Vědecký výbor pro potraviny

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Název dokumentu:

Slovníček pojmů používaných v oblasti hodnocení rizika a hodnocení expozice (IPCS) & Glossary of terms used in Risk Assessment and Exposure assessment (IPCS)

Poznámka:

Slovníček určený pro odborníky obsahuje harmonizované pojmy (IPCS) pouze v angličtině.

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Preambule

Informace Výboru byla připravena v souladu s formální procedurou plynoucí z „Procedurálního manuálu Vědeckého výboru pro potraviny". Informace je přehledný nebo technický dokument, pokud není uvedeno jinak. Tato informace je určena pro odborníky pracující v oblasti hodnocení zdravotních rizik a speciálně v oblasti hodnocení dietární expozice. Připomínky a názory k tomuto dokumentu je možné zasílat na sekretariát Výboru.

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Právní odpovědnost

Podle článku 1, odstavec 2, Statutu, Výbor nemá právní subjektivitu. Jeho závěry a usnesení mají charakter doporučení a signálních informací pro členy a sekretariát KS. Výbor sám proto nenese právní odpovědnost za jakékoli škody způsobené jako důsledek použití jeho závěrů a usnesení.

Klíčová slova:

hodnocení rizika, hodnocení expozice, pojmy, slovník

Slovníček pojmů používaných v oblasti hodnocení rizika a hodnocení expozice (IPCS)

1.

Poslední dobou roste počet odborníků, kteří využívají systém analýzy rizika ve své práci. Po mnoha letech se tak i v oblasti hodnocení zdravotních rizik a speciálně hodnocení dietární expozice vyskytují skupiny odborníků, kteří využívají odbornou terminologii, avšak její význam v mnoha případech chápou odlišně ve srovnání s jinými skupinami odborníků. Vzniká tak potřeba průběžně harmonizovat odbornou terminologii, aby se jednotlivé skupiny navzájem domluvily a odborná stanoviska vyznívala shodně po formální stránce.

2.

Velký díl práce na tomto poli odvedly především mezinárodní organizace, včetně WHO, FAO, ILSI, IPCS, aj. V oblasti chemické bezpečnosti pak v poslední době vyniká především snaha IPCS o harmonizaci odborné terminologie.

3.

Následující slovníček pojmů v anglickém jazyce je extraktem tří dokumentů IPCS, které zahrnují přehled harmonizovaných pojmů v oblasti hodnocení rizik a hodnocení expozice. Následující tabulka zahrnuje zdroje, ze kterých byl slovníček pojmů vytvořen:

References	
1	IPCS Harmonization Project: *IPCS/OECD key generic terms used in chemical hazard/risk assessment.* In IPCS RISK ASSESSMENT TERMINOLOGY, World Health Organization, Geneva, 2004, p. 7 – 95, ISBN 92 4 156267 6
2	IPCS Harmonization Project: *IPCS glossary of key exposure assessment terminology* In IPCS RISK ASSESSMENT TERMINOLOGY, World Health Organization, Geneva, 2004, p. 95 - 111, ISBN 92 4 156267 6
3	Environmental Health Criteria XXX, PRINCIPLES FOR MODELLING DOSE-RESPONSE FOR THE RISK ASSESSMENT OF CHEMICALS, Draft prepared by the WHO TASK GROUP ON ENVIRONMENTAL HEALTH CRITERIA FOR PRINCIPLES FOR MODELLING DOSE-RESPONSE FOR THE RISK ASSESSMENT OF CHEMICALS , International Programme on Chemical Safety, World Health Organization, Geneva, February 2004

4.

Je zřejmé, že i tyto pojmy mohou podléhat určitým změnám ve výkladu v budoucnu. Jistě nejde o vyčerpávající přehled, ale níže uvedených cca 200 pojmů může významným způsobem pomoci i při komunikaci odborníků na národní úrovni.

5.

VVP je toho názoru, že v dané chvíli je vhodné ponechat pojmy bez překladu, pouze v jazyce anglickém, protože slovníček není určen pro širokou veřejnost, ale pro veřejnost odbornou, u které se předpokládá širší znalost problematiky a bezproblémový překlad významu do jazyka českého, pokud bude použit.

