

Food Safety in Europe (FOSIE)

Final Project results

Risk Assessment of Chemicals in Food and Diet

The safety of our food supply is a shared responsibility, from farm to fork, of the food producing industry, regulatory authorities and consumers. As part of this safety assurance it is essential to assess the potential risks posed by food and food ingredients.

Aims of the project were:

- 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.



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Organised by International Life Sciences Institute – ILSI Europe

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Structure of the project

A collaborative, multidisciplinary, and primarily European network has been established to critically assess the current knowledge in Risk Assessment and to examine the science base for new qualitative and quantitative methodologies for risk assessment with respect to the various food chemical categories. In total more than 120 experts coming from all European countries including Central and Eastern Europe countries, the USA, Canada, Australia and Japan participated in the project. Individual Theme groups (ITGs) were formed to address all steps involved in risk assessment and to integrate them in the most relevant manner. All papers were revised in Plenary Meetings prior to their publication.

First set of ITG Papers

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

Items addressed by each ITG

- Current status
- Limitations
- Reliability
- Potential for improvement
- Gap analysis and research needs

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

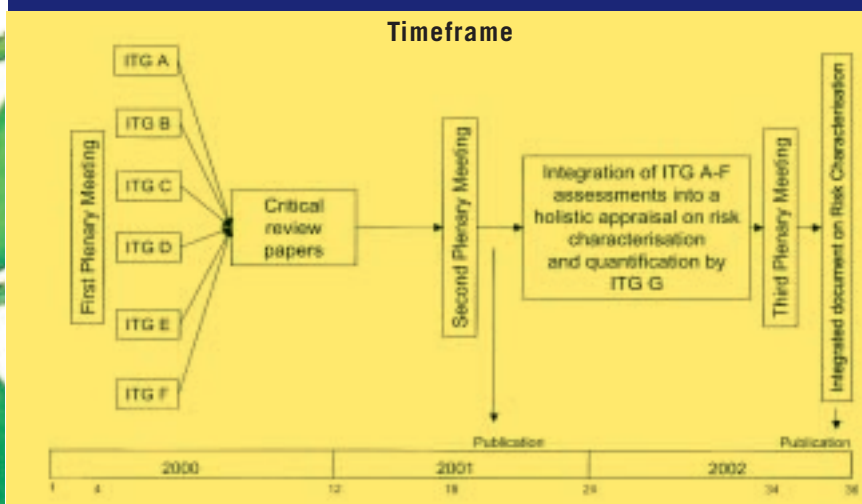
Gaps and research needs identified by the 6 ITGs can be found on the FOSIE website (www.ilsi.org/europe/fosie)

Final ITG Papers

Based on the outcome of the previous paper, a final ITG on Risk Characterisation prepared one integrated document on the characterisation and quantification of risk in the food area.

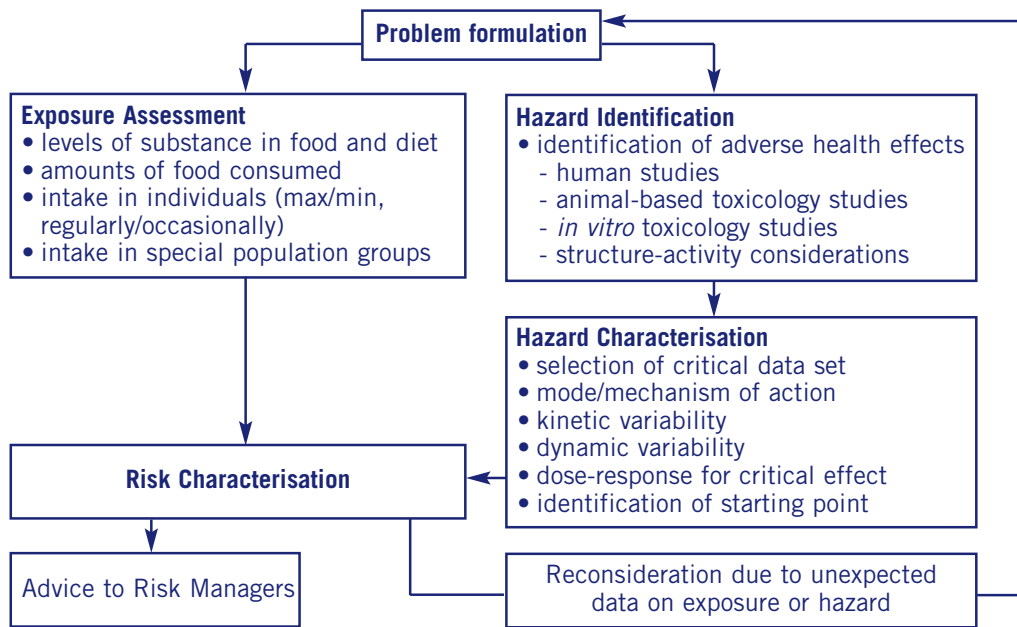
The following categories of compounds were considered:

