terize the risks for those groups. Such risk characterizations can serve as examples for detailed risk assessments by governments.

Potential intake is an integral component of the Procedure for the Safety Assessment of Flavouring Agents adopted by the Committee at its forty-sixth meeting (Annex 1, reference *122*). When the Committee establishes an ADI "not specified" for a food additive, the potential intake of the additive is also considered to ensure that consumers are unlikely to be exposed to concentrations greater than that associated with no appreciable risk when the additive is used in accordance with good manufacturing practice for its technological function. Potential intake is determined on the basis of the probable use of the food additive at the time of assessment, which may change subsequently. As stated in section 2.2.4 of the report of the thirty-ninth meeting of the Committee (Annex 1, reference *101*), a food additive should be referred to the Committee for re-evaluation when new uses that would significantly increase its intake are envisaged. It is critical that the uses on which the ADI "not specified" is based be well documented by the scientific committee concerned.

Specifications of identity and purity are integral to assessing the risk associated with the use of food additives. Such specifications make it possible to define the product that was tested toxicologically; they also include requirements for the identity and purity of the additive. Specifications proposed by the Expert Committee are considered by the Codex Committee for adoption as "Codex Advisory Specifications", which are used in risk management to ensure the appropriate purity of the product in commerce.

The assessments of food additives and of contaminants differ fundamentally, primarily because food additives, which generally show little toxicity, are deliberately added to food to confer specific benefits, whereas contaminants (except for micronutrients) are of no benefit. Food additives can be controlled easily, while the elimination of contaminants from foods often incurs costs which may result in a reduction in the availability and/or affordability of foods. Thus, different terms are used for the two, the word "tolerable" being considered more appropriate for the intake of contaminants that are unavoidably associated with the consumption of otherwise wholesome, nutritious foods (Annex 1, reference *76*).

Conservative assumptions are made in establishing ADIs to ensure that intake up to the maximum value of the ADI represents no appreciable risk. This process is described in *Principles for the safety assessment of food additives and contaminants in food* (Annex 1, reference *76*). In those rare instances in which long-term intake

exceeds the ADI, the risk may not be negligible, but it is difficult to quantify since the available data on adverse effects in humans are usually not sufficient to define a dose–response relationship.

Risk assessments of contaminants

The Expert Committee agreed that the relationship between the intake of contaminants and the probability of an adverse response in humans should ideally be identified in the risk assessment process. If the risk is adequately documented and explained, risk managers can use the assessment to decide on the appropriate degree of protection that can reasonably be achieved for the population of concern on the basis of the levels of intake and a comparison of the risks and of the risks in relation to the benefits. The Expert Committee used this approach at its forty-ninth meeting (Annex 1, reference *131*), when it estimated the carcinogenic potency of aflatoxins in individuals infected with hepatitis B virus and in uninfected persons. The risks for the population were calculated on the basis of the available information on the intake of aflatoxins and hypothetical standards. The calculations were presented as examples. In regard to those examples, risk managers should base national standards for aflatoxin contamination on the patterns of consumption and contamination of foods and the incidence of hepatitis B viral infection in their countries, and on the Expert Committee's estimates of carcinogenic potency. They should keep in mind that the population risks calculated in the report are only indicative of the range of potential risks.

Although the relationship between intake and the probability of an adverse response should be determined for contaminants, this is usually difficult in practice because of the paucity of quantitative data on the relationship between intake and the incidence of effects in humans, which are necessary to provide confidence in any observed association between intake and response. For this reason, the Expert Committee will probably continue to establish tolerable intakes for some contaminants for the foreseeable future, as was done for zearalenone at the present meeting. Adherence to a defined tolerable intake may not always be feasible, for instance because it results in removing a major, nutritious food item from the local diet. Risk managers must therefore closely consult the results of the Expert Committee's evaluations in order to appreciate the risks associated with high levels of intake.

The Expert Committee sometimes recommends an "irreducible level" for a food contaminant, which it has defined as "that concentration of a substance which cannot be eliminated from a food without

involving the discarding of that food altogether, severely compromising the ultimate availability of food supplies" (Annex 1, reference *76*). The Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues (*3*) referred to this concentration as ALARA (as low as reasonably achievable). Although the risk is not quantified, the general nature and, when possible, the magnitude of the potential risks for toxic effects due to intake are described in the report of the Expert Committee evaluating such substances. Possible control measures are often given, which are among those that risk managers should consider in establishing standards. When providing such qualitative information on toxicity and possible control options, the Expert Committee performs a risk assessment function.