6.

Slovníček pojmů není chápán jako závazný, měl by jen pomoci odborníkům v orientaci a posloužit jako referenční zdroj informací pro další odbornou práci.

7.

Slovníček obsahuje pojmy tak, jak byly užívány k 1.6.2005. Termíny jsou řazeny abecedně, u každého je označena literatura, ze které byl pojem s výkladem převzat.

8.

Tato informace VVP volně navazuje na dřívější tuzemské publikace, které uváděly přehled odborných pojmů v oblasti hodnocení zdravotních rizik, např. Bláha,K.-Cikrt,M.: Základy hodnocení zdravotních rizik, SZÚ, 1996; Provazník,K.-Cikrt,M.-Komárek,L.-et al.: Manuál prevence v lékařské praxi: VIII. Základy hodnocení zdravotních rizik, NPZ, SZÚ, 2000.

Glossary of terms used
in Risk Assessment and Exposure assessment (according to the IPCS)

A-Z order   *Description of terms*   *Citations under the table.*

Term	Description	Reference
Absorption barrier	Any exposure surface that may retard the rate of penetration of an agent into a target. Examples of absorption barriers are the skin, respiratory tract lining, and gastrointestinal tract wall (see also *Exposure surface*).	2
Acceptable daily intake	Estimated maximum amount of an agent, expressed on a body mass basis, to which individuals in a (sub)population may be exposed daily over their lifetimes without appreciable health risk. Related terms: *Reference dose, Tolerable daily intake*	1
Acceptable risk	This is a risk management term. The acceptability of the risk depends on scientific data, social, economic, and political factors, and the perceived benefits arising from exposure to an agent.	1
Activity pattern data	Information on human activities used in exposure assessments. These may include a description of the activity, frequency of activity, duration spent performing the activity, and the microenvironment in which the activity occurs.	2
Acute exposure	A contact between an agent and a target occurring over a short time, generally less than a day. (Other terms, such as "short-term exposure" and "single dose," are also used.)	2
Additional Risk (Extra Risk)	The additional proportion of total animals that respond in the presence of the dose, or the probability of response at dose d, P(d), minus the probability of response in the absence of exposure, P(0).	3
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.	1
Agent	A chemical, biological, or physical entity that contacts a target.	2
Akaike Information Criteria	A statistical procedure that provides a measure of the goodnesso-fit of a dose-response model to a set of data.	3
Analysis	Detailed examination of anything complex, made in order to understand its nature or to determine its essential features.	1
Assessment	Evaluation or appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process.	1
Assessment end-point	Quantitative/qualitative expression of a specific factor with which a risk may be associated as determined through an appropriate risk assessment.	1
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*	1
Asymptotic Test	Statistical tests that approach known properties as sample sizes increase.	3
Background level	The amount of an agent in a medium (e.g., water, soil) that is not attributed to the source(s) under investigation in an exposure assessment. Background level(s) can be naturally occurring or the result of human activities. (Note: Natural background is the concentration of an agent in a medium that occurs naturally or is not the result of human activities.)	2
Benchmark Concentration (BMC)	The concentration of a substance that is associated with a specified low incidence of risk of a health effect, or the concentration associated with a specified measure or change of a biological effect.	3
Benchmark Dose (BMD)	An exposure due to a dose of a substance associated with a specified low incidence of risk, generally in the range of 1% to 10%, of a health effect; or the dose associated with a specified measure or change of a biological effect.	3
Benchmark Dose Lower Confidence Limit (BMDL)	A lower one-sided confidence limit on the BMD.	3
Benchmark Response (BMR)	The response, generally expressed as in excess of background, at which a benchmark dose or concentration is desired.	3
Bernoulli Distribution	A theoretical distribution of the number of successes in a finite set of independent trials with a constant probability of success. It is discrete distribution having two possible outcomes labelled by n = 0 and n = 1in which n = 1 ("success") occurs with probability p and n = 0 ("failure") occurs with probability q ≡ 1 - p, where 0 < p < 1.	3

