

APPENDIX 2

GLOSSARY OF TERMS

1. KEY TERMS

HAZARD: The potential of a risk source to cause an adverse effect (s)/event(s).

[Inherent property of an agent or situation capable of having adverse effects on something. Hence, the substance, agent, source of energy or situation having that property]

RISK: The probability and severity of an adverse effect /event occurring to man or the environment following exposure, under defined conditions, to a risk source(s).

[The probability of adverse effects caused under specified circumstances by an agent in an organism, a population or an ecological system]

RISK SOURCE: Agent, medium, commercial/industrial process, procedure or site with the potential to cause an adverse effect(s)/event(s)

RISK ANALYSIS: A process consisting of three components: risk assessment, risk management and risk communication.

[A process for controlling situations where populations or ecological systems could be exposed to a hazard. It usually comprises three steps, namely risk assessment, risk management and risk communication]

RISK ASSESSMENT: A process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect (s) /event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s). A risk assessment comprises hazard identification, hazard characterisation, exposure assessment and risk characterisation.

[A process intended to calculate or estimate the risk for a given target system following exposure to a particular substance, taking into account the inherent characteristics of a substance of concern as well as the characteristics of the specific target system. The process includes four steps: hazard identification, dose-response assessment, exposure assessment, risk characterisation]

HAZARD IDENTIFICATION: The identification of a risk source(s) capable of causing adverse effect(s)/event(s) to humans or the environment species, together with a qualitative description of the nature of these effect(s)/event(s).

[The first stage of risk assessment consisting in the determination of particular hazards a given target system may be exposed to, including attendant toxicity data. (Depending on the context, another definition emerged: the determination of substances of concern, the adverse effects they may inherently have on target systems under certain conditions of exposure, taking into account toxicity data)]

HAZARD CHARACTERISATION: The quantitative or semi-quantitative evaluation of the nature of the adverse health effects to humans and/or the environment following exposure to a risk source(s). This must, where possible, include a dose response assessment.

[The qualitative and, whenever possible, quantitative description of the nature of the hazard (alternative: of the nature of the possible adverse effects) associated with a biological, chemical or physical agent, based on one or more elements, such as

mechanisms of action involved, biological extrapolations, dose-response and dose-effect relationships, and their respective attendant uncertainties]

DOSE-RESPONSE ASSESSMENT: The determination of the relationship between the magnitude of exposure to risk source(s) [dose] and the magnitude or frequency and/or severity of associated adverse effect(s) [responses].

[The analysis of the relationship between the total amount of an agent absorbed by a group of organisms and the changes developed in it in reaction to the agent, and inferences derived from such an analysis with respect to the entire population]

EXPOSURE ASSESSMENT: The quantitative or semi-quantitative evaluation of the likely exposure of man and/or the environment to risk sources from one or more media.

[The quantitative and qualitative analysis of the presence of an agent (including its derivative) which may be present in a given environment and the inference of the possible consequences it may have for a given population of particular concern]

RISK CHARACTERISATION: The quantitative or semi-quantitative estimate, including attendant uncertainties, of the probability of occurrence and severity of adverse effect(s)/event(s) in a given population under defined exposure conditions based on hazard identification, hazard characterisation and exposure assessment.

[Integration of evidence, reasoning and conclusions collected in hazard identification, doseresponse assessment and exposure assessment and the estimation of the probability, including attendant uncertainties, of occurrence of an adverse effect if an agent is administered, taken or absorbed by a particular organism or population.

Or

The qualitative and/or quantitative estimation, including attendant uncertainties, of the severity and probability of occurrence of known and potential adverse effects of a substance in a given population]

The process of weighing policy alternatives in the light of the result of a risk assessment and other relevant evaluation and, if required, selecting and implementing appropriate control options (which should, where appropriate, include monitoring / surveillance).

[Decision-making process involving consideration 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 the optimal decisions and actions for safety from that hazard]

(N.B. Codex Alimentarius Commission, ALINORM 99/37 (report of the 23rd session of the CAC): the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other relevant factors relevant for the health protection of consumers and for the promotion of fair practices, and, if needed, selecting appropriate prevention and control options)

RISK COMMUNICATION: The interactive exchange of information and science based opinions concerning risk among risk assessors, risk managers, consumers and other actual or potential stakeholders.

[Interactive exchange of information about risks among risk assessors, managers, news media, interested groups and the general public] (N.B. Codex Alimentarius Commission, ALINORM 99/37 (report of the 23rd session of the CAC): the interactive exchange of information and opinions throughout the risk analysis process concerning

risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions)

2. OTHER TERMS USED IN THE REPORT :

Acceptable daily intake (ADI): an estimate of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60kg).

Accuracy^d : (i) the closeness of agreement between the "true" value and the measured values; (ii) the degree to which a measurement, or an estimate based on measurements, represents the true value of the attribute that is being measured.

