codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3b **CX/FAC 05/37/3**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, the Netherlands, 25 – 29 April 2005

MATTERS OF INTEREST ARISING FROM FAO/WHO

INTRODUCTION

1. This paper describes FAO/WHO activities in the area of Scientific Advice implemented since the 36th Session of the Codex Committee for Food Additives and Contaminants, which are complementary to the work of the Codex Alimentarius Commission.

A. PROGRESS REPORT ON THE FAO/WHO CONSULTATIVE PROCESS ON PROVISION OF SCIENTIFIC ADVICE TO CODEX AND MEMBER COUNTRIES

2. The review of the FAO/WHO programs providing scientific advice to Codex and member countries is ongoing, as requested by the Codex Alimentarius Commission[1] and in response to recommendations of the Codex Evaluation[2].

3. Progress to date includes the completion of the two of the three planned steps in the review process, namely an electronic forum[3] held in the second half of 2003, and an FAO/WHO Workshop on the Provision of Scientific Advice to Codex and Member Countries was held in Geneva, Switzerland, from 27-29 January, 2004[4]. The executive summary and the recommendations of the Workshop report were circulated through the Codex Contact Points to member countries and international observer organisations in March 2004 soliciting official comments to be submitted to FAO and WHO. Comments received and steps undertaken by FAO and WHO since the implementation of the Workshop were made available at the 27th Session of the Codex Alimentarius Commission (ref. CAC/27 INF 3A).

4. Activities prioritised by FAO/WHO to enable implementation of the workshop recommendations include the following:

- Elaborate a ***Procedural Guideline*** that would compile all written procedures followed by FAO and WHO in the provision of scientific advice;
- Establish an ***Internal FAO/WHO Task Force*** to review the management options for the provision of scientific advice and consider improved coordination;
- Prepare ***Review Papers*** to address procedures for the selection of experts, to consider factors associated with enhanced openness of meetings, and to improve procedures on use of data;

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1 24th Codex Alimentarius Commission, ALINORM 01/41, paras 58-62

2 Report of the Evaluation of the Codex Alimentarius and other FAO and WHO Food Standards Work, Rome, 2002

3 The report of the e-forum can be found on this FAO webpage: http://www.fao.org/es/ESN/proscad/forum_en.stm.

4 The report of the Workshop is available on the websites of FAO (http://www.fao.org/es/ESN/proscad/index_en.stm) and WHO (http://www.who.int/foodsafety/en/).

- Convene a ***Workshop*** (brain-storming session) to explore new approaches to enhance the participation of experts and use of data from developing countries in the international scientific advice activities.

5. In addition to the review process described above, specific projects are ongoing to strengthen the working procedures of certain aspects of scientific advice by FAO and WHO. Results and recommendations of these parallel review processes will be considered by FAO/WHO.

6. For the FAO/WHO Joint Project to Update the Principles and Methods for the Risk Assessment of Chemicals in Food, two additional workshops are planned. The Workshop on the Intake Assessment for Chemicals in Food will be held in Annapolis, MD, USA, from 2-6 May 2005. The Workshop on MRLs for Residues of Pesticides and Veterinary Drugs will be held in Bilthoven, The Netherlands, from 7-10 November 2005. The draft document "Principles and Methods for the Risk Assessment of Chemicals in Food" will be posted on the FAO and WHO internet sites for review and comment and will be reviewed at future meetings of JECFA and JMPR. The final product will be an internet based guide. The format will facilitate the incorporation of new principles and methods as they are elaborated by JECFA and JMPR.

7. In a related project, as part of its international risk assessment harmonization efforts, the International Programme on Chemical Safety (IPCS) has developed a draft guidance document on Principles for Modelling Dose-Response for the Risk Assessment of Chemicals http://www.who.int/ipcs/methods/harmonization/dose_response/en/. The principles elaborated in this document were used by the sixty fourth meeting of JECFA in the risk assessment of several chemicals that are genotoxic and carcinogenic (See paragraph 14., below).