| A-Z order | Description of terms | Citations under the table. |

Term	Description	Reference
Beta-Binomial Distribution	A statistical distribution of clustered values, e.g., measures on offspring in a litter, where the average proportions of an event for clusters are described by a 98 Beta distribution and the proportions of events in a cluster are described by a binomial distribution.	3
Binomial Distribution	The statistical distribution of the probabilities of observing 0,1,2,- - - ,n events in a sample of n independent trials each with the same individual probability that the event occurs.	3
Bioavailability	The rate and extent to which an agent can be absorbed by an organism and is available for metabolism or interaction with biologically significant receptors. Bioavailability involves both release from a medium (if present) and absorption by an organism.	2
Biomarker/biological marker	Indicator of changes or events in biological systems. Biological markers of exposure refer to cellular, biochemical, analytical, or molecular measures that are obtained from biological media such as tissues, cells, or fluids and are indicative of exposure to an agent.	2
Bootstrap	A statistical technique based on multiple re-sampling with replacement of the sample values or re-sampling of estimated distributions of the sample values that is used to calculate confidence limits or perform statistical tests for complex situations or where the distribution of an estimate or test statistic cannot be assumed.	3
Bounding estimate	An estimate of exposure, dose, or risk that is higher than that incurred by the person with the highest exposure, dose, or risk in the population being assessed. Bounding estimates are useful in developing statements that exposures, doses, or risks are "not greater than" the estimated value.	2
Cancer Potency (Cancer Slope Factor)	A number that estimates the cancer risk (incidence) for a lifetime exposure to a substance per unit of dose which is generally expressed as mg / kg body wt / day.	3
Categorical Data	Results obtained where observations or measurements on individuals or samples are stratified according to degree or severity of an effect, e.g., none, mild, moderate, or severe.	3
Categorical default factor	A factor based on common characteristics of a group of compounds, e.g., physical / chemical properties or pathways of metabolism.	3
Clustered Data	Measurements collected on some grouping of individuals, e.g., litters in reproductive and developmental studies.	3
Concentration	Amount of a material or agent dissolved or contained in unit quantity in a given medium or system.	1
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*	1
Confidence Interval (Two-Sided)	An estimated interval from the lower to upper confidence limit of an estimate of a parameter. This interval is expected to include the true value of the parameter with a specified confidence percentage, e.g., 95% of such intervals are expected to include the true values of the estimated parameters.	3
Confidence Interval (One-Sided)	An interval below the estimated upper confidence limit, or interval above the estimated lower confidence limit, that is expected to include the true value of an estimated parameter with a specified confidence (percent of the time).	3
Confidence Limit	An estimated value below (or above) which the true value of an estimated parameter is expected to lie for a specified percentage of such estimated limits.	3
Constrained Dose-Response Model	Estimates of one or more parameters of the model restricted to a specified range, e.g., equal to or greater than zero.	3
Contact volume	A volume containing the mass of agent that contacts the exposure surface.	2
Continuous Data	Effects Measured on a continuum, e.g., organ weight or enzyme concentration, as opposed to quantal or categorical data where effects are classified by assignment to a class.	3
Convergence	Estimates of a parameter approach a single value with increasing sample size or increasing number of computer iterations.	3
Convex	Region of a dose-response relationship that curves upward, i.e., the slope becomes steeper with increasing dose.	3
Correlated Binomial Distribution	Clustered data where the individual values in a cluster, e.g., a litter, each have the same probability of expressing an effect.	3
Covariate	An independent variable other than dose that may influence the outcome of an effect, e.g., age, body weight, or polymorphism.	3

| A-Z order | Description of terms | Citations under |

the table.

