



WORLD HEALTH ORGANIZATION

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Expert committees and study groups¹

Report by the Secretariat

EVALUATION OF CERTAIN FOOD ADDITIVES

**Sixty-third report of the Joint FAO/WHO Expert Committee on Food Additives
Geneva, 8-17 June 2004²**

Main recommendations

1. The Committee made recommendations on the safety of several food additives and flavouring agents. In addition, antimicrobial solutions used for disinfection purposes in the contact with food, and glycyrrhizinic acid, a natural constituent of liquorice, were evaluated. Specifications were prepared or reviewed for numerous food additives and flavours. The report contains also several general considerations, such as recommendations on the principles of intake estimates for flavouring agents; the evaluation of flavour complexes derived from natural sources, and its views on the evaluation of dietary nutrients and other ingredients.

2. The Committee evaluated nine food additives and ingredients toxicologically and established acceptable daily intakes. The Committee considered the safety of antimicrobial solutions (containing peroxyacids) used for disinfection purposes in food contact on a component-by-component basis, and concluded that there is no safety concern. The Committee noted that the use of these antimicrobial solutions does not replace the need for good hygienic practices in the handling and processing of food. Nine further food additives were considered for specifications only, and specifications of the limits for heavy metals were revised for a large number of food additives. A total of 178 flavours in eight different groups were evaluated by application of the decision-tree Procedure for the Safety Evaluation of Flavouring Agents. In addition 21 flavouring agents were considered for specifications only. For glycyrrhizinic acid, a safe level of consumption was established. 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 flavours will be published in the WHO Food Additives Series and as a FAO Food and Nutrition Paper, respectively.

¹ The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report on meetings 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. 928, 2005.

Significance for public health policies

3. The Committee's work emphasizes the public health significance of the risk assessment of additives, flavours, chemical residues in food and natural food components. It highlights the complexity of the process, which includes assembling and analysing all relevant data; interpreting studies on, for instance, carcinogenicity, genotoxicity, reproductive toxicity, and teratogenicity; extrapolating to humans the effects observed in studies with animals; and characterizing hazards to humans based on available toxicological and epidemiological data.

4. Although all Member States face the problem of assessing potential risks of chemicals in food, only a few scientific institutions, on a national or regional basis, can assess the relevant toxicological and related data. Therefore it is important to provide Member States with valid information on both the general aspects of risk assessment and specific evaluations on the additives, flavours, and contaminants covered in this report. The Committee's work, in its complexity and in reaching a consensus among international experts in the evaluation of these compounds, is unique, and no other organization has a comparable importance and impact on public health decisions related to food safety.

5. 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, thereby ensuring that food commodities in international trade meet strict safety standards.

Implications for the Organization's programmes

6. The evaluation of chemicals in food by the Committee is an ongoing activity. Four meetings of the Expert Committee, two on food additives, one on contaminants, and one on residues of veterinary drugs in food, are scheduled in the 2004-2005 biennium.

7. 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 that of the Commission.

8. 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

Thirty-ninth report

Geneva, 25-29 October 2004¹

Main recommendations

9. The Expert Committee made numerous detailed recommendations in the various specific areas of quality assurance work discussed during the meeting. The areas covered are extensive, ranging from

¹ WHO Technical Report Series, No.929, 2005.

good manufacturing practices and regulatory guidance (e.g. regarding the interchangeability of medicines, fixed-dose combination products and stability testing) to counterfeit and substandard medicines. Quality-control specifications and International Chemical Reference Substances were established, focusing on essential medicines and medicines used in the treatment of large populations for which often no international quality requirements are publicly available.

10. The Expert Committee emphasized the need to make sufficient resources available for these core normative functions of WHO so as to enable sustainability and avoid duplication of efforts worldwide. The guidelines, specifications and international nomenclature developed under the aegis of this Expert Committee serve all Member States, international organizations, bodies of the United Nations system, regional and interregional harmonization efforts, and underpin important initiatives, including the “3 by 5” initiative.

11. The Committee strongly recommended that sufficient resources should be made available to enable the prequalification programme to continue, with regard to prequalification of products, quality-control laboratories, update of the procedure and requalification as necessary.

12. The following new standards and guidelines were recommended for use:

list of available International Chemical Reference Substances and International Infrared Reference Spectra;

good manufacturing practices: requirement for the sampling of starting materials;

WHO good manufacturing practices: water for pharmaceutical use;

WHO guideline for sampling of pharmaceutical products and related materials;

draft guidelines for registration of fixed-dose combination medicinal products;

The Committee endorsed inclusion in *The International Pharmacopoeia* of monographs on didanosine, indinavir sulfate, nelfinavir mesilate, nevirapine, ritonavir, saquinavir, and saquinavir mesilate.

Significance for public health policies

13. Access to high-quality drugs is being challenged through new ways of distribution and supply worldwide. Increasing trade and commerce and the new supplying of life-saving drugs by various private and public parties require new approaches to quality assurance internationally, regionally and nationally. Reports of cases of counterfeit and substandard drugs have been increasing in developing and developed countries. Vigorous implementation of good manufacturing practices and good distribution practices is a prerequisite for prevention. However, as proposed by the Committee, international agreements should also be considered in order to strengthen preventive measures.

14. Problems regarding the quality assurance of pharmaceuticals persist, especially the growing incidence worldwide of production, distribution and sale of counterfeit, spurious and substandard pharmaceutical products. A waste of money for the people who buy them, counterfeit and substandard drugs prolong treatment periods, exacerbate the conditions being treated, increase the emergence of drug resistance and can even cause death. The statutory instruments, advice and recommendations provided in the Committee’s report can help national authorities (in particular drug regulatory

authorities), procurement agencies, major international bodies and institutions (such as the Global Fund to Fight AIDS, Tuberculosis and Malaria) and international bodies (such as UNICEF) to combat these problems.

15. The prequalification of medicines and laboratories (and possibly also procurement agencies in the future) could not function without the set of guidelines, standards, specifications and new guidance texts recommended by this Committee after passage through the usual, rigorous consultative process. In return, the prequalification programme provides valuable feedback to the Expert Committee.

16. Another valuable aspect of the prequalification programme is that participating members of drug regulatory authorities obtain practical experience in joint inspections and joint regulatory assessment activities with the participation of both developed and developing countries. This practical side is later taught in training workshops, thereby spreading the benefit further. The special advice given in the inspection reports is of service to manufacturers and quality-control laboratories, and national authorities benefit from the availability of those inspection reports and their regulatory information.

Implications for the Organization's programmes

17. The Organization should continue to promote a comprehensive approach to quality assurance of pharmaceutical products. It should also lead and coordinate international efforts to define and harmonize clear and practical standards and guidelines for pharmaceuticals, particularly in response to increased globalization of trade and supply by third parties.

18. A global approach will enable the Organization to act locally in the area of quality assurance of medicines. Internationally agreed standards in quality assurance will serve specific disease programmes and other international, regional and national efforts.

19. At the same time as the Organization seeks to enhance the rational use of scarce resources and consumers' confidence in health care, its priority goal should be the safety, efficacy and high quality of medicinal products for maintaining and improving public health. Meeting this objective is evidently a constant and rigorous process.

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