B

Base pair (bp): Two complementary nucleotide bases in DNA joined together by hydrogen bonds.

Benchmark dose (BMD) modelling: An alternative quantitative approach to dose-response assessment using more of the data than the NOAEL process. This approach utilises mathematical models to fit all available data points and uses the best fitting model to interpolate an estimate of the dose (benchmark dose) that corresponds to a particular level of response (a benchmark response). A measure of uncertainty is also calculated, and the lower confidence limit on the benchmark dose is called the BMDL. The BMDL accounts for the uncertainty in the estimate of the dose-response that is due to characteristics of the experimental design such as sample size and biological variability. The BMDL can be used as the point of departure (see POD) for derivation of a health-based guidance value or a margin of exposure.

Benign tumour: Tumours showing a close morphological resemblance to their tissue of origin, growing in a slow expansile fashion and with a circumscribed form, usually encapsulated masses. They may stop growing and they may regress. Benign tumours do not infiltrate through local tissues and they do not metastasise. They are rarely fatal.

Bias: An interference which at any stage of an investigation tends to produce results that depart systematically from the true values (to be distinguished from random error). The term does not necessarily carry an imputation of prejudice or any other subjective factor such as the experimenter's desire for a particular outcome.

Bioavailability: A term referring to the proportion of a substance which reaches the systemic circulation unchanged after a particular route of administration.

Bioinformatics: The science of informatics as applied to biological research. Informatics is the management and analysis of data using advanced computing techniques. Bioinformatics is particularly important as an adjunct to -omics research, because of the large amount of complex data this research generates.

Biological relevance: an effect considered by expert judgement as important and meaningful for human, animal, plant or environmental health. It therefore implies a change that may alter how decisions for a specific problem are taken.

Biomarker: Observable change (not necessarily pathological) in an organism, related to a specific exposure, effect or susceptibility.

Biomarker of effect: A measurable biochemical, physiologic, behavioural, or other alteration in an organism that, depending on the magnitude, can be recognised as associated with an established or possible health impairment or disease.

Biomarker of exposure: a chemical, its metabolite, or the product of an interaction between a chemical and some target molecule or cell that is measured in the human body indicative of exposure

Biomarker of susceptibility: An indicator of an inherent or acquired ability of an organism to respond to the challenge of exposure to a specific chemical substance.

Biomonitoring (human): the direct measurement of people's integrated exposure to toxic substances by measuring the substances, their metabolites or a biochemical change in human specimens, such as blood or urine.

Biomonitoring equivalent: an estimated concentration or range of concentrations of an environmental chemical in humans which is consistent with existing health-based guidance values such as the TDI or RfD/RfC. BEs provide a way of interpreting biomonitoring data in the context of these values.

Body burden: Total amount of a chemical present in an organism at a given time.

Bradford Hill considerations: Sir Austin Bradford Hill established a set of ‘principles’ (not be taken as ‘criteria’) that may be used to assist in the interpretation of associations reported from epidemiological studies:

- Strength – The stronger the association the more likely it is causal. The COC has previously noted that the relative risks of <3 need careful assessment for effects of bias or confounding.

- Consistency – The association has been consistently identified by studies using different approaches and is also seen in different populations with exposure to the chemical under consideration.

- Specificity – Limitation of the association to specific exposure groups or to specific types of disease increases likelihood that the association is causal.

- Temporality – The association must demonstrate that exposure leads to disease. The relationship of time since first exposure, duration of exposure and time since last exposure are all important in assessing causality.

- Biological gradient – If an association reveals a biological gradient or dose response curve, then this evidence is of particular importance in assessing causality.

- Plausibility – Is there appropriate data to suggest a mechanism by which exposure could lead to concern? However, even if an observed association may be new to science or medicine it should not be dismissed.

- Coherence – Cause and effect interpretation of data should not seriously conflict with generally known facts.

- Experiment – Can the association be demonstrated experimentally? Evidence from experimental animals may assist in some cases. Evidence that removal of the exposure leads to a decrease in risk may be relevant.

- Analogy – Have other closely related chemicals been associated with the disease?

Bronchial: Relating to the air passages conducting air from the trachea (windpipe) to the lungs.