996)
2. Uncertainty with respect to parameter values and model formulations of processes. (USES, 1994)
3. A felt state of imperfect knowledge where one may seek to increase the chances of successful action by improving available information. (Guen 1995)
4. Felt deficiency in knowledge relevant to forthcoming decisions of critical importance. (Guen 1995)

Uncertainty Factor

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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. (Leeuwen 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. (Holland 1996). For example an uncertainty factor is generally applied to the no-observed-effect level to derive an acceptable daily intake.
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 N0AEL 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. (WHOTER)
6. A product of several single factors by which the NOAEL or LOAEL of the critical effect is divided to derive a TI. (WHO 1994a)

Validation

Def.	All Respondents	Percentage	Chemistry	Pharmaceuticals	Ecological - Aquatic	Env. Science	Epidemiology	Occ. Health	Pesticides	Risk Ass. - General	Risk Ass. - Env.	Risk Ass. - Hum. Health	Risk Ass. - Meth.	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 HARMONISED DESCRIPTIONS OF GENERIC TERMS IN HAZARD AND RISK ASSESSMENT

The below is a reproduction of material which appeared in the draft report, for the purpose of providing more detailed information on the approach taken by the Terminology Planning Group. Readers will need to turn to the section on the report titled 'Approach to the work' for information on the process employed in finalising the draft report.

INTRODUCTION

1. The overall objective of this project is to harmonize 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 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 the International Programme on Chemical Safety (IPCS) and Organisation for Economic Co-operation and Development (OECD) to harmonize technical terms used in chemical hazard/risk assessment.

2. The current focus is on the harmonization of terms used by risk assessors in the hazard/risk assessment of chemicals (including pesticides) to be used 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 by 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.

3. 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

4. The principles of good practice in international terminology work has 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

5. 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

6. The IPCS and OECD, in consultation with the other 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

7. 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 350 definitions.

Survey

8. 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. Responders were asked to

a) identify or to provide their preferred definition for each term,

b) identify terms considered as synonyms, and

c) indicate whether any important key documents/sources were omitted.

9. Additional information on the individual responding was requested such as their area of expertise, years of experience with risk assessment, affiliation, etc. Responses were received from approximately 200 respondents from different countries, institutions and scientific disciplines.

Terminology Planing Working Group

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

11. The Workgroup 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 toward harmonizing this first set of generic terms.

Members of the planning group

Dr J. H. Duffus
Director, EdinTox
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
GB-London SE1 6LW

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

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

Dr N. Grandy
Environmental Directorate
OECD
2 rue Andre 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 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, Ohio 45241 , USA

Critical Analysis of Results

12. The Terminology Planning Workgroup agreed upon a mechanism for reaching consensus on the definitions. Using "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. Five such terms were added. It is hoped that these 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 analyzing 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).

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

Output

14. 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 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 definition 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, can be modified or enhanced as appropriate. Thus, it is hoped that these definitions be adopted as commonly used "root definitions" which can be built upon to suit the needs of specific disciplines.

ELEMENTS OF TERMINOLOGY

15. The set of generic terms under review clearly displays two kinds of terms. Alongside 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 on the other hand is more process- or action-oriented.

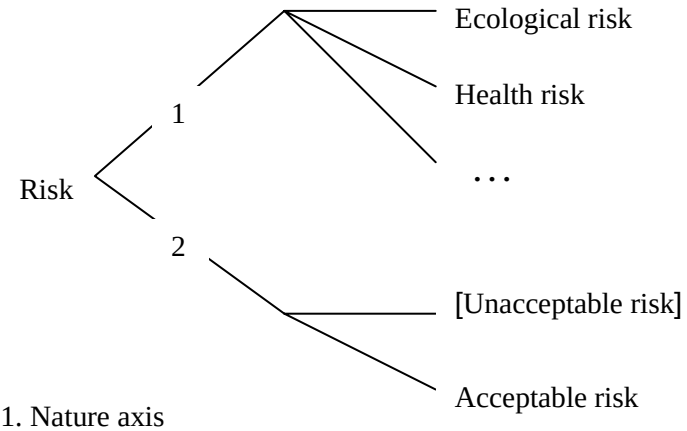
Data-oriented Terms

16. 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.

17. The advantage of such a representation is that is visualizes the relations between terms and points at apparent logical inconsistencies, which have to be further addressed in the course of the detailed analysis.

Concept System



1. Nature axis
2. Acceptability axis

18. 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

19. 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 call 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

20. All the verbs used to generate the collocations are normally used transitively. The bases in the combinations represent therefore 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 which do not involve action collocates, such as *safety factor*, etc.

21. The action collocates enter in combinations with a number of different bases. *Risk* is the most proliferous 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, risk monitoring.* There are only four combinations based on *hazard*: *hazard assessment, hazard characterization, hazard evaluation* and *hazard identification*.

22. 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 like *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.