codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 13 **CX/NFSDU 00/13**
March 2000

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-second Session
Berlin, Germany, 19-23 Juni 2000

RECOMMENDATIONS OF THE FAO/WHO EXPERT CONSULTATION ON FOOD CONSUMPTION AND AND EXPOSURE ASSESSMENT OF CHEMICALS: DISCUSSION PAPER ON POTENTIAL FOR THE INCORPORATION OF NUTRIENT INTAKE ASSESSMENT IN A RISK-BASED APPROACH TO ASSIST DECISION MAKING PROCESSES OF CCNFSDU

(Prepared by Australia)

BACKGROUND

1. At the 19th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in 1995, the Committee agreed that: "Australia would prepare a paper on the role of dietary modelling for nutrients for consideration by the 20th Session". Discussion on the issue was deferred from the 20th Session to await recommendations from the Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals later held in Geneva in 1997 (1997 Geneva Consultation)[1]. The 42nd CCEXEC Session then requested clarification from CCNFSDU on this matter expressing a view that consideration of dietary models for nutrient intake did not appear to be consistent with the Committee's mandate.

2. A preliminary paper 'Dietary modelling of nutrient intakes', prepared by Australia in 1996 for the 20th session was presented at the 21st Session of CCNFSDU in 1998 (CX/NFSDU 98/10). The meeting again deferred discussion, however, requesting that a revised paper be prepared by Australia on the application of the recommendations from the 1997 Geneva Consultation to the work of the Committee, for consideration at this Session.

3. This paper provides a brief outline of the outcomes of the 1997 Geneva Consultation and discusses a possible broader role for nutrient intake assessments within a risk-based

1 FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals, WHO Headquarters, Geneva, 10-14 February 1997.

approach to assist CCNFSDU's decision making in relation to setting international food standards. It is noted that CCNFSDU has no guidelines for risk analysis procedures for developing food standards.

4. The terminology used in this paper has been adopted by Codex to describe the risk analysis process (Appendix 1, Glossary of terms). The term 'dietary modelling' used in Australia's previous paper, is not defined by Codex but refers simply to the process of conducting dietary exposure assessments, including nutrient intake assessments[2].

INTRODUCTION

5. This paper is divided into four sections to discuss the following:

    - a risk-based approach for Codex food standards setting;
    - recommendations from the 1997 Geneva Consultation relevant to CCNFSDU;
    - nutrient intake assessments, including food consumption and food composition data; assumptions and uncertainties in constructing dietary models; and
    - a potential role for nutrient intake assessments within a risk-based approach to decision making at CCNFSDU.

RISK-BASED APPROACH FOR CODEX FOOD STANDARDS SETTING

6. The World Trade Organization (WTO) was established in 1995, with Member countries being signatories to the Sanitary and Phytosanitary (SPS) Agreement and Technical Barriers to Trade (TBT) Agreement. These agreements place obligations and responsibilities on countries to ensure that food standards developed by them do not create unnecessary and arbitrary barriers to international trade. The WTO referenced the Joint Food and Agricultural (FAO)/World Health Organization (WHO) Codex food standards system in the SPS Agreement as representing the international consensus for food standard regulation.

7. In practice, this means that Member countries should have a clear justification on public health and safety grounds, based on sound science, for setting standards or any other measures that are more stringent than Codex standards, where these international standards exist.

8. As a result of the SPS agreement, there is also agreement at both national and international levels that maximum permitted levels of food chemicals[3] be set using scientific principles of risk assessment and management. These scientific principles have been established in a series of FAO/WHO consultations on risk analysis as outlined below.

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2 The terms 'total exposure' and 'dietary exposure' are now commonly used for other food chemicals such as food additives, pesticide residues or contaminants, to denote total intake of these chemicals from all routes or intake from the diet only. Although the term 'dietary exposure' can be applied to nutrients, the terms 'total nutrient intake' and 'nutrient intake from the diet' are retained in this paper in accord with convention, but the term 'food consumption' is used instead of 'food intake'.

3 The term 'food chemicals' includes food additives, contaminants, pesticide and veterinary drug residues and nutrients, as used in the 1997 Geneva Consultation.

