

codex alimentarius commission



FOOD AND AGRICULTURE
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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REPORT ON ACTIVITIES OF FAO AND WHO COMPLEMENTARY TO THE WORK OF THE CODEX ALIMENTARIUS COMMISSION

INTRODUCTION

1. This paper describes FAO/WHO activities in the area of Scientific Advice implemented since the 7th Session of the Codex Committee for North America and the South West Pacific, 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 Commission¹ and in response to recommendations of the Codex Evaluation².

3. Progress to date includes the completion of the two of the three planned steps in the review process, namely an electronic forum³ 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, 2004⁴.

4. The Workshop resulted in a set of recommendations on 1) essential principles, definitions and scope governing the provision of scientific advice, 2) management issues and 3) procedures and mechanisms. Due regard was given to enhancing the participation of developing countries in the provision of scientific advice.

5. 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).

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/>).

6. 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;
- 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.

7. 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.

FAO/WHO worksharing activities with national governments and regional authorities for the evaluation of pesticide residues and toxicology

8. A pilot project on worksharing was initiated in response to the request from the CCPR on ways to improve the timeliness of the recommendations of the JMPR in establishing MRLs. One substance has been identified for this pilot project and will be evaluated at the 2004 JMPR, using national and regional evaluations as a basis. The 36th Session of the CCPR was advised that the purpose of this worksharing pilot project was to investigate the feasibility of using national and regional evaluations to expedite JMPR evaluations and make better use of the resources available, increase the transparency of the evaluation process, facilitate the international acceptance of JMPR evaluations by governments and facilitate the submission of dossiers by the industry. The results and experience of the worksharing pilot project will be summarised in an evaluation report and will be presented to the 37th Session of the CCPR.

Follow-up on the implementation of the York and Zoning reports

9. The 36th Session of the CCPR was informed that the JMPR had already been using the recommendations of the York and Zoning reports whenever possible but that JMPR needs further information from the national governments before their full utilization. The York workshop implemented in 1999 focussed on “Developing minimum data requirements for the estimation of MRLs and import tolerances”. The “Zoning meeting” (2001), concluded that the impact of climate on the behaviour of residues of some foliar applied pesticides on certain crops is negligible, and residue trials could be extrapolated from one place to another when good agriculture practices and agronomical factors were similar.

10. Recognizing that practical experience would be necessary to see how recommendations could be implemented, the JMPR agreed to pilot test the practical applicability of the principles with one pesticide scheduled for evaluation by JMPR in 2004. A survey on the issues raised at the York and Zoning meetings, on which consensus was not achieved at that time, have been considered in the survey and distributed to member governments of the CCPR and the OECD for comments by the end of May 2004. The results would be improved transparency of pesticide evaluation at national and international level.

B. REQUESTS FOR SCIENTIFIC ADVICE FROM CODEX SUBSIDIARY BODIES

11. FAO and WHO have presented the current list of requests⁵ for scientific advice, received from Codex subsidiary bodies and direct from member countries, at the Fifty-Third Session of the Executive Committee of the Codex Alimentarius Commission held in Geneva, Switzerland on 4-6 February 2004⁶. The Executive Committee following the request of the 26th Session of the Commission considered the large number of requests for scientific advice with a view of their prioritization, including a preliminary set of criteria to establish priorities.

⁵ CX/EXEC 04/53/4

⁶ ALINORM 04/27/3, paras 55-85

12. As part of this prioritisation exercise, FAO/WHO advised that the current budget of FAO and WHO available for the provision of scientific advice would not allow for a timely response to all these requests. Adequate funding from Regular Budgets and from extra budgetary sources need to be secured to ensure the provision of scientific advice in a more sustainable manner.

13. Further discussion on this matter took place at the 27th Session of the Commission⁷ and the Commission agreed that priority for the provision of scientific advice should be given to requests coming from Codex subsidiary bodies rather than from Member governments and that the work plan of Codex shall take into account the availability of relevant scientific advice. The Commission noted the view that priority should also be given to the concerns of developing countries, the decisions of the Commission and prioritised requests by Codex subsidiary bodies.

14. The Commission noted that in the absence of Codex criteria for setting priorities for the provision of scientific advice, FAO and WHO would continue planning expert meetings and consultations considering the following criteria: a) clear scope of the advice requested; b) urgency of the advice requested, c) availability of required data or commitment of countries to provide such data; and d) availability of financial resources.

