

Report on meetings of expert committees and study groups¹

Report by the Secretariat

EVALUATION OF CERTAIN FOOD ADDITIVES AND CONTAMINANTS IN FOOD

**Seventy-second Joint FAO/WHO Expert Committee on Food Additives²
Rome, 16–25 February 2010**

**Seventy-third Joint FAO/WHO Expert Committee on Food Additives³
Geneva, 8–17 June 2010**

Main recommendations

Seventy-second meeting

1. The Committee made recommendations on the risks to health associated with six important contaminants in food (acrylamide, arsenic, deoxynivalenol, furan, mercury, and perchlorate). The report also contains general considerations, in particular on the principles of estimating dietary exposure from epidemiological studies, and on the modelling of dose–response data.
2. Health concerns relating to current estimated levels of intake were identified for acrylamide, arsenic and furan. These assessments will be discussed at upcoming meetings of the Codex Committee on Contaminants in Food to identify and recommend appropriate risk mitigation and management measures to reduce human exposure.

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. 959, 2011.

³ WHO Technical Report Series, No. 960.

Seventy-third meeting

3. The Committee made recommendations on the risks to health associated with two important contaminants (cadmium and lead), and made recommendations on the safety of 12 groups of related flavouring agents. Specifications were prepared or reviewed for additional flavours and food additives. The report also contains general recommendations, in particular on improvement of exposure estimations.

4. WHO published summaries of the toxicological and related information upon which the safety assessments of the compounds were made.¹ FAO published summaries of the identity and purity of food additives and flavours.²

Significance for public health policies

5. The Committee's work identifies and, if possible, quantifies the public health significance of food additives and contaminants through an international consensus scientific risk assessment. Clear recommendations are given if a health concern is identified for action by national governments or through the Joint FAO/WHO Food Standards Programme.

6. Although all Member States face the problem of assessing the potential risks posed by chemicals in food, only a few scientific institutions, on a national or regional basis, systematically assess all relevant toxicological and related data. It is, therefore, important to provide Member States with valid information on both the general aspects of risk assessment and the specific evaluations of contaminants and food additives covered in these reports. The Committee's work, in its complexity and in reaching an international consensus in the evaluation of these compounds, is unique in its importance and impact on global public health decisions related to food safety.

7. The Committee's recommendations are used by the Codex Alimentarius Commission for setting international food standards. Such standards are established only for substances that have been evaluated by the Committee. This ensures that food commodities in international trade meet strict safety standards.

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

Implications for the Organization's programmes

9. The evaluation of chemicals in food by the Committee is an ongoing activity. Three meetings of the Joint FAO/WHO Expert Committee on Food Additives were planned for 2010–2011, two were held in 2010 and one will be held in June 2011, all on food additives and contaminants.

10. WHO is a partner in the Joint FAO/WHO Food Standards Programme, whose principal organ is the Codex Alimentarius Commission. The Committee's work is crucial to the work of the Commission. International standards and recommendations on food additives and contaminants in

¹ WHO Food Additives Series, No. 63 (in press).

² Food and Agriculture Organization of the United Nations. *Compendium of food additive specifications*. Joint FAO/WHO Expert Committee on Food Additives, 72nd meeting, 2010. JECFA Monograph 8. Rome, FAO, 2010.

food developed by the Codex Alimentarius Commission are based on the work of the Joint FAO/WHO Expert Committee on Food Additives.

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

SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

Forty-fifth Expert Committee on Specifications for Pharmaceutical Preparations¹ Geneva, 18–22 October 2010

Main recommendations

12. The Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General and Member States in the area of quality assurance of medicines. It provides recommendations and tools to assure the quality of medicines from their development phase to their final distribution to the patients. Detailed recommendations can be found under each relevant section in the report.

13. The Forty-fifth Expert Committee adopted 25 new monographs and texts for inclusion in *The international pharmacopoeia*. The specifications under development are internationally applicable methods for testing antimalarial, antituberculosis, antiretroviral and radiopharmaceutical medicines, as well as medicines for children. It also approved a new process for adoption of International Chemical Reference Substances to accelerate their availability and release between Expert Committee meetings.