1997 GENEVA CONSULTATION

9. The 1997 Geneva Consultation was the fourth in a series of consultations sponsored by FAO and WHO related to risk analysis and food safety (FAO/WHO 1997a). Other consultations in this series examined the application of risk analysis[4] to food standards issues (FAO/WHO 1995a); the revision of the guidelines for predicting dietary intake of pesticide residues (FAO/WHO 1995b); the application of risk management to food safety matters (FAO/WHO 1997b); and risk communication (FAO/WHO 1998).

10. Representatives from several Codex committees, including food additives and contaminants (CCFAC), pesticide residues (CCPR), veterinary drugs (CCRVDF) and nutrition (CCNFSDU) participated in the 1997 Geneva Consultation. The five objectives identified for that meeting were:

    - to review, and if necessary, revise the five regional diets used by the WHO GEMS/Food Program for dietary exposure assessment conducted at the international level;
    - to further develop acute dietary exposure assessment methodology, particularly for application to pesticide residues, including the generation of a data base for large portion weights;
    - to promote a consistent approach to national and international dietary exposure assessment across different food chemicals;
    - to promote consistency and transparency in the conduct of dietary exposure assessments; and
    - to give special consideration to the needs of developing countries in relation to dietary exposure assessment.

11. As the objectives indicate, the 1997 Geneva Consultation emphasised dietary exposure assessments for pesticide residues, given that dietary exposure assessments are conducted routinely for pesticide residues and the dietary exposure methodology was most advanced for these food chemicals. Notwithstanding this emphasis, general procedures for dietary exposure assessments were developed relevant to all food chemicals, including nutrients. Of the five objectives outlined above, recommendations from the last three are most relevant to CCNFSDU.

Harmonisation issues

12. The 1997 Geneva Consultation made recommendations to ensure that the overall approach to dietary exposure assessment is rational, consistent across different Codex committees and makes the best use of available information. Although the procedures used may differ for different food chemicals, it was recognised that all estimates of dietary exposure are based on a common methodology in which food consumption data are integrated with food chemical or nutrient content data and the results adjusted for bodyweight.

13. It was also recognised that an important function of exposure assessments carried out at the international level is to screen food chemicals and to identify those that raise potential public

4 Although risk analysis is made up of three components, namely, risk assessment, risk management and risk communication, the 1995 consultation mainly focused on risk assessment.

health and safety concerns. The 1997 Geneva Consultation therefore recommended that the terminology used in its Report in relation to dietary exposure assessment be used in all relevant Codex committees, including CCNFSDU. Also, that dietary exposure assessments be conducted in a consistent and scientific manner so as to standardise dietary exposure assessment procedures and to satisfy the SPS Agreement.

14. The 1997 Geneva Consultation also noted that although international dietary exposure assessments are useful for those countries with no capacity to undertake national dietary exposure assessments, such exposure assessments could not be used to estimate actual dietary exposures to food chemicals (including nutrients) for individual countries or for specific population subgroups.

Consistency and transparency of dietary exposure assessments

15. The 1997 Geneva Consultation recognised that the process of dietary exposure assessment and risk management is iterative in nature and requires good communication between the risk assessor and the risk manager. Communication from risk managers should provide sufficiently detailed explanations of risk assessment policy, whereas risk assessors should adequately describe the quality and quantity of data supporting exposure assessment. Additional guidance on the form and presentation of such information may need to be developed.

16. For nutrient risk assessment, a recent report from the United States National Academy of Sciences on 'Risk assessment models for establishing upper levels for nutrients' emphasised that documentation of uncertainties associated with the results is particularly important because of the variability in nutritional risk due to physiological changes according to life stage (growth, maturation) that may affect sensitivity to nutritional risk (NAS 1998). In addition, information about assumptions used in the risk assessment in relation to factors such as bioavailability, effect of nutrient-nutrient interactions, nutritional status and the form of intake is required (NAS 1998).

Consideration of developing countries

17. The 1997 Geneva Consultation recognised the special requirements of developing countries: first, to learn the procedures proposed for dietary exposure assessment and second, to apply that knowledge utilising the available resources and personnel. Specific recommendations were made regarding the need for assistance at the international level and for better integration of developing country participation into the Codex standard setting processes.