15. With regard to specific requests for scientific advice, member countries at the Commission agreed that Codex requests for scientific advice related to functional foods, active chlorine and transport of fats and oils in bulk for scientific advice should not be considered as cancelled but be retained. Some delegations proposed to give a higher priority to the Codex request from the 13th Session of the Coordinating Committee for Asia, to evaluate the safety and regulatory issues related to functional foods, given their importance to developing countries. Other delegations indicated that the Committee on Nutrition and Foods for Special Dietary Uses gave priority to the evaluation of upper limits of vitamins and minerals and that there was no international definition of functional food and no work was being undertaken by the Codex in this area and that from a legal point of view functional foods could be considered as common foods or foods for special dietary uses.

16. A FAO/WHO Workshop is planned to provide information on the characteristics and use of functional foods, and to provide a venue to exchange information on the status of functional foods in selected countries in Asia.

17. The Commission noted that the Committee on Food Additives and Contaminants and the Committee on Food Hygiene were preparing the draft Terms of Reference for the proposed expert consultation on safety of active chlorine used in and on foods.

18. In relation to the request regarding the evaluation of the safety of acceptable previous cargoes, the Commission confirmed its earlier request to FAO and WHO to convene an expert consultation, preferably before the next Session of the Committee on Fats and Oils. The Delegation of the United States stated that future work by the Committee on Fats and Oils should concentrate on criteria but not on the list.

C. FAO/WHO EXPERT MEETINGS AND CONSULTATIONS

Residues of veterinary drugs without ADI/MRL

19. 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.

⁷ ALINORM 04/27/10G

Outputs from Completed Meetings

Risk assessments of food additives and contaminants

20. In June 2003, the Sixty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated twenty-three food additives, 7 of them for specifications only, and revised the levels for arsenic and heavy metals for an additional 39 additives. JECFA also evaluated 144 flavour agents in 7 different groups applying the decision tree approach and prepared specifications for an additional 101 flavours. The Expert Committee also evaluated a water treatment agent (sodium dichloroisocyanurate NaDCC) and a nutritional source of iron (ferrous glycinate). JECFA assessed cadmium and methyl mercury as contaminants. For cadmium, the new data did not provide a sufficient basis for revising the provisional tolerable weekly intake (PTWI), therefore, the PTWI of 7 µg/kg of BW was maintained. In the case of methyl mercury the Expert Committee considered a variety of new data from human studies and derived from them a lower PTWI of 1.6 µg/kg BW, down from 3.3 µg/kg BW. The Summary Report is available at http://www.fao.org/es/ESN/jecfa/works_en.stm; the report is available as WHO Technical Report Series No 922; the specifications were published as Addendum 11 to the Compendium of Food Additives Specifications.

21. 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 meeting of the report will appear in the WHO Technical Report Series. New and revised specifications will be published in the FAO Food and Nutrition Paper Series 52, Addendum 12.

Risk assessments of residues of veterinary drugs

22. In February 2004, the sixty second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated eleven veterinary drugs and their residues in foods. In addition, the Committee concluded that it is not appropriate to establish an ADI for chloramphenicol and that it was unlikely that chloramphenicol was an environmental contaminant. The Expert Committee also considered several general issues that relate to the risk assessment of residues of veterinary drugs in foods among them a risk assessment policy proposal from CCRVDF. The Summary Report is available at http://www.fao.org/es/ESN/jecfa/works_en.stm; the report and the toxicological monographs will be published by WHO and the residue monographs by FAO.

Risk assessment of pesticides residues

23. In September 2003, a Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group (JMPR) evaluated 23 pesticides, including four new compounds and nine compounds that were re-evaluated within the periodic review programme of the CCPR for toxicity or residues, or both. The Meeting estimated 179 MRLs and recommended 98 existing MRLs for withdrawals for pesticides under the periodic review programme of the CCPR. There were 26 exceedances of the acute RfD based on estimated short-term intake for acephatate, dimethoate, fenitrothion, methamidophos, methoxyfenozide and phosmet. The Report is available at <http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPPP/Pesticid/Default.HTM>. Publications of the detailed toxicological evaluations and evaluations of pesticide residues in food will be prepared by WHO and FAO, respectively.

