Chapter 5: Risk characterisation

5.1 INTRODUCTION

Risk characterisation is the final step in the risk assessment process that:

- integrates the information from hazard identification, dose–response assessment and exposure assessment
- discusses chemicals of potential concern (COPC) and quantifies risks associated with these specified chemicals
- identifies the contributions to risk from all the relevant exposure pathways, and aggregates these risk estimates
- considers the possibility that multiple COPCs may have cumulative effects, and considers options for best integrating the effects of combined exposures (see Chapter 12)
- describes the risks to individuals and populations in terms of nature, extent and severity of potential adverse health effects
- provides an evaluation of the overall quality of the assessment and the degree of confidence the risk assessors have in the estimates of risk and conclusions drawn; this should be based on appropriate uncertainty and sensitivity analyses
- communicates results of the risk assessment to the risk manager
- provides key information for risk communication.

Risk characterisation is identified as part of Phase II of the expanded framework for EHRA outlined in Figure 2.

The overall objective of the risk characterisation stage is to determine that exposures to COPCs from the environmental source under consideration do not exceed a level considered to be protective of human health. In practice, this means that the estimated total exposure (including background where relevant) does not exceed a toxicological reference value or a health-based guideline value, usually one that has been set using the same principles of health risk assessment set out in these enHealth guidelines (see Section 5.5).

The final risk characterisation is limited by the available data, and this should be discussed in the uncertainty assessment. The process requires considerable expertise. If data is collected and analysed according to the principles and guidelines in this enHealth document, the process will become more transparent and consistent. Some parts of the risk assessment process such as 'data collection' and 'exposure assessment' will be, at least in part, quantitative and possibly based on modelling or extrapolations from measured data. These guidelines are intended to assist the qualitative process of determining whether environmental health intervention is required or not required.

Risk characterisation may involve comparing environmental data, exposure data, intakes and biological monitoring results with established criteria, including guideline values (GVs) established or published by authoritative sources.

Due to the complexities of the matter, the risk characterisation process cannot be reduced to a 'cookbook'. In this context, the guidance in this document consistently recommends that the choice of default parameters, GVs or risk assessment methodology must include an assessment of their suitability for use in the EHRA at hand. In other words, care must be taken to ensure that published or derived health-based GVs are 'fit for purpose'.

5.2 KEY PRINCIPLES IN ENVIRONMENTAL HEALTH RISK CHARACTERISATION

There are a number of key principles for health risk characterisation:

1. Protection of human health is the primary objective. Human health risk assessment is generally undertaken with an appreciation that the health risk assessment is part of a larger assessment that encompasses ecological risk assessment. However, actions based on the risk characterisation taken should always adequately protect public health and the environment, putting these responsibilities before all other considerations.
2. Risk assessments should be transparent (Schreider et al. 2010). The nature and use of default values and methods, assumptions and policy judgements in the risk assessment should be clearly identified and documented. Conclusions drawn from the evidence should be distinguished from policy judgements, and the influence of 'scientific judgement' made clear.
3. Risk characterisations should include a summary of the key issues and conclusions of each of the other components of the risk assessment, as well as describing the nature and likelihood of adverse health effects. The summary should include a description of the overall strengths and limitations of the assessment and conclusions.
4. To protect public health and the environment an appropriate degree of conservatism must be adopted to guard against uncertainties. There should be a detailed description of the areas of uncertainty and an analysis of the effects of these on any derived values.
5. Risk characterisations (and risk assessments) should be undertaken using methodologies outlined in this enHealth document, noting that methodologies may be revised as needed to maintain consistency with best scientific practice. Reports should follow a consistent general format (see Chapter 7), bearing in mind the need to recognise the unique characteristics of each specific situation.
6. Risk assessors should review the most up-to-date scientific literature relevant to the risk assessment under consideration and to the toxicological profile of the identified COPC. Information in appropriately peer-reviewed articles should be accorded greater weight than information in articles that are not peer-reviewed.
7. Variations in risk assessments as a result of particular statutory requirements, resource limitations, and other specific factors should be explained as part of the risk characterisation. For example, a reason will be required to explain why certain elements are incomplete.

5.3 QUANTITATIVE AND QUALITATIVE RISK CHARACTERISATION

The level of risk estimated in any risk assessment can be described either qualitatively (i.e. by putting risks into categories such as 'high', 'medium' or 'low') or quantitatively (with a numerical estimate). Current risk assessment methods described in this enHealth document provide quantitative estimates of risk but the precision of any such estimate will be limited by the data available to use in the assessment.

Differentiation of the approaches used in qualitative and quantitative risk assessments are informed by definitions that have been developed for each of these two processes.

Qualitative assessment: An inquiry process that generates non-numerical data, providing an 'understanding of a social or human problem, based on building a complex and holistic picture formed with words, reporting detailed views of informants and conducted in a natural setting' (Creswell 1994); or 'a classification process, where objects or materials are assigned to some class on the basis of tests made against established or implied criteria' (Ellison et al. 1998)

Quantitative assessment: The application of a set of scientifically measurable, reproducible and mathematically sound data values to estimate value, probability and associated risk of loss.

In quantitative risk assessment, reporting of a measurement is an approximation or an estimate of the value of the subject being measured. Such a result should only be considered complete after it has been evaluated and the uncertainties in the measurement explained. There are different ways of measuring uncertainty. Statistical analysis allows for the evaluation of random events and from those arising from a systematic effect.

Accounting for uncertainty in a qualitative assessment is the acknowledgement that the original classification has been made on the basis of the available evidence and that misidentifications may have occurred. There may be a lack of evidence in an observation that has caused it to be placed in a particular class, and this may result in either a 'false positive' or 'false negative' classification. Methods used in describing the identification of any classification should reflect the uncertainties associated with the evidence, permit updating on the basis of further evidence, and consider the probability of both types of error. Other desirable features include a lack of ambiguity, ease of calculation, clarity (especially for the presentation of the results) and broad acceptability of the reasoning for the determined classification.

Numerical estimates of risk may be an outcome of a quantitative assessment, but with the qualification that these are mathematical constructs incorporating various degrees of uncertainty. Numbers may give a misleading implication of accuracy, especially when based on poor or uncertain information (Langley 2003). The numbers generated should never be portrayed as being highly precise or accurate (IEH 1999b). The risk level should never be expressed in a way that suggests a greater degree of precision than is warranted by the data, for example, a risk level of 4.73×10^{-6} (i.e. using three significant figures rather than 5×10^{-6}) is probably meaningless in the context of an EHRA outcome (Langley 2003).

Variability associated with the identified hazards, the nature of the exposed populations or groups of people ('receptors'), and limitations in the toxicological and exposure data will all contribute to these uncertainties.

The most conservative mathematical models used in quantitative EHRA can be virtually insensitive to the actual experimental data and should be viewed only as a risk management solution, not a risk assessment technique (IEH 1999b). The extent to which manipulation of the input data can influence the resultant risk estimates should be determined using 'sensitivity analysis' techniques (see Section 5.15).

Estimates do not have to depend on the use of numbers to be useful; ordinary language may be used to indicate the level of risk. A finely divided ranking system can give a relatively accurate indication of quantity without using numbers (ACDP 1996).