NUTRIENT INTAKE ASSESSMENTS

18. A total nutrient intake assessment estimates the total nutrient intake from all sources (food, water and non-food sources such as dietary supplements or pharmaceuticals) then assesses that estimate against reference health standards. Such assessments may be conducted at the local, national or international level. Some of the key issues affecting international nutrient intake assessments are discussed below.

International risk assessments

19. The 1997 Geneva Consultation recognised that Codex was unlikely to undertake international nutrient assessments because of the problems associated with a lack of internationally recognised reference health standards for nutrients and the lack of detailed food consumption or food composition databases available for collation at international level (p20, 1997 Report). It was noted, however, that FAO has developed procedures for the use of food balance sheet (FBS) data in estimating nutrient intakes from raw commodities at a global or regional level for other policy-making purposes.

Reference health standards

20. There are no internationally agreed reference health standards for nutrients other than Nutrient Reference Values for the purposes of nutrition labelling (Codex 1993, CX/NFSDU 98/8). To date, only national reference health standards have been set, recognising that population nutritional needs vary according to factors such as nutritional status. It is recognised in economies such as United States (US), Canada and the European Union (EU) that dietary intakes of nutrients may range from sub-optimal amounts to potentially toxic amounts and that a range of national reference nutrient standards is more appropriate than a single reference standard. For example, reference health standards may be set for sub-optimal nutrient intakes, estimated average requirements, recommended daily intakes/dietary allowances and tolerable upper levels of intake (NAS 1998).

21. Only the latter type of reference health standard, tolerable upper levels of intake, is derived from toxicological data, and is thus similar to reference health standards used for other food chemicals, such as acceptable daily intakes (ADIs) for food additives, pesticide and veterinary drug residues or provisional tolerable weekly or daily intakes (PTWI/PTDIs) for contaminants. A fundamental difference between nutrients and the other food chemicals however, is recognised in the 1998 NAS report: "*within a certain range of intakes many nutrients are essential for human well-being and usually for life itself*". Furthermore, because evidence of the safety of nutrient intakes is generally available for humans, the uncertainty factors applied to no observable (adverse) effect levels (NOAELs) are much lower for nutrients than those applied for other food chemicals (NAS 1998).

Sources of food consumption data

22. The 1997 Geneva Report states "*the primary requirement for consumption data at the international level for chronic (long term) dietary exposure assessments is that it should take into account the differences in food consumption patterns, both within and among countries*". At an international level, the main source of food consumption data are the WHO regional diets, derived from FBS data for raw commodities submitted by Member countries to FAO.

23. The 1997 Geneva Consultation recommended these regional diets be updated and used for international risk assessments of contaminants, pesticide and veterinary drug residues because food standards for these chemicals are set for raw, not processed, commodities. Conversely, raw commodity data were recognised as not necessarily being appropriate for dietary exposure assessments of food additives or nutrients for food-standard-setting

purposes. In assessing nutrient risk, for example, data are also needed on the consumption and nutrient composition of mixed foods, including processed foods.

24. Food consumption data for foods 'as eaten' are generally available only at the national or local level within a country. Such data sets may include individual dietary records. Data sets on pharmaceutical or nutrient supplement intake, or the mineral content of water supplies are rare even at national level so that few countries could conduct a total nutrient intake assessment.

Sources of food composition data

25. In the case of international nutrient risk assessment, no centrally collected databases of nutrient content of foods are available. Given the many factors that affect nutrient content of foods such as climate, soil type, species, processing and preparation methods, it is generally considered feasible to collect nutrient composition data only at national level. It is noted, however, that FAO previously has collated regional food composition tables that may be useful for countries unable to conduct their own national food composition programs.

