



Risk Assessment of Chemicals in Food and Diet

The project “**Food Safety in Europe: Risk Assessment of Chemicals in the Food and Diet (Acronym: FOSIE)**” is an EU Fifth Framework Programme Concerted Action funded by the European Commission, Quality of Life and Management of Living Resources Programme, Key Action 1 on Food Nutrition and Health.

The aims of the project are:

- To explore means of improving the principles applied to, and scientific basis of, risk assessment with respect to food additives and contaminants, micronutrients and nutritional supplements, macronutrients and whole foods.
- To consider possible interactions between individual chemicals and effects of the food matrix.
- To identify the gaps in knowledge that might lead to differences in interpretation of toxicological and exposure data, and the research needs to reduce these.
- To determine the nature and level of testing needed for safety evaluation relevant to the nature of the chemical, level of use/occurrence in the diet and human exposure.
- To add a European contribution to international initiatives to harmonise principles, terminology and methodology for risk assessment.
- To contribute towards a consensus on risk assessment issues that is scientifically transparent and justifiable.
- To assist risk managers in developing appropriate, defensible food standards that adequately protect the safety of the consumer while allowing for innovation in food production and processing.

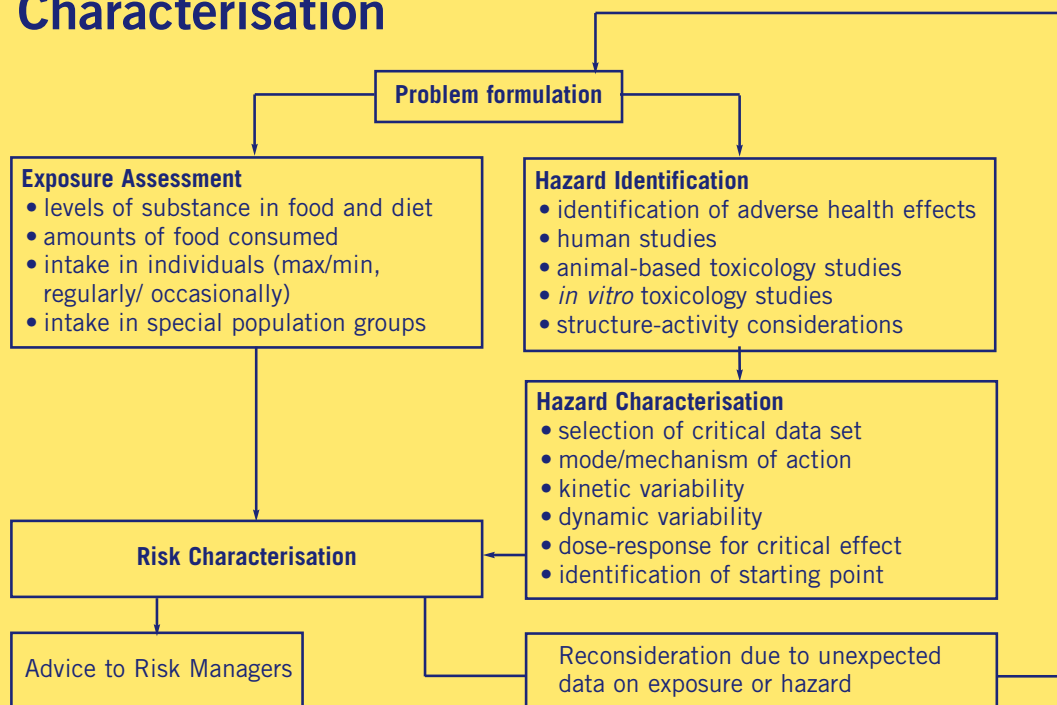
Six Individual Theme Groups (ITGs) were organised to consider the first three steps of the risk assessment process as follows:

- **Hazard identification by methods of animal-based toxicology**
- **Methods of *in vitro* toxicology**
- **Hazard characterisation of chemicals in food and diet: dose-response, mechanisms and extrapolation issues**
- **Mathematical modelling and quantitative methods**
- **Assessment of intake from the diet**
- **The contribution of epidemiology**

