

ALPHABETICAL LIST OF SELECTED GENERIC TERMS IN HAZARD AND RISK ASSESSMENT AND THEIR DEFINITIONS

| <u>Term</u> | Description |
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| <u>Acceptable Daily Intake</u> | <p>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.</p> <p>Related terms: <i>Reference Dose, Tolerable Daily Intake</i></p> |
| <u>Acceptable Risk</u> | <p>This is a risk management terms. The acceptability of the risk depends on scientific data, social, economic, and political factors, and on the perceived benefits arising from exposure and probability of adverse effects to an agent.</p> |
| <u>Adverse Effect</u> | <p>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.</p> <p>Related terms: <i>Detrimental Effects</i></p> |
| <u>Analysis</u> | <p>Detailed examination of anything complex, made in order to understand its nature or to determine its essential features.</p> |
| <u>Assessment</u> | <p>Evaluation or appraisal of an analysis of facts and the inference of probable consequences concerning a particular object or process.</p> |
| <u>Assessment Endpoint</u> | <p>Qualitative/Quantitative expression of a specific factor with which a risk may be associated as determined through an appropriate risk assessment.</p> <p>Related terms: <i>ALARP (As Low As Reasonably Possible)</i></p> |
| <u>Assessment Factor</u> | <p>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.</p> <p>Related terms: <i>Safety Factor, Uncertainty Factor</i></p> |
| <u>Concentration</u> | <p>Amount of material or agent dispersed in unit quantity in a given medium or system.</p> |
| <u>Concentration-Effect Relationship</u> | <p>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 continuously-graded effect to that organism, system or (sub) population.</p> <p>Related terms: <i>Effect Assessment, Dose-Response Relationship</i></p> |

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| <u>Dose</u> | Total amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population. |
| <u>Dose-Effect Relationship</u> | <p>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.</p> <p>Related terms: <i>Effect Assessment, Dose-Response Relationship, Concentration-Effect Relationship</i></p> |
| <u>Dose-Related Effect</u> | Any effect or change to an organism, system or (sub) population as the result of the quantity of an agent administered to, taken up or absorbed by that organism, system or (sub) population. |
| <u>Dose Response</u> | <p>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.</p> <p>Related terms: <i>Dose-Effect Relationship, Effect Assessment, Concentration-Effect Relationship</i></p> |
| <u>Dose-Response Assessment</u> | <p>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 magnitude of 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.</p> <p>Dose-Response Assessment is the second of four steps in risk assessment.</p> <p>Related terms: <i>Hazard Characterisation, Dose-Effect Relationship, Effect Assessment, Dose-Response Relationship, Concentration-Effect Relationship</i></p> |
| <u>Dose-Response Curve</u> | Graphical presentation of a dose-response relationship. |
| <u>Dose-Response Relationship</u> | <p>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 changes developed in that organism, system or (sub) population in reaction to that agent.</p> <p>Related terms: <i>Dose-Effect Relationship, Effect Assessment, Concentration-Effect Relationship</i></p> |
| <u>Effect</u> | Change in the state or dynamics of an organism, system or (sub) population caused by the exposure to an agent. |
| <u>Effect Assessment</u> | Combination of analysis and inference of probable 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. |

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| <u>Expert Judgement</u> | Opinion of an authoritative person on a particular subject. |
| <u>Exposure</u> | Concentration or amount of a particular agent that reaches a target organism, system or (sub) population in a specific frequency for a defined duration. |
| <u>Exposure Assessment</u> | 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. |
| <u>Exposure Scenario</u> | 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. Related terms: <i>Exposure ???</i> |
| <u>Fate</u> | 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. |
| <u>Guidance Value</u> | 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 informed decisions. (See also: reference dose) |
| <u>Hazard</u> | Inherent property of an agent or situation having the potential to cause harm when an organism, system or (sub) population is exposed to that agent. |
| <u>Hazard Assessment</u> | A process designed to determine the probable adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed. (Often expressed as the probability of the adverse effect occurring). 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. |
| <u>Hazard Characterization</u> | 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 Characterization is the second stage in the process of hazard assessment, and the second step in risk assessment. Related terms: <i>Dose-Effect Relationship, Effect Assessment, Dose-Response Relationship, Concentration-Effect Relationship</i> |