Nutrient risk assessments

26. The 1997 Geneva Consultation noted that for some nutrients "*the difference between suboptimal intakes, which are likely to lead to nutrient deficiency, and exposure leading to toxicity is small. In these cases, the dietary exposure assessment method should be such that the level of uncertainty in the food consumption or nutrient composition data and resulting dietary exposure assessment does not exceed the difference between suboptimal and toxic nutrient exposures. This may require the use of individual consumer intake data. For some populations, exposure to micronutrients from consumption of supplements or their use as food additives may also need to be considered in dietary exposure assessments, although the bioavailability of nutrients from these sources may not be the same as from natural food sources*". Reliance on food consumption as the sole source of nutrients may underestimate total nutrient intake.

27. The 1997 Geneva Consultation noted that many of the procedures developed for the risk assessment of other food chemicals could be applied to nutrients (p20 1997 Report). However, the approach for all other chemicals tends to overestimate dietary exposure because a 'worst case scenario' is used in assessing the potential risk of exceeding a reference health standard derived from toxicological data. Although this approach could be taken to estimate the risk of exceeding a tolerable upper level of nutrient intake, it is likely to be invalid for the assessment of risk of nutrient inadequacy because of the overestimation of intake inherent in the method. There is also the proviso, quoted above, that for some nutrients, individual food consumption data records are required for risk assessment of nutrients. Such data are only available at a national level or local level in a limited number of countries.

POTENTIAL ROLE OF NUTRIENT INTAKE ASSESSMENTS IN A RISK-BASED APPROACH TO DECISION MAKING AT CCNFSDU

28. In general, Codex food standards that determine maximum limits of specified chemicals in food are set where the following criteria are met:

- the existence of public health and safety concerns regarding the level of the chemical in the food, based on a scientific risk assessment; and
- significant amounts of a processed food or a raw commodity are moving in international trade.

For nutrients in particular, Codex also provides general principles for the addition of essential nutrients to foods for the purposes of restoration, nutritional equivalence of substitute foods, fortification and ensuring the appropriate nutrient composition of a special purpose food (CAC 1991).

29. There appear to be some instances in the work of CCNFSDU where a risk-based approach may be required to assess the risk of exceeding a tolerable upper level of intake: setting maximum nutrient levels in vitamin and mineral supplements or setting maximum levels of nutrient content in specific foods such as infant formula, infant cereals or foods for special medical purposes. In such cases, a formal risk assessment could be undertaken using the agreed FAO/WHO principles of risk analysis.

30. Such a risk assessment process requires the use of internationally agreed reference health standards for the tolerable upper levels of the nutrients to ensure the proposed maximum levels of nutrients for dietary supplements or foods in Codex food standards would not cause a potential risk for populations in Member countries, due to different consumption patterns.

31. It would not be appropriate to conduct international risk assessments when developing nutrient fortification standards, where fortification is defined as *"the addition of one or more essential nutrients to food, whether or not it is normally continued in the food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups"* (CAC 1991). The Codex guidelines for the addition of nutrients to foods state clearly, that in such cases of nutrient deficiency that *"fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area"* (CAC 1991).

Responsibility for risk assessment processes

32. Risk assessment consists of four components: (1) hazard identification, (2) hazard characterisation, (3) exposure assessment, and (4) risk characterisation (FAO/WHO 1995a). For food chemicals other than nutrients, the first two steps of risk assessment (steps 1 and 2) are conducted at the international level by expert committees: the Joint Expert Committee on Food additives (JECFA) sets ADIs for food additives, veterinary drug residues and PTWI/PTDIs for contaminants, and the Joint Meeting on Pesticide Residues (JMPR) sets ADIs for pesticide residues. Dietary exposure assessments (steps 3 and 4) are also conducted by these committees. Results of these risk assessments are then presented to the relevant Codex committee (CCFAC, CCRVDF or CCPR) for risk management decisions.

33. In general, dietary exposure assessments may be conducted at the international level for pesticide and veterinary drug residues and contaminants, using food consumption data as reported in the WHO GEMS/Food regional diets (raw commodities). JECFA issues

additional data calls for national food additive and contaminant dietary exposure assessments to assist in its evaluations.

34. It should be noted that the CCNFSDU has no equivalent expert committee to support its food standards work; either to set internationally agreed tolerable upper levels of intake for nutrients or to conduct nutrient risk assessments to inform the risk management decisions taken by CCNFSDU.