Term	Description	Reference
Critical effect	The adverse effect, or its known precursor, that is relevant to human risk assessment and that occurs in the dose/concentration scale in the most sensitive animal species.	3
Cubic	An effect is a function of a measure raised to the third power.	3
Default value	Pragmatic, fixed or standard value used in the absence of relevant data.	3
Degrees of Freedom	For dose-response model fitting, the number of data points minus the number of model parameters estimated from the data.	3
Delta Method	Variance of a function of random variables approximated from the derivatives of the function with respect to the random variables and the variances of the random variables.	3
Dichotomous Data	Quantal data where an effect for an individual may be classified by one of two possibilities, e.g., dead or alive, with or without a specific type of tumour.	3
Dispersion	Variation (differences) from a central (mean or median) value.	3
Dose (1)	Total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population. *1 This term is also contained in the list of IPCS key exposure assessment terminology (see Dose (2), Ref. 2); both definitions are consistent and interchangeable, depending on user preference.*	1
Dose (2)	The amount of agent that enters a target after crossing an exposure surface. If the exposure surface is an absorption barrier, the dose is an absorbed dose/uptake dose (see uptake); otherwise, it is an intake dose (see intake). (See introductory comments.) *1 This term is also contained in the list of IPCS/OECD key generic terms used in chemical hazard/risk assessment (see Dose (1), Ref. 1); both definitions are consistent and interchangeable, depending on user preference.*	2
Dose rate	Dose per unit time.	2
Dose-effect relationship	Relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the magnitude of a continuously graded effect to that organism, system, or (sub)population. Related terms: *Effect assessment, Dose–response relationship, Concentration–effect relationship*	1
Dose-related effect	Any effect to an organism, system, or (sub)population as a result of the quantity of an agent administered to, taken up by, or absorbed by that organism, system, or (sub)population.	1
Dose-response	Relationship between the amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the change developed in that organism, system, or (sub)population in reaction to the agent. Synonymous with *Dose–response relationship*. Related terms: *Dose–effect relationship, Effect assessment, Concentration–effect relationship*	1
Dose-response assessment	Analysis of the relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the changes developed in that organism, system, or (sub)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population. Dose–response assessment is the second of four steps in risk assessment. Related terms: *Hazard characterization, Dose–effect relationship, Effect assessment, Dose–response relationship, Concentration–effect relationship*	1
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.	3
Dose–response curve	Graphical presentation of a dose–response relationship.	1
Dose-Response Model	A mathematical relationship (function) that relates (predicts) a measure of an effect to a dose.	3
Dose–response relationship	Relationship between the amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the change developed in that organism, system, or (sub)population in reaction to the agent. Related terms: *Dose–effect relationship, Effect assessment, Concentration–effect relationship*	1
Dose-Response Trend	Relationship between incidence or severity of a biological effect and a function of dose. Simply the slope for a linear dose-response.	3
EDx	Effective dose associated with a biological effect in x% of the individuals. Dose may be the external exposure often expressed in mg per day of the substance per kg body weight raised to a power (generally 1, 3/4, or 2/3) or area under the curve (AUC) in blood or target tissue 20 where the substance remains in the body over a period of time.	3
Effect	Change in the state or dynamics of an organism, system, or (sub)population caused by the exposure to an agent.	1