Acute Reference Dose (Acute RfD)^e : the estimated amount of a substance in food or drinking-water, expressed on a body weight basis, that can be ingested over a short period of time, usually one meal or one day, without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation. It is usually expressed in milligrams of the chemical per kilogram of body weight.

Adverse effect^b : change in morphology, physiology, growth, development or life span of an organism which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to the harmful effects of other environmental influences. Decisions on whether or not any effect is adverse require expert judgement.

Benchmark dose (BMD)^b : the lower confidence limit of the dose calculated to be associated with a given incidence (eg 5 or 10% incidence) of effect estimated from all toxicity data on that effect within that study.

Biotransformation^d : a process in which a chemical is modified by a living organism.
Carcinogen^d : an agent, chemical, physical or biological, that can act on living tissue in such a way as to cause a malignant neoplasm.

Critical effect(s)^g : the adverse effect(s) that are relevant to human risk assessment and that occur at the lowest doses in the most sensitive animal species.

Default value^b : pragmatic, fixed or standard value used in the absence of relevant data.

Effect^d : a biological change in an organism, organ or tissue.

Exposure^d : the amount of an environmental agent that has reached the individual (external dose) or has been absorbed into the individual (internal dose, absorbed dose). In the document on quantitative risk assessment for toxic chemicals, exposure is taken to refer to the external dose.

^f concentration, amount or intensity of a particular agent that reaches a target system. It is usually expressed in numerical terms of substance, concentration, duration, frequency and intensity.

Health : a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity (World Health Organisation)

Incidence^d : the number of instances of illness commencing or of persons falling ill, during a given period in a specific population. Incidence is usually expressed as a rate, the denominator being the average number of persons in the specified population during a defined period or the estimated number of persons at the mid-point of that period. The basic distinction between incidence and prevalence is that whereas incidence refers only to new cases, prevalence refer to all cases, irrespective of whether they are new or old. When the terms incidence and prevalence are used, it should be stated clearly whether the data represent the numbers of instances of the disease recorded or the numbers of persons ill.

Intake^d : the amount of a substance or material that is taken into the body, regardless of whether or not it is absorbed. The daily intake may be expressed as the amount taken in by a particular exposure route, e.g. ingestion or inhalation. The daily intake from food is the total amount of a given substance taken in during one day through the consumption of food. The daily intake by inhalation is calculated by multiplying the concentration of the substance (or agent) in air by the total amount of air inhaled during one day (24 hours). The total daily intake is the sum of the daily intake by an individual from food, drinking-water, and inhaled air.

Lowest-observed-adverse-effect-level (LOAEL)^b : lowest concentration or amount of a substance, found by experiment or observation, which causes an adverse alteration of morphology, functional capacity, growth, development or life span of the target organism distinguishable from normal (control) organisms of the same species and strain under the same defined conditions of exposure.

Maximum tolerated dose (MTD)^a : a term in common use in carcinogenicity testing meaning a dose that does not shorten life expectancy nor produce signs of toxicity other than those due to cancer. Operationally, the MTD has been set as the maximum dose level at which a substance induces a decrement in weight gain of no greater than 10% in a subchronic toxicity test.

Mutagen^d : an agent that induces mutation.

Mutagenicity^d : the property of a physical, chemical, or biological agent to induce mutations in living tissue.

Mutation^d : any heritable change in genetic material. This may be a chemical transformation of an individual gene (a gene or point mutation), which alters its function. On the other hand, this change may involve a rearrangement, or a gain or loss of part of a chromosome, which may be microscopically visible. This is designated a chromosomal mutation.

No-observed-effect-level (NOEL)^a : the greatest concentration or amount of a chemical, found by experiment or observation, that causes no detectable adverse alteration of morphology, functional capacity, growth, development, or life span of the target.

No-observed-adverse-effect level (NOAEL)^b : greatest concentration or amount of a substance found by experiment or observation, which causes no detectable adverse alteration of morphology, functional capacity, growth, development or life span of the target organism under defined conditions of exposure. Alterations of morphology, functional capacity, growth, development or life span of the target may be detected which are judged not to be adverse.

Precision^d : the closeness of agreement between the results obtained by applying the experimental procedure several times under prescribed conditions.

Quantal effect^d : an effect that can be expressed only as "occurring" or "not occurring". Typical examples of quantal effects are death or occurrence of a tumour.

Reference Dose (RfD) [term used in certain contexts, e.g. in US EPA's non-cancer health risk assessments] : an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used.

Response d : the proportion of an exposed population with an effect or the proportion of a group of individuals that demonstrate a defined effect in a given time.

Risk estimation :^d the quantification of dose-effect and dose-response relationships for a given environmental agent, showing the probability and nature of the health effects of exposure to the agent.

^f quantification of the probability, including attendant uncertainties, that a chemical, physical or biological agent administered, taken or absorbed by a system will have a specific effect, based on hazard identification, dose-response assessment and exposure assessment for that particular agent in relation to that particular system.