35. National nutrient risk assessments could be submitted directly to CCNFSDU to substantiate relevant Member country comment on proposed food standards, or CCNFSDU could consider establishing a group of technical experts with responsibility for evaluating national nutrient intake assessments. This latter approach has resource implications for CCNFSDU, particularly because there is no foreseen supporting expert committee for Codex work on nutrition standards.

36. As discussed previously, responsibility for assessing the risk of exceeding reference nutrient standards in cases of developing fortification standards would appear to be at a national level. Such national assessments would be derived from national dietary surveys, preferably with access to individual dietary records, integrated with the proposed Codex nutrient levels and assessed against national reference nutrient standards. In other cases where maximum nutrient levels are proposed by CCNFSDU, responsibility could be taken at the international level but there are currently several limitations on conducting international nutrient intake assessments: the absence of international reference health standards for nutrients, and/or the absence of appropriate regional diets and contemporary food composition databases.

37. CONCLUSION

38. This paper has outlined recommendations relevant to the CCNFSDU from the 1997 FAO/WHO Consultation on Food Consumption and Exposure to Chemicals, held in Geneva. The potential for a risk-based approach to setting food standards within CCNFSDU is discussed, including the role of nutrient intake assessments.

39. It is concluded that such a risk-based approach may be required for CCNFSDU to meet WTO obligations, for example, when setting maximum nutrient levels in vitamin and mineral supplements, or maximum nutrient content levels in foods cereals moving in international trade, such as infant formula or infant.

40. In cases of setting fortification levels or minimum requirements, such as a minimum level for thiamin in infant formula, international nutrient intake assessments may not be appropriate or feasible because of the variability in nutrient composition of similarly-described foods across countries, the lack of regional diets that include processed food consumption and the lack of appropriate international reference nutrient standards (sub-optimal intakes, estimated average requirements or recommended daily intakes).

RECOMMENDATIONS

41. It is recommended that CCNFSDU:

- continue to explore the potential for establishing international reference standards for nutrients (tolerable upper levels of nutrient intake) for the purposes of risk analysis, to be used during the course of development of Codex food standards; and
- request Member countries to submit national nutrient risk assessments that indicate the potential impact of adopting proposed Codex standards on their population, taking into account food consumption patterns. Comment could include an assessment of the potential risks for their populations or sub-populations of exceeding upper tolerable levels of intake in relation to proposed maximum nutrient levels in food standards or , when proposing minimum nutrient levels, the risk of not reaching sub-optimal intakes, estimated average requirements or national recommended daily intakes. Comment from Member countries of this nature would assist in relevant standards development.

If the above recommendations were adopted, then it is further recommended that CCNFSDU:

- facilitate the development of guidelines for national risk assessments to promote a consistent and transparent approach to nutrient intake assessments and to provide guidance to developing countries; acceptance of this recommendation foreshadows the need to convene in the future either a working group within CCNFSDU or an ad-hoc expert consultation; and
- consider the requirement for a working group within CCNFSDU to evaluate complex nutrient risk assessment submissions from Member countries.

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Appendix 1

GLOSSARY OF TERMS

(Adapted from Report of the 1997 Geneva Consultation with the definitions for risk analysis adopted by CAC[5])

Acceptable daily intake (ADI)

The ADI of a chemical is the estimate of the amount of a substance in food and/or drinking-water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation. It is usually expressed in milligrams of the chemical per kilogram of body weight.

Exposure assessment

The qualitative and/or quantitative evaluation of the likely intake of biological, chemical or physical agents via food as well as exposure from other sources if relevant.

Food consumption

Food consumption is an estimate of per capita quantity of a food or group of foods eaten by a specified population over a defined period of time. Food consumption is expressed in grams of food per person per day.

Hazard

A biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard characterization

The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological and physical agents, a dose-response assessment should be performed if the data are obtainable.

Hazard identification

The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or groups of foods.

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5 Codex Alimentarius Commission Procedural Manual 10 ed pp 44-45, Rome 1997 and Risk Analysis 1, and Definitions Related to Risk Management CX/GP 98/3, except for the risk communications and risk management definitions that were revised in 1999, refer to 23rd CAC, ALINORM 99/37, Appendix 1V, 1999.