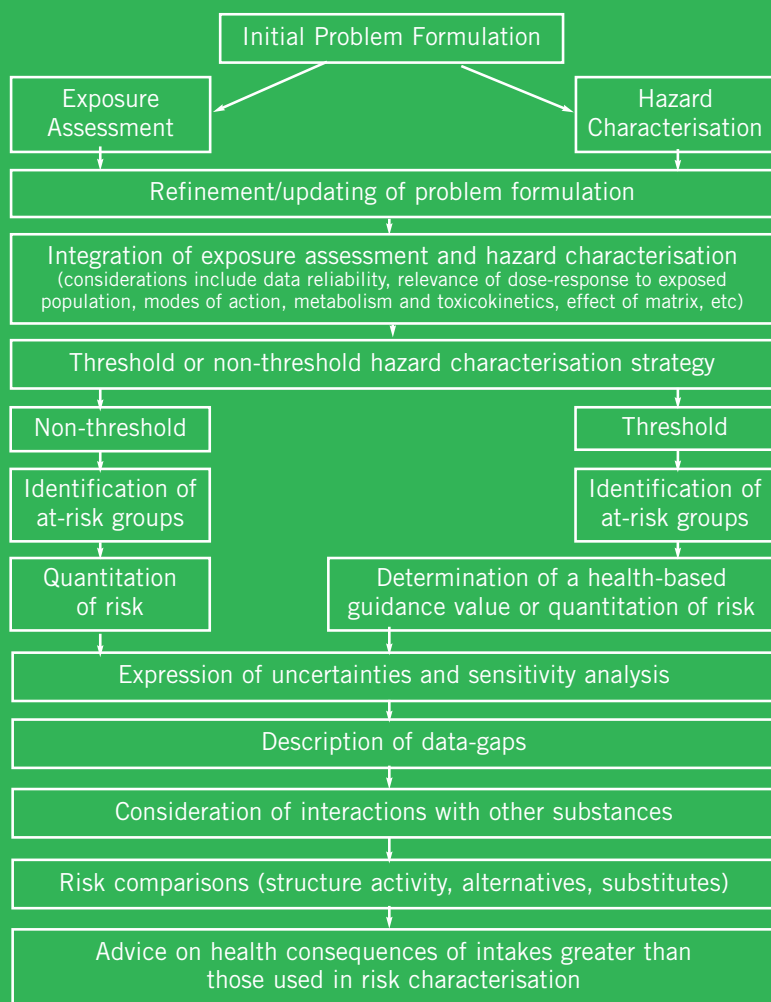
The reports from these six groups were published in a separate issue of *Food and Chemical Toxicology* (Volume 40, No 2/3, pages 137-427).

A final ITG was convened to consider risk characterisation and was composed of S. Barlow, A. Boobis, E. Dybing, L. Edler, G. Eisenbrand, J. Greig, J. Kleiner, R. Kroes (chairman), D. Müller, A. Renwick, M. Smith, A. Trischer, S. Tuijelaars and R. Walker.

Risk Characterisation



Decision tree for consideration of all classes



The advice to risk managers may be quantitative or qualitative, dependent on problem formulation, data availability and the nature of the compound or substance.