The acceptable or tolerable intake is an indication of both the magnitude and the duration of acceptable intake. Unless otherwise indicated, the ADI refers to the average daily intake over the lifetime of an individual. Tolerable intakes are expressed on a weekly basis (provisional tolerable weekly intake or PTWI) for contaminants that accumulate in the body and whose toxicity is associated with long-term intake, whereas they are expressed on a daily basis (provisional maximum tolerable daily intake or PMTDI) for contaminants that are not known to accumulate in the body and which are of concern when consumed in high quantities over a short period. These end-points should be compared with the results of surveys of intake of appropriate duration in the assessment of risk.

Risk assessment policy

The Expert Committee agreed with the Codex Committee on Food Additives and Contaminants that risk assessment policy is an important component of risk analysis. Such policies should be reviewed to ensure that they serve the needs of the Codex Alimentarius Commission. All parties should be aware that this is particularly difficult at the international level because the Expert Committee responds to requests for evaluation not only from the Codex Alimentarius Commission but also directly from FAO and WHO and from their Member States.

The Expert Committee considered that most of the risk assessment policies identified by the Joint FAO/WHO Consultation on Risk Management and Food Safety (*4*) represent principles that should be established by risk assessors. For example, the Expert Committee considered that the magnitude of safety factors is a matter of scientific judgement. The safety factors most appropriate for meeting the Committee's goal of establishing levels of intake that represent no appreciable risk vary, depending on the quality and quantity of the

available toxicological data and data on chemical analysis and intake. Application in the risk assessment process of an additional, non-scientific factor to protect infants and children, for example, would override the use of scientific judgement based on the available data. An implicit risk assessment policy that has been in effect with regard to food additives for many years is that the Expert Committee should establish ADIs that represent no appreciable risk over a lifetime. The Expert Committee is responsible for deciding on the appropriate safety factor in order to accomplish that goal.

2.3 Principles governing the toxicological evaluation of compounds on the agenda

In making recommendations on the safety of food additives, food ingredients, flavouring agents and contaminants, the Expert Committee took into consideration the principles established and contained in Environmental Health Criteria, No. 70, *Principles for the safety assessment of food additives and contaminants in food* (Annex 1, reference *76*) as well as the principles elaborated subsequently at meetings of the Committee (Annex 1, references *77*, *83*, *88*, *94*, *101*, *107*, *116*, *122*, *131* and *137*), including the present one. Environmental Health Criteria, No. 70 (Annex 1, reference *76*) embraces the major observations, comments and recommendations on the safety assessment of food additives and contaminants contained, up to the time of its publication, in the reports of the Committee and other associated bodies. The Committee noted that the document reaffirms the validity of recommendations that are still appropriate and points out the problems associated with those that are no longer valid in the light of modern technical advances.

2.4 Food allergies

The primary role of the Committee is to evaluate the safety and assess the risks associated with consumption of food additives and contaminants, and it has elaborated principles and guidelines for that purpose (Annex 1, reference *76*). In general, it has not evaluated specific foods or commodities and has not developed general principles to do so. The Expert Committee was, however, asked by the Codex Committee on Food Labelling at its Twenty-sixth Session in 1998 to consider draft recommendations for the labelling of foods that can elicit hypersensitivity reactions (*8*).

In response, WHO convened an ad hoc Panel on Food Allergens in February 1999 that considered and prepared recommendations on the following points:

- the identification of criteria for adding foodstuffs to the list of common allergenic foods developed by the Codex Committee on Food Labelling, if found to be necessary;
- the development of criteria for identifying products of foodstuffs on the Codex Committee's list for which labelling of the food source is unnecessary; and
- consideration of ways in which FAO and WHO could provide continued guidance in this area to the Expert Committee.

The report of the Panel is attached as Annex 4.

The Expert Committee considered the Panel's report and recommendations and concluded that the scientific criteria given for adding foodstuffs to the Codex Committee's list of common allergenic foods and for identifying food products to be excluded from the list form a suitable basis for addressing the allergenicity of food and food products. The Expert Committee agreed that advice from specialists would be essential in addressing future requests of this nature.