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

JECFA is the abbreviated title of the Joint FAO/WHO Expert Committee on Food Additives, which has been meeting since 1956. JECFA has been engaged in collecting and evaluating scientific data on food additives and making recommendations on safe levels of use. This has been accomplished (a) by elaborating specifications for the identity and purity of individual food additives that have been toxicologically tested and are in commerce and (b) by evaluating toxicological data on these food additives and estimating acceptable intakes by humans.

In 1972 the scope of the evaluations was extended to include contaminants in food, while in 1987 the scope was extended even further to include residues of veterinary drugs in food. When evaluating the latter compounds, maximum residue limits are recommended based upon acceptable intakes estimated by the Committee and data relating to good practice in the use of veterinary drugs.

Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

JMPR is the abbreviated title for the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. Their meetings are convened annually. The FAO Panel of Experts is responsible for reviewing residue and analytical aspects of pesticides, including data on their metabolism, fate in the environment, and use patterns and for estimating the maximum residue levels and supervised trials median residue levels that might occur as a result of the use of the pesticide according to good agricultural practice. The WHO Core Assessment Group is responsible for reviewing toxicological and related data on the pesticides and, when possible, for estimating acceptable daily intakes (ADIs) and long-term dietary intakes of residues. As necessary, acute reference doses (acute RfDs) for pesticides are estimated along with appropriate estimates of short-term dietary exposure.

No-observed-adverse-effect level (NOAEL)

The NOAEL is the highest dose of a substance that does not cause any detectable toxic effects in experimental animals and is usually expressed in milligrams per kilogram of body weight per day.

Provisional tolerable weekly intake (PTWI)

The provisional tolerable weekly intake (PTWI) is the reference value, established by JECFA, used to indicate the safe level of intake of a contaminant. The PTWI is calculated on a weekly basis for contaminants, which may accumulate in the human body over time, in order to minimise the significance of daily variations in intake. This value generally applies to contaminants such as lead, cadmium and mercury many contaminants. The PTWI is a primary health standard which applies to total exposure, ie, both food and non-food sources. The contribution from non-food exposure, therefore, has to be taken into account when comparing food sources with the PTWI.

The tolerable intake is also generally referred to as ‘provisional’ since data on the consequences of human exposure at low levels is often insufficient, and new data may result in a change to the tolerable level.

Provisional tolerable daily intake (PTDI)

The provisional tolerable daily intake (PTDI) is the reference value, established by JECFA, used to indicate the safe level of intake of a contaminant. The PTDI is calculated on a daily basis for contaminants which do not accumulate in the human body, such as arsenic. The PTDI is a primary health standard which applies to total exposure, ie, both food and non-food sources. The contribution from non-food exposure, therefore, has to be taken into account when comparing food sources with the PTDI.

The tolerable intake is also generally referred to as 'provisional' since data on the consequences of human exposure at low levels is often insufficient, and new data may result in a change to the tolerance level.

Recommended daily intake (RDI)

Recommended Daily Intakes (RDIs) is the level of intake of an essential nutrient considered on the basis of available scientific knowledge to be adequate to meet the known nutritional needs of practically all healthy people. RDIs for nutrients were originally developed to assess the adequacy of total diets for populations and not to assess the adequacy of the diets of individuals. For this reason, and because nutrient requirements differ between individuals of the same age, sex and physiological state, RDIs are set at a level which exceeds the requirements of virtually all healthy people in a given age and sex group, that is, they incorporate safety margins to accommodate variations in absorption and metabolism.

Regional diet

In the context of the 1997 Geneva Report, a regional diet is one of the several model diets prepared by GEMS/Food to represent a regional group of countries in which the quantitative consumption of major food commodities is similar. Regional diets are based on data derived from FAO Food Balance Sheets. As certain regional diets can also represent cultural groups, populations that share the same regional diet need not be in the same geographical region.

Risk analysis

A process consisting of three components: risk assessment, risk management and risk communication.

Risk assessment

A scientifically based process consisting of the following steps: (I) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Risk characterization

The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Risk communication

The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk management

The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.