Term	Description	Reference
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.	1
Estimate	An empirical value derived from data for a parameter.	3
Excess Risk	Proportion of individuals or animals observed or estimated to possess an effect in addition to the spontaneous background risk.	3
Expert judgement	Opinion of an authoritative person on a particular subject.	1
Exposure (1)	Concentration or amount of a particular agent that reaches a target organism, system, or (sub)population in a specific frequency for a defined duration. *1 This term is also contained in the list of IPCS key exposure assessment terminology (see also Exposure (2), Ref. 2); both definitions are consistent and interchangeable, depending on user preference.*	2
Exposure (2)	Contact between an agent and a target. Contact takes place at an exposure surface over an exposure period. *1 This term is also contained in the list of IPCS/OECD key generic terms used in chemical hazard/risk assessment (see also Exposure (1), Ref. 1); both definitions are consistent and interchangeable, depending on user preference.*	1
Exposure assessment (1)	Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives). Exposure assessment is the third step in the process of risk assessment. *1 This term is also contained in the list of IPCS key exposure assessment terminology (see also EA (2), Ref. 2); both definitions are consistent and interchangeable, depending on user preference.*	2
Exposure assessment (2)	The process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and the uncertainties in the assessment. *1 This term is also contained in the list of IPCS/OECD key generic terms used in chemical hazard/risk assessment (see also EA (1), Ref. 1); both definitions are consistent and interchangeable, depending on user preference.*	2
Exposure concentration	The exposure mass divided by the contact volume or the exposure mass divided by the mass of contact volume, depending on the medium.	2
Exposure duration	The length of time over which continuous or intermittent contacts occur between an agent and a target. For example, if an individual is in contact with an agent for 10 min per day for 300 days over a 1-year time period, the exposure duration is 1 year.	2
Exposure event	The occurrence of continuous contact between an agent and a target	2
Exposure frequency	The number of exposure events in an exposure duration.	2
Exposure loading	The exposure mass divided by the exposure surface area. For example, a dermal exposure measurement based on a skin wipe sample, expressed as a mass of residue per skin surface area, is an exposure loading.	2
Exposure mass	The amount of agent present in the contact volume. For example, the total mass of residue collected with a skin wipe sample over the entire exposure surface is an exposure mass.	2
Exposure model	A conceptual or mathematical representation of the exposure process.	2
Exposure pathway	The course an agent takes from the source to the target.	2
Exposure period	The time of continuous contact between an agent and a target.	2
Exposure route	The way in which an agent enters a target after contact (e.g., by ingestion, inhalation, or dermal absorption).	1
Exposure scenario (1)	A set of conditions or assumptions about sources, exposure pathways, amounts or concentrations of agent(s)involved, and exposed organism, system, or (sub)population (i.e., numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation. *1 This term is also contained in the list of IPCS key exposure assessment terminology (see also ES (2), Ref. 2); both definitions are consistent and interchangeable, depending on user preference.*	2
Exposure scenario (2)	A combination of facts, assumptions, and inferences that define a discrete situation where potential exposures may occur. These may include the source, the exposed population, the time frame of exposure, microenvironment(s), and activities. Scenarios are often created to aid exposure assessors in estimating exposure. *1 This term is also contained in the list of IPCS/OECD key generic terms used in chemical hazard/risk assessment (see also EA (1), Ref. 1); both definitions are consistent and interchangeable, depending on user preference.*	2
Exposure surface	A surface on a target where an agent is present. Examples of outer exposure surfaces include the exterior of an eyeball, the skin surface, and a conceptual surface over the nose and open mouth. Examples of inner exposure surfaces include the gastrointestinal tract, the respiratory tract, and the urinary tract lining. As an exposure surface gets smaller, the limit is an exposure point.	1

| *A-Z order* | *Description of terms* | *Citations under the table.* |

Term	Description	Reference
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.	1
Gamma Distribution	A unimodal statistical distribution (relative proportion of responders as a function of some measure) that is restricted to effects greater than or equal to zero that can describe a wide variety of shapes, e.g., flat, peaked, asymmetrical.	3
Gaussian (Normal) Distribution	a unimodal symmetrical (bell-shaped) distribution where the most prevalent value is the mean (average) and the spread is measured by the standard deviation. Mathematically, the distribution varies from minus infinity with zero probability to plus infinity with zero probability.	3
Generalized Estimating Equation (GEE)	A statistical technique used for estimating parameters that requires only specification of the first two moments of the distribution of the estimator as opposed to a complete specification of the distribution.	3
Goodness-of-Fit	A statistic that measures the dispersion of data about a dose-response curve in order to provide a test for rejection of a model due to lack of an adequate fit, e.g., a P-value < 0.1.	3
Guidance value	Value, such as concentration in air or water, that is derived after allocation of the reference dose among the different possible media (routes) of exposure. The aim of the guidance value is to provide quantitative information from risk assessment to the risk managers to enable them to make decisions. (See also *Reference dose*)	1
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.	1
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.	1
Hazard characterization	The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties. Hazard characterization is the second stage in the process of hazard assessment and the second of four steps in risk assessment. Related terms: *Dose–effect relationship, Effect assessment, Dose–response relationship, Concentration–effect relationship*	1
Hazard identification	The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population. Hazard identification is the first stage in hazard assessment and the first of four steps in risk assessment.	1
Hill Equation	A dose-response curve, frequently used for enzyme kinetics, that monotonically approaches an asymptote (maximum value) as a function of dose raised to a power.	3
Hybrid Model	For continuous data establishes abnormal values based on the extremes in controls (unexposed individuals or animals) and estimates the risk of abnormal levels as a function of dose.	3
Chemical Specific Adjustment Factor	A factor based on quantitative chemical-specific toxicokinetic or toxicodynamic data, which replaces some or all of the default uncertainty factor.	3
Chi-square Test	A statistical test used to examine the deviation of an observed number of events from an expected number of events.	3
Chronic exposure	A continuous or intermittent long-term contact between an agent and a target. (Other terms, such as "long-term exposure," are also used.)	2
Incidence	Proportion or probability of individuals or animals exhibiting an effect that varies from zero to one, sometimes expressed as a percent from 0% to 100%.	3
Independence	The result in one animal or individual does not influence the result in another animal or individual.	3
Intake	The process by which an agent crosses an outer exposure surface of a target without passing an absorption barrier, i.e., through ingestion or inhalation (see *Dose*).	2
Intercept Term	The estimated value at zero dose or the dose corresponding to a zero effect.	3
Least Squares	A statistical procedure that estimates the values of dose-response parameters such that the sum of squares of deviations of data points from their estimated values is minimized, i.e., minimizes the estimated variance.	3
Likelihood Function	Relative probabilities that various values of population parameters would arise from the sample observations.	3