14. In the area of quality control, the Expert Committee responded to the needs of the United Nations Programme on Prequalification of Medicines (managed and operated by WHO) in approving a new *Guidance for pharmaceutical microbiology laboratories*, and revising both the *Procedure for prequalification of laboratories* and *Guidelines for preparing a laboratory information file*,² to be in line with the good practices for pharmaceutical quality control laboratories adopted in 2009.

15. In the series on good manufacturing practices, the main principles were revised; furthermore, revised texts were adopted for such practices in *WHO good manufacturing practices for sterile pharmaceutical products*³ and *Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms*.⁴ Jointly with the Expert Committee on Biological Standardization, the Expert Committee adopted the *Good manufacturing practices for blood establishments* in response to resolution WHA63.12 on availability, safety and quality of blood products, adopted in 2010 by the World Health Assembly. Based on those developed under the Pharmaceutical Inspection Co-operation Scheme, *Guidelines for preparing a site master file* were adopted for use within the context of inspections. New trends have been covered by the newly adopted *Guidelines on transfer of technology in pharmaceutical manufacturing*. In response

¹ WHO Technical Report Series, No. 961 (in press).

² WHO Technical Report Series, No. 917, 2003, Annex 5.

³ WHO Technical Report Series, No. 957, 2010, Annex 4.

⁴ WHO Technical Report Series, No. 937, 2006, Annex 2.

to urgent requests by major aid programmes with a view to overcoming current shortages in malaria medicines, consideration is being given to the preparation of *Quality requirements for artemisinin as a starting material in the production of antimalarial active pharmaceutical ingredients*.

16. Covering the area of distribution and supply, the *Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services* was updated jointly with the International Pharmaceutical Federation, and the *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products* was newly endorsed in a joint effort with the Expert Committee on Biological Standardization.

17. In order to serve the prequalification programme, the *Procedure for prequalification of pharmaceutical products* was revised and the *Guidance on submission of documentation for prequalification of innovator finished pharmaceutical products approved by stringent regulatory authorities* was recommended for use. In a larger context, but also intended for implementation within the prequalification programme, a new *Guideline for submission of documentation for a multisource (generic) finished product* was adopted by the Forty-fifth Expert Committee to facilitate exchange of information by national medicines regulatory authorities.

18. The Committee strongly recommended the continuation of the External Quality Assurance Assessment Scheme for the quality control laboratories series with the involvement of regional offices to enable improvement of the participating laboratories' performance.

Significance for public health policies

19. The international guidelines, specifications, nomenclature and standards developed under the aegis of the Expert Committee since 1947 are designed to serve all Member States, international organizations, programmes, funds and specialized agencies of the United Nations system, and regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, and essential medicines, as well as medicines for children. The advice and recommendations provided by this Expert Committee are intended to help national and regional authorities (in particular, national medicines regulatory authorities), procurement agencies, and major international bodies and institutions, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, and international organizations such as UNICEF – to work towards access to good quality medicines.

20. The activities of the Forty-fifth Expert Committee on Specifications for Pharmaceutical Preparations result in scientifically sound and independent recommendations, written and physical standards, as well as international guidelines for quality medicines. Standards in this area are developed by the Committee following a wide international consensus-building process.

Implications for the Organization's programmes

21. The activities that were discussed during the Forty-fifth Expert Committee have broad intercluster and intracluster relationships and links. 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 needed, for medicines recommended by WHO programmes.

22. The Expert Committee on Specifications for Pharmaceutical Preparations also meets a particular need for the prequalification programme: in order to fulfil its function, the latter requires the international guidelines, standards and specifications that are adopted by the Expert Committee. As a result of the immediate implementation of those guidelines and specifications, practical feedback for clarification, potential revision or the need for additional guidance are communicated promptly to the Expert Committee.

23. Based on the Expert Committee's recommendation, the Organization is in a position to provide updated standards and guidance in the area of medicines quality assurance to the Organization and to relevant external bodies, in response to the need for internationally harmonized approaches as a function of increasing globalization.

24. The recommendations mentioned fully support WHO's objective to assist Member States and other relevant bodies involved in supplying medicines, and in providing tools that will help to ensure the safety, efficacy and quality of medicines for maintaining and improving public health.

ACTION BY THE EXECUTIVE BOARD

25. The Board is invited to note the report.

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