World Health Organization

EXECUTIVE BOARD **EB125/10**
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Expert Committees and study groups[1]

Report by the Secretariat

EVALUATION OF CERTAIN FOOD ADDITIVES

Sixty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives[2]
Rome, 17–26 June 2008

Main recommendations

1. The Committee made recommendations on the safety of several food additives and flavouring agents, and prepared or reviewed specifications for a number of them. It also made several general recommendations, in particular on the principles for the safety assessment of flavouring agents and on the importance of the relationship between the safety assessment and the specifications of food additives.

2. The Committee evaluated several food additives and ingredients, some of them for specifications only. Acceptable daily intakes or other safety advice were established for nine food additives.

3. WHO, in its Food Additive Series,[3] and FAO, in its compendium of food additive specifications,[4] will publish, respectively, summaries of the toxicological and related information on which the safety assessments of the compounds were made, and of the identity and purity of food additives and flavouring agents.

[1] The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken.

[2] WHO Technical Report Series No. 952, in press.

[3] Safety evaluation of certain food additives, WHO Food Additives Series.

[4] Compendium of food additive specifications, FAO Food and Nutrition Paper.

Significance for public health policies

4. The Committee's work identifies and, if possible, quantifies the public health significance of additives, flavouring agents and contaminants in food through an international consensus scientific risk assessment, which highlights the complexity of the process, including collating and analysing all relevant data; interpreting studies of, for instance, general toxicity, carcinogenicity, genotoxicity, reproductive toxicity and teratogenicity; extrapolating to human beings the effects observed in experimental animals; and characterizing hazards to human beings, on the basis of available toxicological and epidemiological data.

5. Although all Member States face the problem of assessing potential risks of chemicals in food, only a few national or regional scientific institutions can assess the relevant toxicological and related data. Member States therefore need to be provided with valid information on both the general aspects of risk assessment and the specific evaluations of food additives and flavouring agents covered in this report. The Committee's complex work in reaching international consensus on the evaluation of these compounds means that no other body has comparable influence on public health decisions related to food safety.

6. The Committee's recommendations are used by the Codex Alimentarius Commission for setting international food safety standards. Such values are established only for substances that have been evaluated by the Committee and allocated an acceptable daily intake, tolerable intake or other relevant safety statement, so ensuring that food commodities in international trade meet strict safety standards.

7. The advice provided by the Committee is also considered by Member States directly when setting national/regional food safety standards.

Implications for the Organization's programmes

8. The evaluation of chemicals in food by the Committee is a continuing activity and four meetings (two on food additives, one on contaminants, and one on residues of veterinary drugs in food) were scheduled for 2008–2009.

9. WHO is a partner in the Joint FAO/WHO Food Standards Programme, which administers the Codex Alimentarius Commission. The Committee's work is crucial for the Commission.

10. Regional offices and WHO Representatives also make use of the Committee's evaluations when advising Member States on food safety regulatory programmes.

WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Forty-third report
Geneva, 13–17 October 2008[1]

Main recommendations

11. The areas covered by this Committee range from good manufacturing practices and regulatory guidance texts (on, for example, interchangeability of medicines, fixed-dose combination products and stability testing) to counterfeit and substandard medicines.

12. The Committee adopted and recommended for use several new standards and guidelines (see Annex), including 24 new monographs for inclusion in *The International Pharmacopoeia* and six related International Chemical Reference Substances. The specifications under development are internationally applicable test methodologies for antimalarial, antituberculosis, and antiretroviral drugs, and specifically also medicines for children. Twenty more individual monographs for radiopharmaceuticals were also adopted subject to final scrutiny by a special working group.

13. The Committee also adopted the revised *Stability testing of active pharmaceutical ingredients and finished pharmaceutical products* after an international consultation process. These new guidelines will provide global stability testing requirements and the definition of storage conditions for worldwide applicability.

14. In order to serve the WHO-managed United Nations Programme on prequalification of medicines, two procedures for evaluation of medicines and of active pharmaceuticals ingredients were adopted.

15. Following the Committee's recommendation, further steps will be undertaken regarding a revision of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce, taking due consideration of all recommendations and comments received during the consultation phase with Member States.

16. In view of the regulatory burden with regard to the increase in the number of inspections, the Committee recommended networking and information sharing among national, regional and other relevant authorities involved in inspections, using a risk-based approach in selection of inspections that is based on increased sharing of information on databases. It was strongly recommended that the databases on international nonproprietary names and quality assurance nomenclature be maintained.

17. Cooperation with WHO on clinical and quality aspects of paediatric formulations and with the Expert Committee on Biological Standardization on reference preparations and other quality assurance-related topics was considered essential in order for WHO to fulfil its mandate in these cross-linking areas.

[1] WHO Technical Report Series No. 953, in press.

18. Based on results of an external assessment scheme carried out under the auspices of the Committee, it was recommended that this series be continued, with greater involvement of WHO regional offices in order to enable capacity building for those laboratories where there were occurrences of doubtful or unsatisfactory results.

Significance for public health policies

19. The international guidelines, specifications and nomenclature developed under the aegis of the Committee serve all Member States, international organizations, bodies in the United Nations system, regional and interregional harmonization efforts, and underpin initiatives such as the prequalification of medicines, the Roll Back Malaria Partnership, Stop TB Partnership, and essential medicines and medicines for children. The advice and recommendations provided by the Committee are intended to help national and regional authorities (in particular drug regulatory authorities), procurement agencies, as well as major international bodies and institutions, such as UNICEF, the Global Fund to Fight AIDS, Tuberculosis and Malaria, to combat problems of counterfeit and substandard medicines and to work towards access to quality medicines.

Implications for the Organization's programmes

20. The Committee's activities are linked to those of several departments across the Organization. There are joint activities, specifically with the WHO Expert Committees on Biological Standardization, and on the Selection and Use of Essential Medicines and its Subcommittee on Medicines for Children. In addition, the Committee serves to develop specific additional guidance and specifications, as required, for the various medicines recommended by WHO's programmes.

21. The Committee also serves the WHO-managed and operated United Nations Programme on prequalification of medicines, as the Programme could not function without the guidelines, standards and specifications adopted by the Committee following the international consultative process. The leading advantage in this process is the feedback for potential revisions or guidance that follows implementation of the guidelines and specifications.

ANNEX

STANDARDS AND GUIDELINES ADOPTED AND RECOMMENDED FOR USE BY THE WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PROGRAMMES

List of available International Chemical Reference Substances.

Stability testing of active pharmaceutical ingredients and finished pharmaceutical products.

Procedure for prequalification of pharmaceutical products.

Procedure for assessing the acceptability, in principle, of active pharmaceutical ingredients for use in pharmaceutical products.

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