The Expert Committee noted that the report of the Panel addresses issues of both risk assessment and risk management, but it considered that only the former was in its purview. Therefore, once the Expert Committee has evaluated the allergenic risk, it is for the Codex Committee to determine the appropriate risk management.

2.5 Principles governing assessments of the intake of contaminants

Assessments of the dietary intake of contaminants may form part of an estimate of total exposure that would include contributions from water and non-dietary sources as well as intake from food. Because an intake assessment is required in order to characterize the risk associated with consumption of contaminants in foods, the Expert Committee established the following principles for assessing intake as part of an assessment of risk. These principles complement the general principles governing intake assessment developed by the Committee at its forty-ninth and fifty-first meetings (Annex 1, references *131* and *137*). The report of the Joint FAO/WHO Expert Consultation on Food Consumption and Exposure Assessment of Chemicals (*9*) contains additional information on the estimation of intake.

The Committee may assess intake over different periods, depending on the toxicological profile of the contaminant being evaluated. An assessment of acute intake refers to intake on a single occasion or a single day. An assessment of chronic intake refers to intake over longer periods.

2.5.1 *Acute intake*

An assessment of the intake of a contaminant that has an adverse effect after a single exposure should also provide a realistic estimate of the intake of a consumer who ingests large amounts of the contaminant, i.e. in the high-percentile range of consumption. Statistically, the combination of data on consumers in the high-percentile range and high concentrations of the contaminant would yield a point estimate of intake that would be higher than that for the whole population. A more realistic assessment can be obtained by making a detailed simulation that includes the entire distribution of short-term food consumption and the concentrations of the contaminant in the foods consumed. In practice, the available data are often inadequate for such an analysis, particularly at the international level, and the objective of the assessment may not require such a detailed evaluation. When a detailed analysis is not appropriate, food consumption by a consumer in the high-percentile range should be combined with a high-percentile concentration of the contaminant in the foods consumed. For assessments of acute exposure to pesticides, for example, use of the 97.5th percentile for both food consumption and residue concentrations has been recommended (*9*). The Committee will determine the most appropriate approach on a case-by-case basis, taking into consideration the objective of the assessment and the available data.

2.5.2 *Chronic intake*

An assessment of the intake of a contaminant that has an adverse effect after long-term consumption should take into account the distribution of long-term food consumption in the population and the mean (average) concentration of the contaminant in the foods consumed. The resulting intake represents the probable lifetime exposure to the contaminant. This principle reflects the likelihood that no consumer of a contaminant would be exposed continually to a higher-than-average concentration of the contaminant throughout the food supply over a lifetime.

A measure of the national intake of a contaminant is derived from national data on food consumption and the concentration of the contaminant. National total diet studies, in which foods that represent the diet of the whole population or of subpopulations at risk are analysed for a contaminant, allow estimates of the intake of contaminants. Mean food consumption in regional diets (such as those described in the WHO Global Environment Monitoring System–Food Contamination Monitoring and Assessment Programme (GEMS/Food)) can be used with representative concentrations of contaminants to derive estimates of intake for broad groups of countries.

Estimates of intake can be adjusted to reflect the proportion of the food supply that is affected and the effects of processing or cooking on the concentrations of residues.

The Committee receives estimates of intake of contaminants and further data relevant for making risk assessments from national governments and other interested parties. The Committee recommended that such submissions include the following:

- a description of the specific chemical form of the contaminant;
- complete descriptions of the foods that contain the contaminant;
- the concentrations of the contaminant in foods as consumed; and
- an explicit description of the values used in an assessment when the concentrations of the contaminant are below the limit of quantification.

2.6 Principles governing the establishment and revision of specifications

2.6.1 *Residual ethanol*

Ethanol is one of several extraction solvents used in the production of various food additives. The specifications for such additives usually include limits for the residues of the solvents. The Committee was requested to consider whether it would be necessary to define a limit for ethanol in such cases. It concluded that from the point of view of good manufacturing practice ethanol should be considered no differently from other extraction solvents, and it reaffirmed the requirement for a limit for residues of all solvents, including ethanol. The Committee noted, for instance, that the existing specifications for two substances, cochineal extract and xanthan gum, indicate that ethanol is used as a solvent in their production but do not include limits for residual ethanol. The specifications for xanthan gum were revised at the present meeting. The Committee decided to postpone its review of the specifications for cochineal extract until its fifty-fifth meeting, to be held in 2000.

