

Report on meetings of expert committees and study groups¹

Report by the Director-General

EVALUATION OF CERTAIN CONTAMINANTS IN FOOD

Ninety-first report of the Joint FAO/WHO Expert Committee on Food Additives, virtual meeting,² 1–12 February 2021^{3,4}

Main recommendations

1. The report contains the Expert Committee's evaluations of technical, toxicological and epidemiological data including for the occurrence of and dietary exposure to ergot alkaloids as a food contaminant, the dietary exposure to cadmium from all food sources, the acceptability of one group of substances as previous cargoes and a revision of the specifications on steviol glycosides.
2. The Committee established an acute reference dose and a tolerable daily intake for ergot alkaloids. The Committee estimated that the dietary exposure to ergot alkaloids for some population groups might exceed the health-based guidance value and that this might indicate a human health concern.
3. The Committee concluded that three of the five assessed substances that may occur as previous cargoes meet the criteria for acceptability as previous cargoes.
4. The assessments, recommendations and comments by the Committee will be discussed by the Codex Committee on Contaminants in Food and the Codex Committee on Fats and Oils in order to generate recommendations to national authorities on the safe use of previous cargoes and to identify and recommend appropriate risk management and risk-mitigation measures to reduce human exposure, where necessary.

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 Coordinated from FAO headquarters, Rome.

³ With an additional meeting day on 25 February 2021 for adoption of the report.

⁴ WHO Technical Report Series, No. 1036 (in press).

5. WHO will publish detailed monographs in the WHO Food Additives Series with the toxicological and other related information upon which the safety assessments of the compounds were based.¹ FAO publishes summaries of the identity and purity of previous cargoes and contaminants.

Significance for public health policies

6. The Committee identifies and, where possible, quantifies the public health significance of exposure to chemicals in food – in these cases, contaminants in food – through scientific risk assessment based on international consensus. When a health concern is identified, clear recommendations are issued for action by national governments or through the Joint FAO/WHO Food Standards Programme (the Codex Alimentarius Commission and its subsidiary bodies).

7. The Committee's recommendations are used by the Codex Alimentarius Commission in the development of international food safety standards and other guidance and recommendations. Such standards are science-based and are established only for substances that have been evaluated by the Committee. This ensures that food commodities that are traded internationally meet strict safety standards to protect the health of the consumer and ensure fair practices in food trade.

8. The advice provided by the Committee is also considered by Member States directly when national or regional food safety standards are being established.

9. The Committee's work, in its complexity and in reaching an international scientific consensus on the evaluation of these compounds, is unique in its importance for and impact on global public health decisions related to food safety.

Implications for the Organization's programmes

10. The evaluation of chemicals in food by the Committee is an ongoing activity. Three meetings of the Committee on food additives and two on contaminants in food were held in the biennium 2019–2020.² One more meeting on food additives and another one on contaminants in food are planned for 2022.

11. WHO is a partner in the Joint FAO/WHO Food Standards Programme, whose principal organ is the Codex Alimentarius Commission. In its capacity to assure the sound scientific basis for international standards and recommendations on food additives, contaminants in food and veterinary drug residues in food, the work of the Committee is crucial to the work of the Codex Alimentarius Commission.

12. The Committee's evaluations are also used by Heads of WHO offices in countries, territories and areas and by regional offices when advice is provided to Member States on food safety issues.

¹ Safety evaluation of certain contaminants in food. WHO Food Additives Series, No. 82. Toxicological monographs of the ninety-first meeting (in preparation).

² For more information, see [https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-\(jecfa\)](https://www.who.int/groups/joint-fao-who-expert-committee-on-food-additives-(jecfa)) (accessed 18 October 2021).

EVALUATION OF CERTAIN FOOD ADDITIVES IN FOOD

Ninety-second report of the Joint FAO/WHO Expert Committee on Food Additives, virtual meeting,¹ 7–18 June 2021²

Main recommendations³

13. The report contains the Expert Committee's evaluations of technical, toxicological and epidemiological data, occurrence and dietary exposure data for six food additives (benzoic acid, its salts and derivatives; collagenase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*; β -glucanase from *Streptomyces violaceoruber* expressed in *S. violaceoruber*; phospholipase A2 from *Streptomyces violaceoruber* expressed in *S. violaceoruber*; riboflavin from *Ashbya gossypii*; and ribonuclease P from *Penicillium citrinum*).

14. Specifications for the following food additive were revised: modified starches.

15. The assessments, recommendations and comments by the Committee will be discussed by the Codex Committee on Food Additives in order to generate recommendations to national authorities on the safe use of these food additives and to identify and recommend appropriate risk management and risk-mitigation measures to reduce human exposure, where necessary.

16. WHO will publish detailed monographs in the WHO Food Additives Series with the toxicological and other related information upon which the safety assessments of the compounds were based.⁴ FAO publishes summaries of the identity and purity of food additives.