REQUESTS FOR SCIENTIFIC ADVICE FROM CODEX SUBSIDIARY BODIES

8. FAO and WHO have presented the current list of requests[5] for scientific advice received from Codex subsidiary bodies and direct from member countries. The Fifty-fifth Executive Committee[6] in Rome on 9-11 February 2005 proposed the following criteria to FAO and WHO to prioritize the request:

- Relevance in relation to the strategic objectives and priorities as defined in the Strategic Plan;
- Clear definition of the scope and objective of the request as well as clear indication of the way in which the advice will be used in the work of Codex;
- Significance and urgency to the development or advancement of Codex texts taking into account public health and/or food trade relevance of the issue and the needs of developing countries;
- Availability of scientific knowledge and data required to conduct the risk assessment or to elaborate the scientific advice;
- High priority assigned by the Codex Alimentarius Commission.

9. The Executive Committee was informed of the critical funding situation in relation to the provision of scientific advice especially due to a decrease in the extra-budgetary funding to WHO which will result in a situation where the requests for such advice cannot be met any more. The Executive Committee expressed its concern on this issue in view of the importance of scientific advice for the work of Codex.

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5 CX/EXEC 04/53/4

6 ALINORM 05/28/3, paras 68-75

10. Recognizing that the provision of scientific advice was critical to progressing the work of Codex related to the protection of consumers' health, the Executive Committee strongly urged FAO and WHO to renew their efforts to provide sufficient ongoing funding through the Regular Programme budget to support the work of JECFA, JMPR, JEMRA and other expert meetings. In the interim, the Committee urged FAO and WHO to seek extra-budgetary funding from Member States for the provision of scientific advice and encouraged Member States to provide such funding. The Committee noted that, in view of the current financial constraints of the parent Organizations, FAO and WHO should explore additional and alternative ways to provide Codex with the requested scientific advice, while ensuring the independence, soundness and neutrality of such advice. The Committee noted that FAO and WHO were considering the opportunity for creating alternative funding mechanisms such as a Trust Fund. The Committee agreed that some flexibility should be allowed for FAO and WHO to employ the most effective means to address requests for scientific advice. Possible options to provide scientific advice in an expeditious way included the convening of meetings of a small group of experts, instead of formal expert consultations.

11. In relation to the request regarding the evaluation of the safety of acceptable previous cargoes[7] FAO and WHO informed the CCFO that the joint FAO/WHO Expert Consultation had been under preparation by the FAO/WHO Secretariats taking into account the discussions in the above mentioned sessions of the Committee and the Commission. It is assumed that the substantial solution for the issue on how to proceed the List of Previous Acceptable Cargoes could be sought with the outcomes from this expert consultation.

12. The CCFO agreed to retain the Draft List and the Proposed Draft List of Acceptable Previous Cargoes respectively at Step 7 and 4, for further consideration by the next session in the light of the results of the scientific advice to be provided by FAO and WHO, and any other relevant information that would become available in the meantime.

B. FAO/WHO EXPERT MEETINGS AND CONSULTATIONS

Residues of veterinary drugs without ADI/MRL

13. In July 2003, the 26th Session the Codex Alimentarius Commission discussed a request from Thailand to assess the issue of "Risk Analysis for Substances with No ADI and/or MRL" and took note of FAO's proposal to examine, at a technical consultation, the regulatory issues, including zero tolerance and *de minimis* limits and risks associated with substances at the limit of detection or *de minimis* levels. The Joint FAO/WHO Technical Workshop on Residues of Substances without ADI/MRL in Foods from 24-26 August 2004, Bangkok, Thailand provided FAO, WHO and Codex with a first analysis of the disruptions in food trade that occurred in 2001/2002, identify the scientific, technical and regulatory problems related to them and discussed appropriate follow-up steps. The identification of gaps within the current framework of JECFA and Codex led to the development of recommendations for further actions by FAO, WHO and Codex. The final report including working papers and case studies to FAO, WHO and the Codex Alimentarius Commission and its relevant subsidiary bodies (e.g. FAO/WHO Coordinating Committee for Asia, Codex Committee on Residues of Veterinary Drugs in Foods, etc.). The report is available for downloading at: http://www.fao.org/es/ESN/food/meetings_vetdrugs_en.stm and as hard copy from the FAO Information Division.

