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Fifty-third report of the
Joint FAO/WHO Expert Committee on
Food Additives

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Monographs containing summaries of relevant data and toxicological evaluations are available from WHO under the title:

Safety evaluation of certain food additives and contaminants. WHO Food Additives Series, No. 44, 2000.

Specifications are issued separately by FAO under the title:

Compendium of food additive specifications, addendum 7. FAO Food and Nutrition Paper, No. 52, Add. 7, 1999.

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

The preparatory work for toxicological evaluations of food additives and contaminants by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is actively supported by certain of the Member States that contribute to the work of the International Programme on Chemical Safety (IPCS).

The International Programme on Chemical Safety (IPCS) is a joint venture of the United Nations Environment Programme, the International Labour Organization, and the World Health Organization. One of the main objectives of the IPCS is to carry out and disseminate evaluations of the effects of chemicals on human health and the quality of the environment.

1. Introduction

The Joint FAO/WHO Expert Committee on Food Additives met in Rome from 1 to 10 June 1999. The meeting was opened by Mr G. Orriss, Chief, Food Quality and Standards Service, Food and Nutrition Division, FAO, on behalf of the Directors-General of the Food and Agriculture Organization of the United Nations and the World Health Organization. Mr Orriss noted the large number of substances to be evaluated by the Committee during its meeting and expressed the appreciation of the sponsoring Organizations for the work done before the meeting and that which would be done during the meeting by the participants. The advice and scientific expertise of experts in safety and risk assessments were the cornerstones of the evaluation process. He further noted that the Codex Alimentarius Commission had established principles relating the role of risk assessments of foods to their standard-setting activities. He also noted that the Codex Committee on Food Additives and Contaminants had recently prepared a paper on the application of the principles of risk analysis for food additives and contaminants. As the principal scientific advisory body to that Committee, the Expert Committee was therefore asked to consider and comment on the paper. Mr Orriss stressed the importance of this advisory role to the Codex Alimentarius Commission and asked the Expert Committee to review the paper in detail at the present meeting.

2. General considerations

As a result of the recommendations of the first Joint FAO/WHO Conference on Food Additives, held in September 1955 (*1*), there have been fifty-two previous meetings of the Expert Committee (Annex 1). The present meeting was convened on the basis of the recommendation made at the fifty-first meeting (Annex 1, reference *137*).

The tasks before the Committee were:

— to elaborate further principles for evaluating the safety of food additives and contaminants (section 2.2);
— to undertake toxicological evaluations of certain food additives, flavouring agents and contaminants (sections 3, 4 and 6 and Annex 2);
— to assess the potential allergenicity of refined oils (section 5 and Annexes 2 and 4);
— to assess the intake of certain food additives and contaminants (sections 6 and 7 and Annex 2); and
— to review and prepare specifications for selected food additives (sections 3 and 8 and Annex 2).

2.1 Modification of the agenda

Hydrogenated poly-1-decene was added to the agenda at the request of the manufacturer. Montanic acid esters were removed from the agenda because no data were submitted. Argon, helium and oxygen were not evaluated toxicologically as no data were submitted. Calcium metabisulfite, calcium sulfite and potassium hydrogen sulfite had been on the agenda for the establishment of specifications only but were removed as no data were received and there was no indication that they were used in food.

On the basis of comments received by the Codex Committee on Food Additives and Contaminants at its Thirty-first Session (*2*), the following substances were added to the agenda for the review of the specifications only: α-acetolactate decarboxylase from *Bacillus brevis* expressed in *B. subtilis*, maltogenic amylase from *B. stearothermophilus* expressed in *B. subtilis*, carob bean gum, guar gum, xanthan gum, carotenes (algal and vegetable), nitrogen, riboflavin from *B. subtilis* and sucrose esters of fatty acids.

2.2 The role of the Committee in risk analysis

2.2.1 *Background*

Risk analysis in the context of the Codex system has been considered at three recent FAO/WHO consultations (*3–5*). These consultations outlined the responsibilities of advisory committees such as the Joint FAO/WHO Expert Committee on Food Additives and of committees of the Codex Alimentarius Commission dealing with general subjects, such as the Codex Committee on Food Additives and Contaminants, and clarified their role in the three components of risk analysis: risk assessment, risk management and risk communication.