SELECTION AND USE OF ESSENTIAL MEDICINES

Report of the twenty-third meeting of the Expert Committee on the Selection and Use of Essential Medicines, virtual meeting,⁵ 21 June to 2 July 2021⁶

Main recommendations

17. The Expert Committee reviewed 88 applications proposing amendments to the WHO Model List of Essential Medicines and WHO Model List of Essential Medicines for Children (the Model Lists). The Committee recommended the addition of 20 new medicines to the WHO Model List of Essential Medicines and 17 to the WHO Model List of Essential Medicines for Children. There were 15 medicines or formulations recommended for deletion. A total of 25 applications, involving 28 medicines, proposing amendments to one or both of the Model Lists, were not recommended. Medicines listed on the

¹ Coordinated from FAO headquarters, Rome.

² WHO Technical Report Series, No. 1037 (in press).

³ Note that the significance for public health policies and implications for the Organization's programmes are the same as those for the ninety-first report of the Joint FAO/WHO Expert Committee on Food Additives, outlined above.

⁴ Safety evaluation of certain food additives. WHO Food Additives Series, No. 83. Toxicological monographs of the ninety-second meeting (in preparation).

⁵ Coordinated from WHO headquarters, Geneva.

⁶ WHO Technical Report Series, No. 1035 (in press).

WHO Model List of Essential Medicines and WHO Model List of Essential Medicines for Children now number 479 and 350, respectively.

18. Over a quarter of the applications reviewed were for medicines for treatment of cancer. Four new cancer medicines for treatment of prostate cancer, leukaemia, brain tumours in children and tumour lysis syndrome demonstrating relevant survival benefit were added to one or both of the Model Lists. For the WHO Model List of Essential Medicines for Children, new indications were endorsed for 16 already listed cancer medicines. A total of 12 applications proposing the addition of new, patented, and often extremely highly priced, cancer medicines were not recommended, despite evidence of relevant survival benefit in some cases.

19. Other new recommended additions to the Model Lists include long-acting insulin analogues and new oral hypoglycaemic medicines for treatment of diabetes, two new oral therapies for smoking cessation, a medicine to prevent organ transplant rejection, three dental preparations for tooth decay, two treatments for rabies post-exposure prophylaxis, a micronutrient supplement for use during pregnancy, and medicines for treatment of bacterial and fungal infections, hepatitis C in children, inflammatory skin conditions, migraines and schizophrenia.

20. Other medicines not recommended for listing include methylphenidate for attention deficit hyperactivity disorder, three medicines for juvenile arthritis and injectable formulations of already listed tuberculosis medicines.

21. For all biological medicines included on the Model Lists, the Committee recommended that quality-assured similar biotherapeutic products (biosimilars) should be considered appropriate therapeutic alternatives to the originator medicines for the purpose of national selection and procurement.

Significance for public health policies

22. The Model Lists provide evidence-informed guidance to Member States for developing or updating national essential medicines lists. The Model Lists represent a prioritization tool for the selection, reimbursement, procurement and use of essential medicines at country level, as part of efforts to ensure access to medicines and universal health coverage.

23. Several new medicines added to the Model Lists in 2021, and a substantial number of already listed medicines, are highly priced. The recommendations to list them were based on evidence of effectiveness and safety and on public health relevance. However, prohibitively high prices, specialized diagnostic requirements and likely unsustainable impact on health budgets were also factors in some recommendations not to list otherwise effective and safe medicines. This signals the growing need for global and national strategies and interventions aimed at reducing prices and facilitating affordability and access.

24. The decision to recommend quality-assured biosimilars as therapeutic alternatives to originator biotherapeutics for selection on national essential medicines lists will support countries to implement health and pricing policies to promote the availability and use of affordable, quality-assured biosimilar medicines.

Implications for the Organization's programmes

25. The update of the Model Lists both informs and supports the work of WHO disease programme areas and contributes to delivery of consistent recommendations across the Organization through alignment between the Model Lists and WHO guidelines and other WHO guidance documents.
26. With the addition of long-acting insulin analogues to the Model Lists, the Committee recommended their inclusion in a call for manufacturers to submit expressions of interest for product evaluation in the WHO prequalification programme. Expansion of the WHO prequalification programme to include other highly priced essential biological medicines, particularly in the areas of cancer and autoimmune diseases, has the potential to significantly improve access and affordability of such medicines in low- and middle-income countries.
27. The work of the Committee has been valuably facilitated by specialized expert working groups on antibiotics and cancer medicines. The ongoing activities and contributions of these working groups will continue to support the Committee and will also contribute to the broader work of WHO programmes on essential medicines, antimicrobial resistance and cancer.
28. With the growing number of highly priced medicines now included on the Model Lists, the Committee recommended establishing a multidisciplinary expert working group to support the Committee in providing advice to WHO on policies and actions to make highly priced essential medicines more affordable and accessible.

ACTION BY THE EXECUTIVE BOARD

29. The Board is invited to note the report.

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