Outputs from Completed Meetings

Risk assessments of food additives and contaminants

14. In June, 2004, the sixty third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated twenty-one food additives, nine of them for specifications only and revised the levels for arsenic and heavy metals for an additional eighty-four additives. JECFA also evaluated 178 flavour agents in 8 different groups and prepared specifications for an additional 21 flavours. A suggested intake of 100 mg per day was proposed for Glycyrrhizinic acid, a natural food constituent. The summary report is available at http://www.fao.org/es/ESN/jecfa/whatisnew_en.stm, and the report of the meeting will appear in the WHO Technical Report Series. New and revised specifications are published in the FAO Food and Nutrition Paper Series 52, Addendum 12 available on ftp://ftp.fao.org/es/esn/jecfa/addendum_12.pdf.

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7 CL 2005/11-FO

15. This sixty fourth JECFA meeting, which took place in February 2005, was devoted solely to food contaminants and the evaluations included acrylamide, cadmium, ethyl carbamate, polybrominated diphenyl ethers, polycyclic aromatic hydrocarbons, and inorganic tin. The summary report is available at http://www.fao.org/es/ESN/jecfa/whatisnew_en.stm. The Committee considered that the evidence for genotoxicity and carcinogenicity of acrylamide, ethyl carbamate, and polycyclic aromatic hydrocarbons was an important issue. The Committee was aware of a number of recent developments relevant to the risk assessment of such compounds. The Committee at its present meeting decided that advice on compounds that are both genotoxic and carcinogenic should be based on estimated Margin of Exposure (MOE). The MOE is calculated by dividing the toxicity estimate from animal experiments by the intake estimate from food. Consequently, the lower the MOE the greater is the public health concern.

16. The Committee considered the values of the MOEs of 300 for the general population and 75 for consumers of high amounts of foods containing high acrylamide levels, were low and that they may indicate a human health concern. Therefore, appropriate efforts to reduce acrylamide concentrations in foodstuffs should continue.

17. The Committee concluded, that intake of ethyl carbamate from foods excluding alcoholic beverages, would be of low concern (MOE = 20,000). The MOE of 3,800 for all intakes, food and alcoholic beverages combined, is of concern and therefore mitigation measures to reduce concentrations of ethyl carbamate in some alcoholic beverages should be continued.

18. Based on the derived MOEs of 25,000 and 10,000 for mean and high intakes, respectively, the Committee concluded that the estimated intakes of polycyclic aromatic hydrocarbons (PAH) were of low concern for human health. Measures to reduce intake of PAHs could include avoiding contact of foods with flames, and cooking with the heat source above rather than below the food. Efforts should be made to reduce contamination with PAHs during drying and smoking processes.

19. The Committee concluded that the effect of different MLs on overall intake of cadmium would be very small. At the proposed Codex MLs, mean intake of cadmium would be reduced by approximately 1% of the PTWI. The imposition of MLs one level lower would result in potential reductions in intake of cadmium of no more than 6% (wheat grain, potatoes) of the PTWI. At the proposed Codex MLs, no more than 9% of a commodity would be violative (oysters). MLs one level below those proposed would result in approximately 25% of molluscs, potatoes, and other vegetables being violative.

20. The Committee concluded that the data available indicated that it is inappropriate to establish an ARfD for inorganic tin, since whether or not irritation of the gastrointestinal tract occurs after ingestion of a food containing tin depends on the concentration and nature of tin in the product, rather than on the dose ingested on a body-weight basis. The Committee reiterated its opinion, expressed at its thirty-third and fifty fifth meetings, that the available data for humans indicated that inorganic tin at concentrations of > 150 mg/kg in canned beverages or 250 mg/kg in canned foods may produce acute manifestations of gastric irritation in certain individuals.

21. Based on limited toxicity data on polybrominated diphenyl ethers (PBDE), the Committee concluded that there appeared to be a large Margin of Exposure for a non-genotoxic compound which, despite the inadequacy of the data on toxicity and intake, gave reassurance that intakes of PBDEs are not likely to be a significant health concern.

Other risk assessments

22. Other outputs from completed meetings are available in CX/NEA 05/3/4 and CX/FH 03/5.

C. OTHER FAO AND WHO ACTIVITIES RELATED TO THE PROVISION OF SCIENTIFIC ADVICE

23. Information related to the following list of Guidance document can be find in CN/NEA 05/3/4:

- Obstacles to the Application of HACCP; Particularly in Small and Less Developed Business (SLDBs) and Approaches to Overcome them;
- Preparedness for response to nuclear emergencies;
- Expert consultation on community based veterinary public health;
- Guidelines for Good Agricultural Practices.