

4. FACTORS INVOLVED IN RISK ASSESSMENT

4.1 Interpretation of data

Risk assessment involves the use of data from *in vivo* and *in vitro* laboratory studies and, where available, human clinical and epidemiological data. Risk assessment can be quantitative or qualitative as noted by Codex in 1994.

Quantitative risk assessment The estimation of risks as numerical representations including point estimates and/or distributions.

Qualitative risk assessment The estimation of risks as categorical representations including ordinal rankings, descriptive classifications, etc.

In principle and whenever possible risk assessment should be based on reliable clinical or epidemiology data in humans. However in most cases, human data lack the precision needed for quantitative risk assessments, notably limited description of effects, inadequate or absent data on the nature and magnitude of exposure, and based on small and possibly non-representative populations. In contrast, it is practicable to derive dose-effect and dose-response relationships on the basis of quantitative toxicity data from experimental animal studies. These data combined with measurement or prediction of human exposure can be used either to estimate or predict the type and magnitude of adverse health effects in humans and the proportion of an exposed population that will be affected (risk assessment), or to derive doses that will not be associated with adverse effects (safety evaluation). Consequently laboratory toxicity studies using animal models are the major source of information for the prediction of toxic risk for human populations. Important practical factors in predictive risk assessment must include the experimental animal species and test design. Ideally, animals used in risk assessment toxicity studies would be selected on the basis of their anatomical, physiological and metabolic similarity to humans but practical factors, such as size, availability, handling, animal husbandry, and lifespan are involved (See Section 3). For these reasons, rodent (rat, mouse) models are widely used. Experimental data from animal studies cannot be used uncritically and require close study and interpretation to take account of the structural and functional differences as well as the similarities between experimental species and humans.

Theoretically, the pattern and duration of exposure of test animals to a chemical should be related to that anticipated for the target species. Extrapolation from animals to humans should take into account not only dose and effects but also the duration of exposure.

4.2 Extrapolation of data

The use of toxicity studies in animals to predict toxicity in humans is based on the general assumption that there are anatomical and physiological similarities between mammalian species and similar responses to many toxic chemicals. Although laboratory animals may replicate individual human toxic responses but there is no single animal