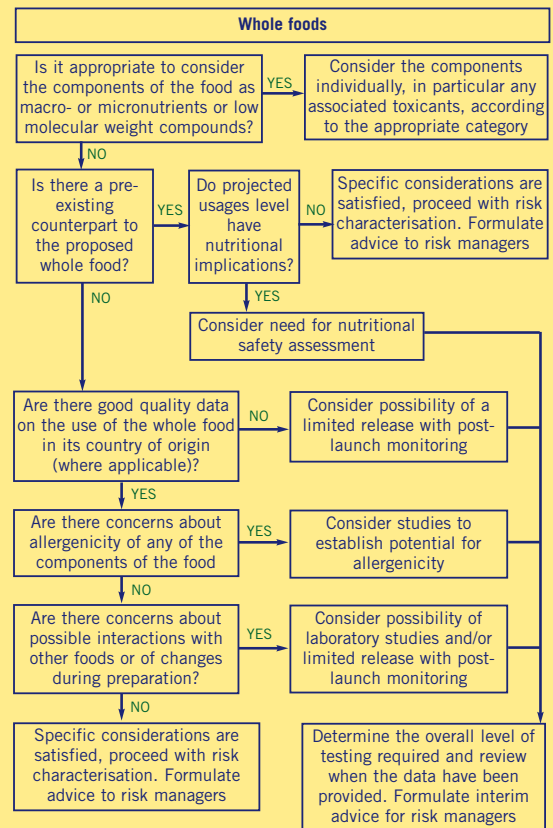
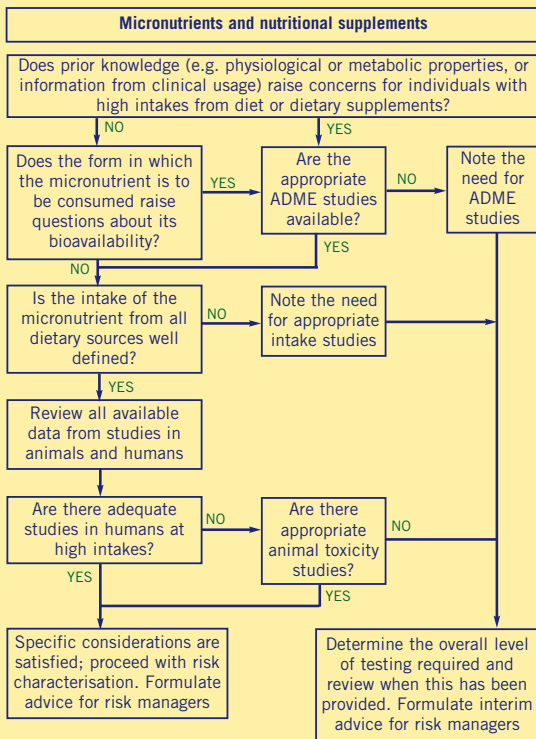
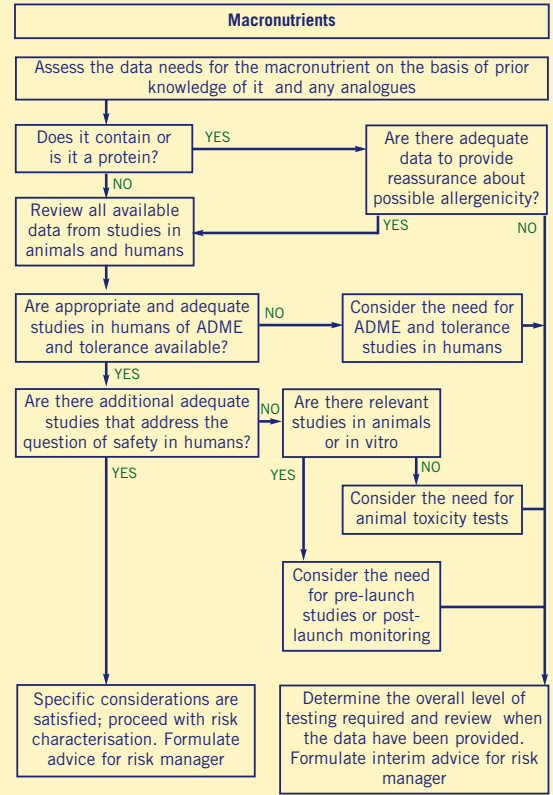
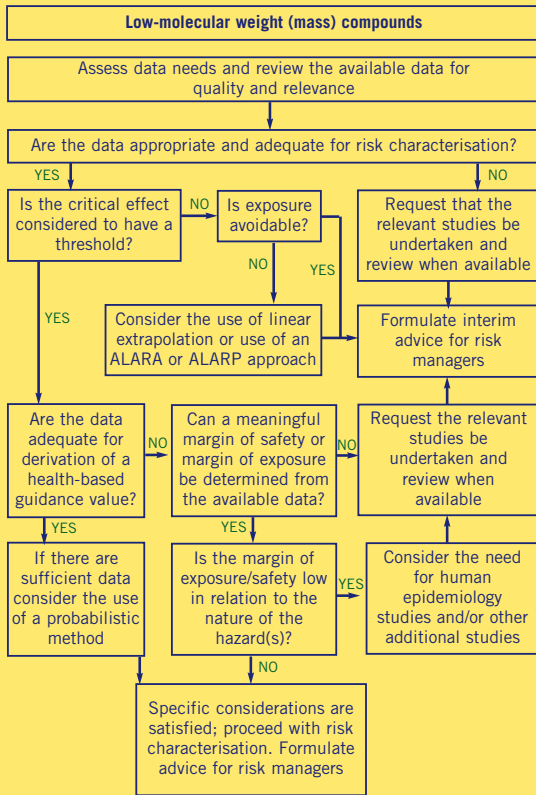
Quantitative advice can be in one of the following forms:

- an estimate of the risks associated with different levels of exposure (e.g. for an unavoidable contaminant);
- a health-based guidance value (e.g. for an additive, pesticide, veterinary drug or other avoidable contaminant);
- as a ratio between the NOAEL in experimental or epidemiological studies, and the estimated amount of human intake/exposure, referred to as a “margin of exposure”;
- as a ratio between the NOAEL and the actual amount of human intake/exposure, referred to as a “margin of safety” or a “safety margin”;
- as recommended minimum and maximum intakes (e.g. for vitamins, minerals and other nutrients).

Qualitative advice can be in the following forms:

- a classification of “ADI not specified” may be allocated (e.g. for an additive when its addition to food under good manufacturing practice does not need to be restricted, because of the absence of any evidence of toxicity even at high dose levels);
- approval may be use-specific, that is, the substance is considered safe in the context of the intake that is estimated from a certain specified use or uses (e.g. a vitamin, mineral or additive);
- to avoid certain foods (e.g. aflatoxin-contaminated nuts from certain sources);
- to avoid certain processes (e.g. use of ethylene oxide for sterilisation of spices);
- to modify production processes (e.g. use of a different production method for hydrolysed vegetable protein to avoid formation of chloropropanols);
- to minimise exposure to as low as reasonably achievable (e.g. for unavoidable toxic contaminants);
- to reduce intakes (e.g. of certain types of fat);
- to reduce or avoid intakes by certain sectors of the population (e.g. liver and vitamin A supplements by pregnant women).

Risk characterisation schemes for different classes of food chemical



Conclusions

Risk characterisation is an iterative process; the output depends on

- the question to be addressed
- the nature of the substance
- the available data
- the nature of the hazard