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| <p><u>Hazard Identification</u></p> | <p>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.</p> <p>Hazard identification is the first stage in hazard assessment and the first step in the process of risk assessment.</p> |
| <p><u>Margin of Exposure</u></p> | <p>Ratio of the no-observed-adverse-effect level (NOAEL) for the critical effect to the theoretical, predicted or estimated exposure dose or concentration.</p> <p>Related term: <i>Margin of Safety</i></p> |
| <p><u>Margin of Safety</u></p> | <p>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.</p> <p>Related term: <i>Margin of Exposure</i></p> |
| <p><u>Measurement Endpoint</u></p> | <p>Measurable (ecological) characteristic that is related to the valued characteristic chosen as an assessment point.</p> |
| <p><u>Reference Dose</u></p> | <p>An estimate of the daily exposure dose that is likely to be without deleterious effect even if continued exposure occurs over a lifetime.</p> <p>A known dosage used to determine a standard set of effects against which other dose effects can be measured.</p> <p>Related term: <i>Acceptable Daily Intake</i></p> |
| <p><u>Response</u></p> | <p>Change developed in the state or dynamics of an organism, system or (sub) population in reaction to exposure to an agent.</p> |
| <p><u>Risk</u></p> | <p>The probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent.</p> |
| <p><u>Risk Analysis</u></p> | <p>A process for controlling situations where an organism, system or (sub) population could be exposed to a hazard.</p> <p>The risk analysis process consists of three components: risk assessment, risk management and risk communication.</p> |
| <p><u>Risk Assessment</u></p> | <p>A process intended to calculate or estimate the magnitude of 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.</p> <p>The risk assessment process includes four steps: hazard identification, hazard characterisation (related term: dose-response assessment), exposure assessment, and risk characterisation. It is the first component in a risk analysis process.</p> |

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| <p><u>Risk Characterization</u></p> | <p>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.</p> <p>Risk Characterization is the fourth step in the risk assessment process.</p> |
| <p><u>Risk Communication</u></p> | <p>Interactive exchange of information about (health and environmental) risks among risk assessors, managers, news media, interested groups and the general public.</p> |
| <p><u>Risk Estimation</u></p> | <p>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.</p> |
| <p><u>Risk Evaluation</u></p> | <p>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. This is often expressed in terms of the magnitude and probability of the occurrence of the adverse effect.</p> <p>It is an element of risk management. Risk evaluation is synonymous with risk-benefit evaluation.</p> |
| <p><u>Risk Management</u></p> | <p>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.</p> <p>Risk Management comprises three elements: Risk evaluation, emission and exposure control, risk monitoring. This would include mitigation and risk reduction of measures obtained through control and intervention.</p> |
| <p><u>Risk Monitoring</u></p> | <p>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.</p> <p>Risk Monitoring is an element of Risk Management.</p> |
| <p><u>Safety</u></p> | <p>Practical certainty that adverse effects will not result from exposure to an agent under defined circumstances. It is the reciprocal of risk.</p> |
| <p><u>Safety Factor</u></p> | <p>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.</p> <p>Related terms: <i>Assessment Factors, Uncertainty Factor</i></p> |
| <p><u>Threshold</u></p> | <p>Dose or exposure concentration of an agent below that a stated effect is not observed or expected to occur.</p> |

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| <u>Tolerable Daily Intake</u> | <p>Analogous to Acceptable Daily Intake.</p> <p>The term Tolerable is used for agents which are not deliberately added such as contaminants in food.</p> |
| <u>Tolerable Intake</u> | <p>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.</p> |
| <u>Toxicity</u> | <p>Inherent property of an agent to cause an adverse biological effect.</p> |
| <u>Uncertainty</u> | <p>Imperfect knowledge concerning the present or future state of an organism, system or (sub) population under consideration.</p> |
| <u>Uncertainty Factor</u> | <p>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.</p> <p>Related terms: <i>Assessment Factor, Safety Factor</i></p> |
| <u>Validation</u> | <p>Process by which the reliability and relevance of a particular approach, method, process or assessment is established for a defined purpose.</p> <p>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.</p> |