Risk assessment as outlined in the FAO/WHO consultations consists of four steps: (i) hazard identification; (ii) hazard characterization (dose–response assessment); (iii) exposure assessment; and (iv) risk characterization on the basis of the hazard characterization and exposure assessment. Scientific committees, which are composed of experts serving in their individual capacities as scientists, are responsible for assessing risks whereas Codex committees dealing with general subjects, which consist of government delegates, are responsible for making recommendations for the management of risk. All participants in the risk analysis process together with other interested parties are involved in the communication of information on risk.

Although the FAO/WHO consultations have indicated that risk management should be functionally separate from risk assessment, risk assessors and risk managers (e.g. scientific committees and Codex

committees, respectively) must be able to communicate effectively to ensure that the questions asked by the risk managers are understood and addressed by the Expert Committee, that the risk assessments are clearly described and that the process operates efficiently.

The Joint FAO/WHO Consultation on Risk Management and Food Safety (*4*) concluded that ". . . in the process of assessing substances scientific committees continually need to select and utilize various scientific assumptions", including the following:

— reliance on animal models to establish potential effects on humans;
— scaling of body weights for comparisons between species;
— use of a 100-fold safety or uncertainty factor to account for likely differences in susceptibility between and within species, with guidelines for situations in which deviations from the Acceptable Daily Intake (ADI) are permitted;
— permitting the presence of contaminants at levels "as low as reasonably achievable" (ALARA); and
— establishing temporary ADIs for additives and residues of veterinary drugs where the available data have been incomplete and specific data have been requested for consideration by the Committee at a future meeting.

The Consultation recommended that the Codex Alimentarius Commission define the role of its committees in providing clear, unequivocal guidance for risk assessment to scientific committees. Such guidance should acknowledge the prerogative of scientific committees to make choices in risk assessment, but should provide guidelines for the value judgements and policy choices that may be required, including the choice of safety (uncertainty) factors at specific stages in the risk assessment process. The Codex Alimentarius Commission recommended at its Twenty-second Session that the Codex Committee on Food Additives and Contaminants, in consultation with the Joint FAO/WHO Expert Committee on Food Additives, propose a policy statement on risk assessment that provides such guidelines (*6*).

At its Thirty-first Session the Codex Committee on Food Additives and Contaminants considered a paper on its role in relation to that of the Expert Committee in the risk analysis process (*7*). The paper included a discussion of priorities for work and principles for risk assessment policy and the outcome of risk assessment. It included a number of recommendations to both the Codex Committee and the Expert Committee. The Expert Committee was invited by the Codex Committee to consider the paper; its comments are summarized below.

2.2.2 *Comments of the Committee*

Any request to the Expert Committee for scientific advice must clearly state the reason for the request and outline the probable options for risk management. Clear communication between risk assessors and risk managers is particularly important at the initial stage because of the long delays between meetings of the Codex Committee and the Expert Committee. At its present meeting, the Expert Committee agreed that the outcome of its own assessments and the basis for its recommendations should be clearly documented and should include descriptions of any uncertainties. Clearer communication between the Codex Committee and the Expert Committee would obviate the need for several rounds of communication and increase the value of the advice provided. Procedures should be developed to enhance communication between meetings of the two Committees.

Characterization of risk

The Expert Committee characterizes risk in one of two ways: (i) by quantifying the dose (or range of doses, usually from zero upwards) at or below which there is judged to be no appreciable risk; or (ii) by describing the relationship between intake and the probability of an adverse response in humans. The former process, usually referred to as a "safety assessment", is used by the Expert Committee when allocating ADIs to food additives and tolerable intakes (expressed on either a weekly or a daily basis) to contaminants. The Expert Committee considered that this process constitutes risk assessment: although the ADI and tolerable weekly or daily intake do not represent quantitative estimates of risk, they represent levels of intake at which there is "no appreciable risk" and are used as measures of the safety of a substance when consumed at that level. Hazard is identified and characterized in the process of establishing ADIs and tolerable intakes, and risk is characterized as being not appreciable when intake does not exceed those values. Uncertainty is incorporated into the value by the magnitude of the safety factor.

The information available to the Expert Committee on toxicological and related aspects (such as pharmacokinetics and pharmacodynamics in animals and humans, and information on dose–response relationships) is generally as complete as that available to national governments. In consequence, the hazards, dose–response relationships, no-observed-effect levels (NOELs) and derived ADIs and tolerable intakes characterized by the Committee are applicable internationally. If detailed information on the intake of a substance by various population groups is available, the Committee can charac-