A-Z order	*Description of terms*	*Citations under the table.*
Term	**Description**	**Reference**
Likelihood Ratio	Ratio of the probability that the observed data arise from a set of model parameters relative to the maximum probability that arises from the set of maximum likelihood estimates.	3
Linear Dose-Response Model	The amount of change in a response is proportional to the amount of change in some function of dose.	3
Linearized Multistage Model	Dose-response model based on the multistage model of carcinogenesis that is restricted to a form that is approximately linear at low doses.	3
Local Maximum	Mathematical solution that maximizes a function in a region that may not be the overall global maximum.	3
Log Transformation	Logarithm of raw data.	3
Logistic Model	A sigmoid (S-shaped) function that relates the proportion of individuals with a specified characteristic to an independent variable.. random variable has a normal distribution	3
Lognormal Distribution	A mathematical description where the natural logarithm of a random variable has a normal distribution	3
Lowest-observed-adverse-effect level (LOAEL)	The lowest concentration or amount of a substance, found by experiment or observation, that causes an adverse alteration of morphology, functional capacity, growth, development or life span of the target organisms distinguishable from normal (control) organisms of the same species and strain under the same defined conditions of exposure.	3
Lowest-observed-effect level (LOEL)	The lowest concentration or amount of a substance, found by experiment or observation, that causes any alteration of morphology, functional capacity, growth, development or life span of the target organisms distinguishable from normal (control) organisms of the same species and strain under the same defined conditions of exposure.	3
Margin of exposure (MOE)	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*	1
Margin of safety (MOS)	For some experts, margin of safety has the same meaning as margin of exposure, while for others, margin of safety means the margin between the reference dose and the actual exposure. Related term: *Margin of exposure*	1
Maximum Likelihood Estimate (MLE)	Estimate of a population parameter most likely to have produced the sample observations.	3
Measurement end-point	Measurable (ecological) characteristic that is related to the valued characteristic chosen as an assessment point.	1
Medium	Material (e.g., air, water, soil, food, consumer products) surrounding or containing an agent.	2
Medium intake rate	The rate at which the medium crosses the outer exposure surface of a target during ingestion or inhalation.	2
Mechanism of action	A detailed description of the precise chain of events from the molecular level to gross macroscopic or histopathological toxicity.	3
Microenvironment	Surroundings that can be treated as homogeneous or well characterized in the concentrations of an agent (e.g., home, office, automobile, kitchen, store). This term is generally used for estimating inhalation exposures.	2
Michaelis-Menten Equation	A dose-response curve, frequently used for enzyme kinetics, with maximum slope at zero dose that approaches a maximum asymptote at increasing dose.	3
Mode of action	A series of events that may lead to induction of the relevant end-point of toxicity for which the weight of evidence supports plausibility.	3
Monotonic Dose-Response	A dose-response that never decreases as dose increases. A monotonic function may be flat (constant) up to a threshold dose or may be flat at high doses if a biological limit, e.g., saturation, is attained.	3
Multinomial	Animals or individuals may be classified by more than two (binomial)categories, e.g., in a reproductive study fetuses may be: dead, alive normal, or alive abnormal.	3
Negligible Risk	A risk management term. In cases where a quantitative risk estimate has been made, it is any risk less than an upper-bound incremental lifetime risk calculated using conservative risk assessment techniques such as the BMD.	3
Nonlinear Dose-Response Model	Mathematical relationship that cannot be expressed simply as the change in response being proportional to the amount of change of some function of dose.	3
No-Observed-Adverse-Effect Level (NOAEL)	The highest concentration or amount of a substance, found by experiment or observation, that causes no detectable adverse alteration of morphology, functional capacity, growth, development or life span of the target organisms under defined conditions of exposure.	3

