

Reports of advisory bodies

Expert committees and study groups¹

Report by the Director-General

EVALUATION OF CERTAIN FOOD ADDITIVES

Eighty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives, Geneva, 12–21 June 2018²

Main recommendations

1. The report contains the Expert Committee's evaluations of technical, toxicological and epidemiological data, occurrence and dietary exposure data for eight food additives (anionic methacrylate copolymer; neutral methacrylate copolymer; basic methacrylate copolymer; erythrosine; indigotine; lutein and lutein esters; sorbitol syrup; and spirulina extract) and for eight groups of flavouring agents (69 flavouring agents in total), which had been evaluated according to the revised Procedure for the Safety Evaluation of Flavouring Agents.³
2. Specifications for the following food additives were revised: erythrosine; indigotine; lutein; cassia gum; citric and fatty acid esters of glycerol; glycerol ester of wood rosin; and modified starches.
3. The assessments, recommendations and comments by the Expert 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.

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. 1014 (in press).

³ WHO Technical Report Series, No. 1000 (<http://apps.who.int/iris/bitstream/handle/10665/250277/9789241210003-eng.pdf;jsessionid=8504F104C9F5ACC48FD918422F8BB315?sequence=1>, accessed 5 December 2018).

4. 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 food additives.

Significance for public health policies

5. The Expert Committee identifies and, where possible, quantifies the public health significance of exposure to chemicals in food – in these cases, food additives including flavouring agents – 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 FAO/WHO Food Standards Programme (the Codex Alimentarius Commission and its subsidiary bodies).

6. The Expert 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 Expert 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.

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

8. The Expert 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

9. The evaluation of chemicals in food by the Expert Committee is an ongoing activity. Four meetings of the Expert Committee were held in the biennium 2016–2017.² Four more meetings besides the eighty-sixth meeting are planned for the biennium 2018–2019.

10. 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 veterinary drug residues in food, the work of the Expert Committee is crucial to the work of the Codex Alimentarius Commission.

11. The Expert 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 food additives. WHO Food Additives Series, No. 77. Toxicological monographs of the eighty-sixth meeting (in preparation).

² For more information, see https://www.who.int/foodsafety/areas_work/chemical-risks/jecfa/en/ (accessed 5 December 2018).

TOBACCO PRODUCT REGULATION

Report of the ninth meeting of the WHO Study Group on Tobacco Product Regulation, Minneapolis, Minnesota, United States of America, 5–7 December 2017¹

Main recommendations

12. The WHO Study Group on Tobacco Product Regulation publishes a series of reports to provide a scientific basis for tobacco product regulation. In line with Articles 9 and 10 of the WHO Framework Convention on Tobacco Control,² the reports identify evidence-based approaches to the regulation of tobacco products.

13. The ninth meeting of the Study Group discussed: the prevalence and health effects of waterpipe tobacco smoking and interventions to reduce its use; approaches to reducing toxicant concentrations in smokeless tobacco products; the state of the science review on a global nicotine reduction strategy; the clinical pharmacology of nicotine in electronic nicotine delivery systems; the sugar content of tobacco products; a regulatory strategy for reducing exposure to toxicants in cigarette smoking; an updated priority list of toxicants in tobacco products for regulatory purposes; heated tobacco products; and the science of flavours in tobacco products. The discussions aimed at updating knowledge in order to inform policy at global level and advancing tobacco product regulation.

14. The report provides guidance through the Executive Board to Member States and focuses primarily on the requests of the Conference of the Parties to the WHO Framework Convention on Tobacco Control to WHO via the Convention Secretariat at its seventh session, in 2016, as articulated in decisions FCTC/COP7(4), FCTC/COP7(9) and FCTC/COP7(14).³ These decisions informed the development of the content of the background papers in the above-mentioned areas, for which Member States have requested technical assistance to inform national policy development. The 10-member Study Group invited subject matter experts, who, in addition to drafting background papers and contributing to discussions, provided the most up-to-date empirical data on the topics considered. Chapters 2–9 of the report provide scientific information and policy recommendations to guide Member States in navigating the regulatory space around difficult tobacco product regulation issues. Further, the report provides guidance to Member States for achieving the most effective and evidence-based means to bridge regulatory gaps in tobacco control and for developing coordinated regulatory frameworks for tobacco products with a view to guiding international policy. Additionally, it identifies areas for further work and future research, focusing on the regulatory needs of Member States; it takes into consideration regional differences, thus providing a strategy for continued technical and targeted support to Member States.

15. The main recommendations to policy-makers include, but are not limited to, the following:

- to monitor and collect reliable data on heated tobacco products in order to understand better behaviours, potential risks to users and bystanders, and to verify claims of reduced risk exposure and risk;

¹ WHO Technical Report Series, No. 1015 (in press).

² For the text of the WHO Framework Convention on Tobacco Control, see <http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf?ua=1> (accessed 5 December 2018).

³ Accessible at <http://www.who.int/fctc/cop/cop7/Documentation-Decisions/en/> (accessed 5 December 2018).

- to consider and examine the design features that determine nicotine flux in electronic nicotine delivery systems and to what extent these products could be beneficial or detrimental to cessation of smoking;
- to consider banning or restricting the use of flavours in nicotine and tobacco products in order to reduce initiation by young people and promote cessation of use of combusted tobacco products;
- to lower the levels of addictive, toxic and carcinogenic agents in tobacco products, including cigarettes and smokeless tobacco, recognizing that decreasing the levels of these agents will not make these products safe; and
- to request manufacturers, as applicable and appropriate, to report priority toxicants using methods based on the standard operating procedures of the WHO Tobacco Laboratory Network.