Risk evaluation :^d the comparison of calculated risks of exposure to a given agent with the risks caused by other agents or societal factors and with the benefits associated with the agent.

^f establishment of a qualitative or quantitative relationship between risks and benefits, involving the complex process of determining the significance of the identified hazards and estimated risks to those organisms or people concerned with or affected by them. It is the first step in risk management.

Note: in the report of the Joint FAO/WHO Consultation, Rome, Italy, 27-31 January 1997, Risk Management and Food Safety (FAO Food and Nutrition Paper n°65), the term "risk evaluation" is applied to a grouping of steps in risk management which includes identification of a food safety problem, establishment of a risk profile, ranking of the hazards, establishment of a risk assessment policy, commissioning of risk assessment, and consideration of risk assessment results (see part 1, table 3.1).

Risk perception : the attitudes and intuitive judgements about risk (Slovic, P. 1992. Perception of risk: reflections on the psychometric paradigm. In S. Krimsky and D. Golding (Ed) Social Theories of Risk. Praeger, Westport, Con.)

Safety (of a drug or other chemical substance for human health)^d : the extent to which a chemical substance may be used in the amounts necessary for intended purposes with a minimum risk of adverse health effects.

Safety factor^a : a factor applied to the no-observed-effect level to derive an acceptable daily intake. The non-observed-effect level is divided by the safety factor to calculate the ADI. The value of the safety factor depends on the nature of the toxic effect, the size and type of population to be protected and the quality of the toxicological information available.

Sensitivity analysis : a method used to examine the behaviour of a model by measuring the variation in its outputs resulting from changes to its inputs (Codex Alimentarius, ALINORM 99/13A)

Target organ(s)^d : organ(s) in which the toxic injury manifests itself in terms of dysfunction or overt disease.

Threshold^f : dose of a substance or exposure concentration below which a stated effect is not observed or expected to occur.

g intake or dose below which homeostatic changes are able to reverse any adverse effects; or an intake or dose below which homeostatic change are unable to compensate; or an intake below which a stimulus ceases to be perceptible.

Toxicity^d : the capacity of a substance to cause injury to a living organism. A highly toxic substance will cause damage to an organism if administered in very small amounts and a substance of low toxicity will not produce an effect unless the amount is very large. However, toxicity cannot be defined in quantitative terms without reference to the quantity of substance administered or absorbed, the way in which this quantity is administered (e.g. inhalation, ingestion, injection) and distributed in time (e.g. single or repeated doses), the type and severity of injury, and the time needed to produce the injury.

Toxicodynamics^b : the process of interaction of chemical substances with target sites and the subsequent reactions leading to adverse effects.

Toxicokinetics^b : the process of the uptake of potentially toxic substances by the body, the biotransformation they undergo, the distribution of the substances and their metabolites in the tissues, and the elimination of the substances and their metabolites from the body. Both the amounts and the concentrations of the substances and their metabolites are studied. The term has essentially the same meaning as pharmacokinetics, but the latter term should be restricted to the study of pharmaceutical substances.

Uncertainty analysis : a method used to estimate the uncertainty associated with model inputs, assumptions and structure/form. (Codex Alimentarius, ALINORM 99/13A)

Uncertainty factor (UF)^b : a product of several single factors by which the NOAEL or LOAEL of the critical effect is divided to derive a TI [Tolerable Intake]. These factors account for adequacy of the pivotal study, interspecies extrapolation, interindividual

variability in humans, adequacy of the overall data base, and nature of toxicity. The term uncertainty factor was considered to be a more appropriate expression than safety factor since it avoids the notion of absolute safety and because the size of this factor is proportional to the magnitude of uncertainty rather than safety. The choice of UF should be based on the available scientific evidence.

Sources :

(Unless otherwise specified)

a = Principles for the Safety Assessment of Food Additives and Contaminants in Food. Environmental Health Criteria 70, World Health Organization, Geneva 1987.

b = Assessing Human Health Risks of Chemicals: Derivation of Guidance Values for Health-based Exposure Limits. Environmental Health Criteria 170, World Health Organization, Geneva 1994.

c = Principles for the Assessment of Risks to Human Health from Exposure to Chemicals. Environmental Health Criteria 210, World Health Organization, Geneva 1999.

d = Glossary of terms on chemical safety for use in IPCS publications. World Health Organization, Geneva 1989.

e = Food consumption and exposure assessment of chemicals. Report of a FAO/WHO Consultation. Geneva, 10-14 February 1997. World Health Organisation, 1997. (WHO/FSF/FOS/97.5)

f = P. Lewalle. Risk Assessment Terminology. Methodological considerations and provisional results. Report on a WHO experiment. Terminology Standardization and Harmonization, Volume II (1999), n° 1-4

g = suggested for the report