| *A-Z order* | *Description of terms* | *Citations under the table.* |

Term	Description	Reference
Normal Distribution	A mathematical description where a continuous random variable x with a mean μ and a variance σ2 has a probability density function	3
Objective Function	Choice of function that is optimized for maximum likelihood estimation.	3
Ordinal Data	Integers designating the rank, order, or counts.	3
Parameter	A value used to numerically describe a population of values, e.g., the mean and standard deviation; or a value used to describe a dose-response curve, e.g., the intercept and the slope of a linear dose-response.	3
Pica	A behavior characterized by deliberate ingestion of non-nutritive substances, such as soil.	2
Point of Departure (POD)	The point on a dose-response curve established from experimental data, e.g., the benchmark dose, generally corresponding to an estimated low effect level (e.g., 1% to 10% incidence of an effect). Depending on the mode of action and available data, some form of extrapolation below the POD may be employed for low-dose risk assessment or the POD may be divided by a series of uncertainty factors to arrive at a reference dose.	3
Polynomial	A mathematical function of the sum of a constant, linear term, quadratic term, cubic term, etc.	3
Probability	The proportion (on a scale of 0 to 1) of cases for which a particular event occurs. Zero indicates the event never occurs and one indicates the event always occurs.	3
Probability Distribution	A mathematical description of the relative probabilities of all possible outcomes of a measurement.	3
Probit Function	Assumes that the relative probabilities of effects as a function of dose are described by a Normal distribution. The cumulative probability as a function of dose has a sigmoid shape.	3
Profile Likelihood	A plot of the likelihood function versus the estimated value of a parameter.	3
P-Value	In testing a hypothesis, the probability of a type I error (false positive). The probability that the sample (experimental) results are compatible with a specific hypothesis.	3
Quadratic Term	A quantity in a mathematical formula that is raised to the second power (squared).	3
Quantal Data	Dichotomous (Binomial) classification where an individual or animal is placed in one of two categories, e.g., dead or alive, with or without a particular type of tumour, normal or abnormal level of a hormone.	3
Quantile	Percentile (cumulative probability) of a distribution that ranges from zero to the 100th percentile.	3
Quasi-Likelihood	Likelihood function that is not totally defined and generally based on only an expression including the mean and variance.	3
Rectangular Hyperbola	A mathematical function of the form y squared equals x squared plus c squared, where x and y are variables and c is a constant.	3
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*	1
Regression Analysis	A statistical process that produces a mathematical function (regression equation) that relates a dependent variable (biological effect) to independent variable, e.g., dose rate, duration of exposure, age.	3
Repeated Measures	A biological endpoint is measured for the same individual or animal at different times (ages).	3
Residual Variance	The variance in experimental measurements remaining after accounting for the variance due to the independent variables, e.g., dose rate, duration of exposure, age. Typically referred to as the inherent unaccountable experimental variation.	3
Residuals	The numerical differences between observed and estimated effects.	3
Response	Change developed in the state or dynamics of an organism, system, or (sub)population in reaction to exposure to an agent.	1
Risk	The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent.	1
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.	1
Risk assessment	A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterization (related term: *Dose–response assessment*), exposure assessment, and risk characterization. It is the first component in a risk analysis process.	1