- Chemicals of low molecular weight, e.g. food additives, pesticides, contaminants
- Micronutrients and nutritional supplements, e.g. vitamins and minerals
- Macronutrients, e.g. proteins, lipids, carbohydrates
- Whole foods, e.g. new varieties of food plants or exotic fruits

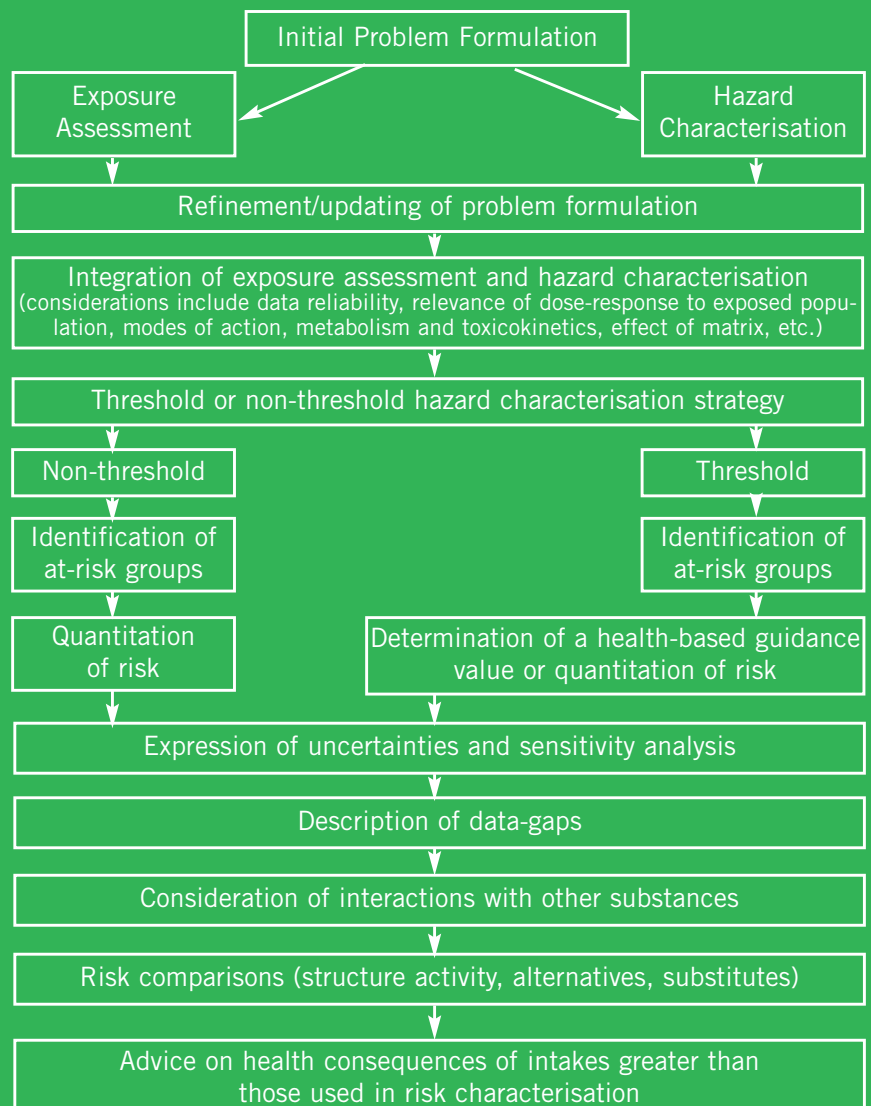


Results of final ITG on Risk Characterisation