2.6.2 *Limit test for heavy metals*

The Committee agreed to implement the decision taken at its forty-ninth and fifty-first meetings (Annex 1, references *131* and *137*) to review and replace the limit test for heavy metals with, as appropriate, limits for individual metals of concern in all existing specifications. In order to accomplish this, the Committee decided to review the existing specifications on the basis of functional use (e.g. antioxidant, preservative), and set a target of 5 years for completion of the task.

The Committee decided to begin by reviewing the limits for heavy metals in emulsifiers at its fifty-fifth meeting, to be held in 2000. The call for data for that meeting will include requests for suggestions about limits for individual heavy metals and supporting data. Once the Expert Committee has considered the submissions, proposals will be submitted for consideration by the Codex Committee on Food Additives and Contaminants for eventual adoption by the Codex Alimentarius Commission.

The Expert Committee reaffirmed its earlier conclusions that it would establish a maximum level of 2 mg/kg for lead and 1 mg/kg for cadmium and for mercury, except when there were good reasons for establishing a lower or higher maximum level. The Committee also reaffirmed its earlier decision to include limits for arsenic only when the source from which the additive is prepared or the nature of the manufacturing method indicated that such a limit was necessary.

The Committee reiterated that replacement of the test for heavy metals by specific limits is intended to ensure that the concentrations of those elements that are likely to be of concern are limited.

2.6.3 *Citation of microbial strains*

At its fifty-first meeting (Annex 1, reference *137*), the Committee revised an addendum to the "General specifications for enzyme preparations used in food processing," which was originally published in Appendix B (General considerations and specifications for enzymes from genetically manipulated microorganisms) to Annex 1 (General specifications for enzyme preparations used in food processing) of the *Compendium of food additive specifications* (Annex 1, reference *96*).

At its present meeting, the Committee further reviewed the specifications for numbering of microbial strains in the light of comments received by the Codex Committee on Food Additives and Contaminants at its Thirty-first Session (*2*).

The Expert Committee reaffirmed that the requirement for identification of a microbial strain by number in the source section of specifications monographs on enzymes prepared from genetically modified organisms might impose unnecessary constraints on the development of organisms for food-grade enzymes. The Committee concluded that the source section of monographs on enzymes derived from non-pathogenic, non-toxicogenic strains that belong to species that include pathogenic and toxicogenic strains should

include the statement that "the strain is non-pathogenic and non-toxicogenic", and a suitable strain number could be included as an example.

The Committee therefore amended the requirement for microbial strain numbers in the specifications section of Appendix B (General considerations and specifications for enzymes from genetically manipulated microorganisms) to Annex 1 (General specifications for enzyme preparations used in food processing) as follows, and decided that this amendment should be published as an annex to the *Compendium of food additive specifications, addendum 7* (*10*).

> *Microbial strain numbers* — Any microbial strain that meets the considerations described above should be a safe and suitable host for the introduced DNA. Citation in the monograph of the genus and species of the host organism is usually adequate for those that have been determined to be safe and suitable. Identification at the strain level may impose unnecessary constraints on the development of production microorganisms used to produce food-grade enzymes. In the case of a non-pathogenic, non-toxicogenic strain that belongs to a species that includes pathogenic and toxicogenic strains (e.g. *Escherichia coli*), there should be a requirement in the monograph that the strain be non-pathogenic and non-toxicogenic. Citation of a suitable strain number may be included by way of example.

The Committee further decided that lack of pathogenicity and toxicogenicity was a general requirement that should apply to all microorganisms used to produce food-grade enzymes. It therefore also agreed to the addition of the following text to the end of the section on source materials of Annex 1 (General specifications for enzyme preparations used in food processing) of the *Compendium of food additive specifications* (Annex 1, reference *96*):

> When a non-pathogenic, non-toxicogenic strain belongs to a species that includes pathogenic and toxicogenic strains, the source section of the monograph for the enzyme should include a requirement that the strain be non-pathogenic and non-toxicogenic. Citation of a suitable strain number may be included by way of example.

The Committee further agreed that the above-mentioned requirement should be extended to all food additives that have been prepared from microorganisms that belong to species that include pathogenic and toxicogenic strains.

2.6.4 *Tentative specifications for food additives*

The Committee noted that many of the older specifications for food additives (other than flavouring agents) published in the