| *A-Z order* | *Description of terms* | *Citations under the table.* |

Term	Description	Reference
Risk communication	Interactive exchange of information about (health or environmental) risks among risk assessors, managers, news media, interested groups, and the general public.	1
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.	1
Risk evaluation	Establishment of a qualitative or quantitative relationship between risks and benefits of exposure to an agent, involving the complex process of determining the significance of the identified hazards and estimated risks to the system concerned or affected by the exposure, as well as the significance of the benefits brought about by the agent. Risk evaluation is an element of risk management. Risk evaluation is synonymous with risk–benefit evaluation.	1
Risk characterization	The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system, or (sub)population, under defined exposure conditions. Risk characterization is the fourth step in the risk assessment process.	1
Risk management	Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk management comprises three elements: risk evaluation; emission and exposure control; and risk monitoring.	1
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.	1
Safety	Practical certainty that adverse effects will not result from exposure to an agent under defined circumstances. It is the reciprocal of risk.	1
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*	1
Severity	the degree to which an effect changes and impairs the functional capacity of an organ system.	3
Shape Parameter	the exponent on dose in a dose-response function that dictates the curvature of the function.	3
Source	The origin of an agent for the purposes of an exposure assessment.	2
Stressor	Any entity, stimulus, or condition that can modulate normal functions of the organism or induce an adverse response (e.g., agent, lack of food, drought).	2
Sub-chronic exposure	A contact between an agent and a target of intermediate duration between acute and chronic. (Other terms, such as "less-than-lifetime exposure," are also used.)	2
Target	Any biological entity that receives an exposure or a dose (e.g., a human, a human population, or a human organ).	2
Threshold	Dose or exposure concentration of an agent below which a stated effect is not observed or expected to occur.	1
Threshold of Toxicological Concern	Nn exposure threshold value below which there is a very low probability of an appreciable risk to human health	3
Time profile	A continuous record of instantaneous values over a time period (e.g., exposure, dose, medium intake rate).	2
Time-averaged exposure	The time-integrated exposure divided by the exposure duration. An example is the daily average exposure of an individual to carbon monoxide. (Also called time-weighted average exposure.)	2
Time-integrated exposure	The integral of instantaneous exposures over the exposure duration. An example is the area under a daily time profile of personal air monitor readings, with units of concentration multiplied by time.	2
Tolerable daily intake	Analogous to *Acceptable daily intake*. The term "tolerable" is used for agents that are not deliberately added, such as contaminants in food.	1
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.	1
Toxicity	Inherent property of an agent to cause an adverse biological effect.	1

Description of terms *Citations under the table.*

Term	Description	Reference
Toxicodynamics	The process of interaction of chemical substances with target sites and the subsequent reactions leading to adverse effects.	3
Toxicokinetics	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.	3
Uncertainty	Imperfect knowledge concerning the present or future state of an organism, system, or (sub)population under consideration.	1
Uncertainty	imperfect knowledge concerning the present or future state of an organism, system or (sub)population under consideration	1
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*	3
Unconstrained Dose-Response Model	No restrictions imposed on the estimates of parameters.	3
Upper-Tail Probability	Probability that a variable exceeds a specified value.	3
Uptake (absorption)	The process by which an agent crosses an absorption barrier (see *Dose*).	2
Validation	Process by which the reliability and relevance of a particular approach, method, process, or assessment is established for a defined purpose. Different parties define "Reliability" as establishing the reproducibility of the outcome of the approach, method, process, or assessment over time. "Relevance" is defined as establishing the meaningfulness and usefulness of the approach, method, process, or assessment for the defined purpose.	1
Variability	Observable diversity in biological sensitivity or response, and in exposure parameters.	3
Variance	Measure of variability, standard deviation squared.	3
Weibull	Form of a dose-response curve characterized by a relatively shallow slope at low doses that increases sharply as dose increases before leveling off at high doses.	3
Weighted Least Squares Estimate	Parameter estimate obtained by minimizing the sum of squares of observed and estimated values weighted by a function, frequently the reciprocal of the variance of an observation.	3