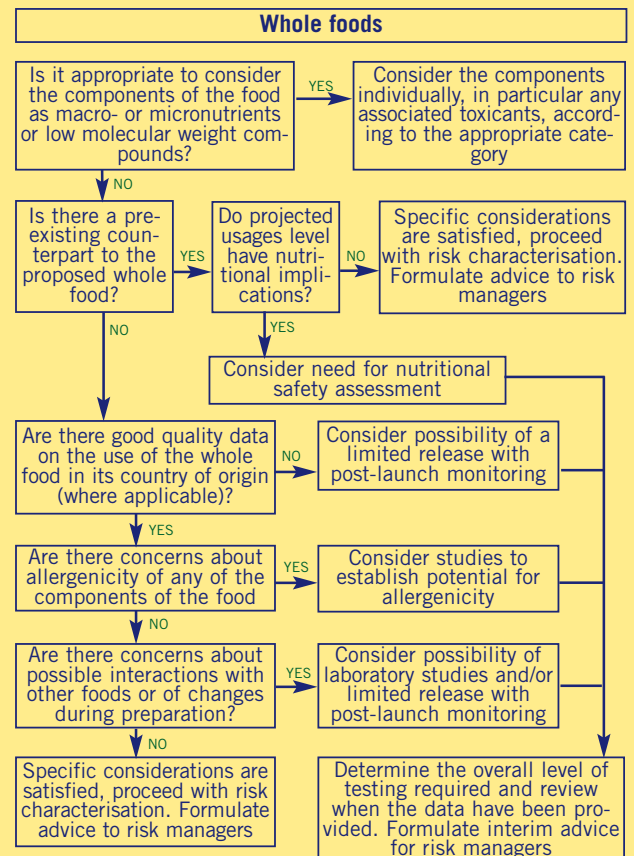
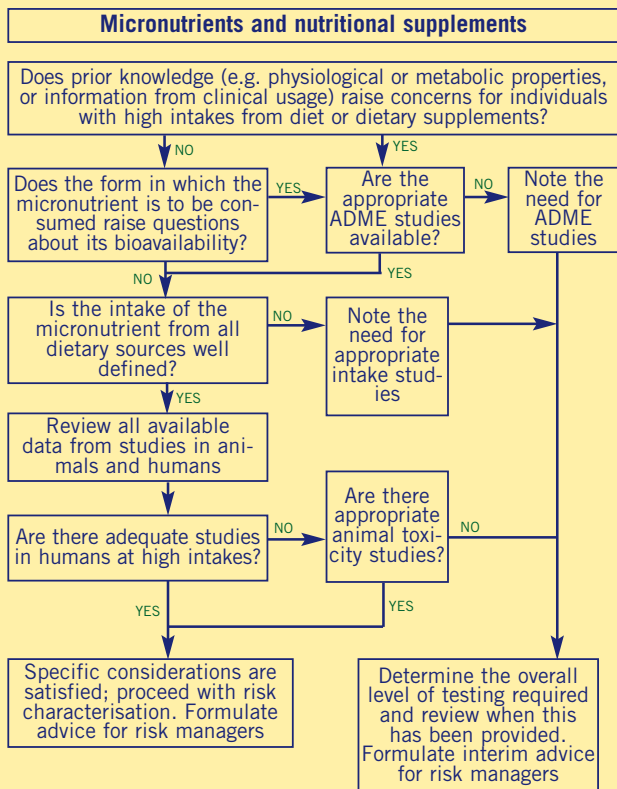
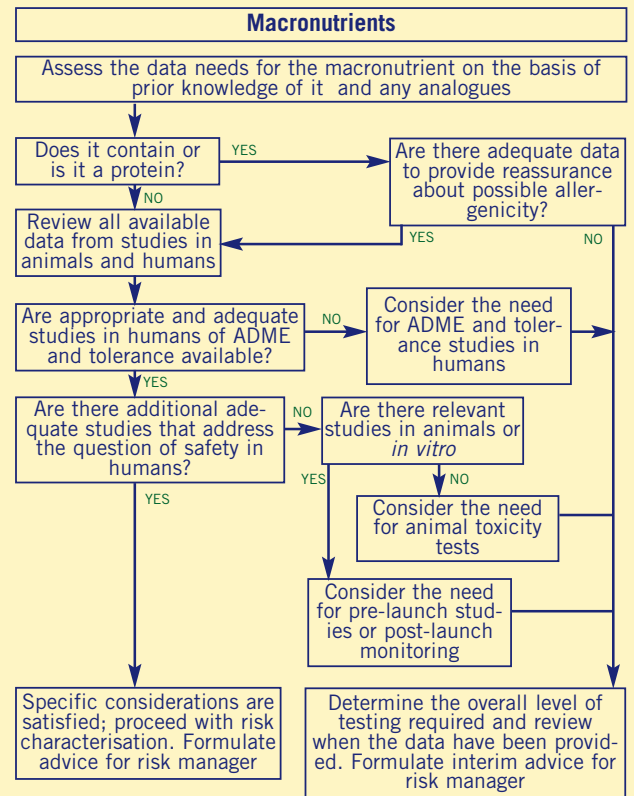
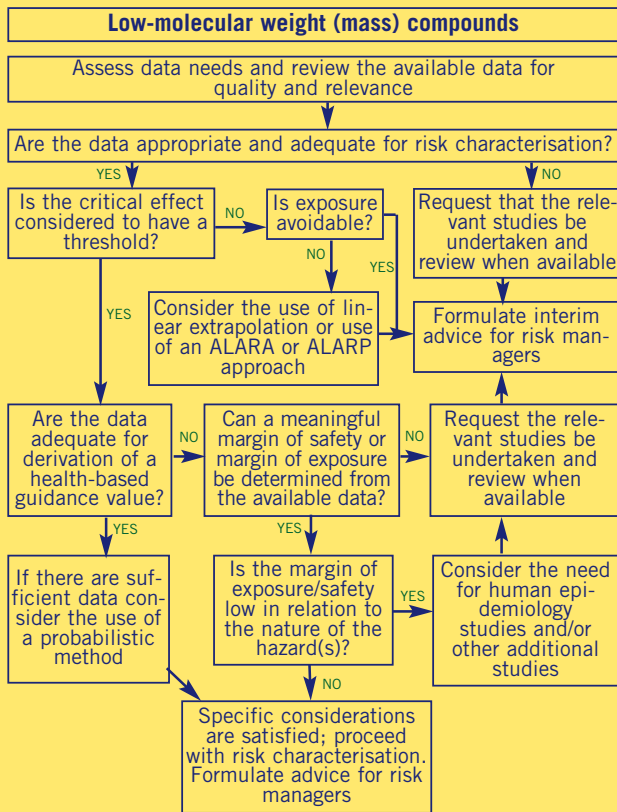
The Risk Assessment Paradigm



Decision tree for consideration of all classes of food chemicals



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

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 of 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).

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Ajinomoto Switzerland Ag

Coca-Cola

Danone Vitapole

Kraft Foods

Masterfoods

Nestlé Research Centre

Nutrasweet AG

Procter & Gamble Service GmbH

Red Bull GmbH

Roche Vitamins Ltd

Seven Seas Ltd

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