Significance for public health policies

16. The Study Group's report provides helpful guidance in understanding the content, emissions and design features of selected products, such as smokeless tobacco, waterpipes, heated tobacco products, and electronic nicotine delivery systems, and highlights the public health impact of these products and/or features. In recent years, unconventional nicotine and tobacco products have permeated several markets, for which there is no precedent, and present unique regulatory challenges to Member States. Further, there is a better understanding of the science, adverse effects, characteristics, contents and emissions of conventional products owing to the advancement of knowledge, thus necessitating the need for an update of Member States' knowledge of novel and emerging tobacco products and nicotine delivery systems to aid the formulation of effective regulatory strategies for tobacco and nicotine products.

17. The Study Group, because of its unique composition of regulatory, technical and scientific experts, navigates and distills complex data and research and synthesizes them into policy recommendations, which inform policy development at country, regional and global levels. Such recommendations promote international coordination of regulatory efforts and the adoption of best practices in tobacco product regulation, strengthen tobacco product regulation capacity-building across all WHO regions, and provide a ready resource to Member States based on sound science.

Implications for the Organization's programmes

18. The report fulfils the mandate of the WHO Study Group on Tobacco Product Regulation to provide the Director-General with scientifically sound, evidence-based recommendations for Member States about tobacco product regulation.¹ Tobacco product regulation is a highly technical area of tobacco control in which Member States face complex regulatory challenges. The outcomes of the Study Group's deliberations and main recommendations will improve Member States' understanding of tobacco and nicotine products. The report's contribution to the body of knowledge on tobacco product regulation will play a pivotal role in informing the work of the tobacco programme within WHO's Department for Prevention of Noncommunicable Diseases, especially in providing technical support to

¹ In November 2003, the Director-General formalized the status of the former Scientific Advisory Committee on Tobacco Product Regulation from a scientific advisory committee to a study group.

Member States. It will also contribute to the further development of partial guidelines to Articles 9 and 10 of the WHO Framework Convention on Tobacco Control.

DRUG DEPENDENCE

Fortieth report of the Expert Committee on Drug Dependence, Geneva, 4–7 June 2018¹

Main recommendations

19. WHO is mandated by the international drug control conventions to evaluate the scientific evidence related to dependence, abuse and harm to health of psychoactive substances and their therapeutic use. This evaluation is done through the WHO Expert Committee on Drug Dependence, which issues recommendations on whether psychoactive substances should be placed under international control. These recommendations are communicated to the Secretary-General of the United Nations and are subject to a vote by the Member States of the United Nations Commission on Narcotic Drugs in Vienna.

20. The fortieth meeting of the Expert Committee on Drug Dependence was dedicated to the review of cannabis and cannabis-related substances. The Committee carried out a formal critical review of preparations considered to be pure cannabidiol and recommended that they should not be scheduled within the international drug control conventions.

21. The Expert Committee at its fortieth meeting undertook preliminary reviews of cannabis and resin; extracts and tinctures of cannabis; and delta-9-tetrahydrocannabidiol and its isomers. The Committee acknowledged that there was enough evidence about abuse, dependence and harm to health to recommend that these substances proceed to the next level of review, called a critical review, at its next meeting in November 2018.

Significance for public health policies

22. The Expert Committee concluded that cannabidiol does not have psychoactive properties, and presents little or no potential for abuse or dependence. However, because cannabidiol can be prepared as an extract from the cannabis plant, it is currently under strict international control.

23. The Expert Committee's recommendation that preparations considered to be pure cannabidiol should be exempted from international control will ensure that these preparations are available for medical and research purposes. Cannabidiol is a component of cannabis for which numerous medical uses are being explored including for seizure reduction in children with epilepsy.

24. Recently, a pure cannabidiol product has received marketing approval by the United States Food and Drug Administration. Several countries have reported ongoing clinical trials on different cannabidiol products for medical use.

25. Cannabis is currently subject to strict international control (Schedules I and IV of the 1961 Single Convention of Narcotic Drugs), alongside substances like opioids. Cannabis extract and tinctures are listed in Schedule I of the 1961 Convention, and the main active component (delta-9-tetrahydrocannabidiol) and its isomers are subject to control under the 1971 Convention on

¹ WHO Technical Report Series, No. 1013 (in press).

Psychotropic Substances. Several Member States have seen increased interest in the availability of these substances for medical use. By recommending that cannabis and its related substances progress to critical review, the Expert Committee indicated that there was enough evidence about the harms to public health and potential therapeutic applications to consider, if relevant, a change in their level of international control.

Implications for the Organization's programmes

26. To ensure that the recommendations of the Expert Committee do not restrict access to essential medicines, it considers the potential for abuse, dependence and harm to health of psychoactive substances alongside their potential for legitimate medical use when issuing its recommendations. The secretariat of the Expert Committee on Drug Dependence works closely with WHO's Expert Committee on the Selection and Use of Essential Medicines which is responsible for updating the WHO Model List of Essential Medicines. The purpose is to ensure that information is shared on the appropriate use of controlled medicines for various conditions, including the management of pain and palliative care.

27. The recommendations of the Expert Committee present broad implications for Member States and WHO's regional and country offices. These include raising awareness of public health risks of psychoactive substances, monitoring drug-related harm through ongoing data collection, and promoting the use of guidelines for the prevention and treatment of drug disorders at country level.

ACTION BY THE EXECUTIVE BOARD

28. The Executive Board is invited to note the report.

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