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*.

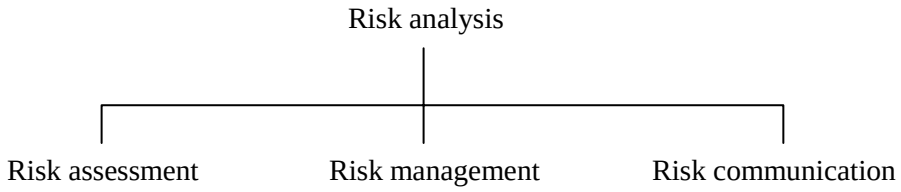
120. The object to which *risk* applies is quoted as *man*, *the environment*, *a biological or other system*. Comments emphasize the absolute need to distinguish between *hazard* and *risk* which, it is said, are often

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.