24. The 35th Session of the CCPR requested the JMPR (ALINORM 03/24A) to consider probabilistic approaches for refining the dietary intake estimates when the results of point estimates exceed the acute reference dose (acute RfD). In principle, the 2003 JMPR agreed to adopt a tiered approach to estimating short term dietary intake in which the second tier would be the probabilistic modelling e.g. considering the model that would be developed by the Working Group led by the Netherlands.

Antimicrobial resistance resulting from non-human usage of antimicrobials

25. In response to a recommendation from the 48th Session of the Executive Committee, FAO, WHO and OIE organized a two-step multidisciplinary expert consultation process to advise the Commission on possible directions to be taken on the issue of antimicrobial resistance.

26. The first Workshop on Non-human Antimicrobial Usage, held in December 2003 in Geneva conducted a preliminary scientific assessment considering all non-human uses of antimicrobials in animals (including aquaculture) and plants, and their role in antimicrobial resistance, based on the available scientific information. Based on the outcome, the second Workshop in Oslo considered the broad range of possible risk management options and included the participation of all major stakeholder groups. In particular, it focused on potential directions of future Codex, FAO, OIE and WHO work in this area, in order to prevent and minimize antimicrobial resistance at the global level. The reports of both workshops were published by WHO and are available on the web pages of all three participating organisations (e.g.: <http://www.who.int/foodsafety/publications/micro/en/>).

Risk assessment of microbiological hazards in food

Pathogen-commodity risk assessments

27. The risk assessment on *Listeria monocytogenes* in ready-to-eat foods, undertaken following the requests of the 32nd and 33rd sessions of the Codex Committee on Food Hygiene (CCFH) has now been completed. The technical report and the interpretative summary are now available on the FAO webpage (www.fao.org/es/ESN/food/risk_mra_riskassessment_listeria_en.stm). In response to the requests of the 32nd and 33rd sessions of the CCFH risk assessments on *Vibrio* spp in seafood and *Campylobacter* spp. in broiler chickens have been undertaken. These are currently undergoing a peer-review. A summary of the findings of each of these risk assessments was made available to the last sessions of the CCFH, the Codex Committee on Meat Hygiene (CCMH) and the Codex Committee on Fish and Fishery Products (CCFFP). These risk assessments will be finalised by the end of 2004.

FAO/WHO meeting on *Enterobacter sakazakii* and other microorganisms of concern in powdered infant formula

28. The Codex Committee on Food Hygiene is revising the International Code of Hygienic Practice for Foods for Infants and Children. FAO/WHO held an expert meeting on *Enterobacter sakazakii* and other microorganisms of concern in powdered infant formula on 2 - 5 February 2004 to provide scientific advice to Codex to facilitate the revision process. In continuing to support the revision process, FAO/WHO will further develop and use the risk assessment model to evaluate the efficacy of various risk mitigation strategies. For this purpose, FAO/WHO have issued a new call for data specifically related to aspects of the manufacture, preparation and use of powdered infant formula as well as data on the characteristics of potential consumers. The report is now available on the FAO webpage (www.fao.org/es/ESN/food/risk_mra_entero_report_en.stm).

FAO/WHO guidelines on exposure assessment and risk characterization of microbiological hazards in food

29. The above mentioned guidelines will be completed during 2004 and will complement the guidelines on hazard characterization for pathogens in food and water presently available (FAO/WHO Microbiological Risk Assessment Series. No. 3).

Risk assessment on biotoxins in bivalve molluscs.

30. At its 25th Session, the Codex Committee on Fish and Fishery Products (CCFFP) asked FAO and WHO to provide scientific advice on biotoxins in conjunction with its work on Proposed Draft Standards for Live and Processed Bivalve Molluscs. The CCFFP, at its 26th Session, specifically requested advice to enable the establishment of maximum levels in shellfish for shellfish toxins (PSP-, DSP-, ASP-, AZP- and NSP-toxins, and YTXs and PTXs), advice on methods of analysis for each toxin group as well as on monitoring of biotoxin-forming phytoplankton and bivalve molluscs, and information on geographical distribution of biotoxin-forming marine phytoplankton.

31. An FAO//IOC/WHO workshop held at the Food Safety Authority of Ireland in Dublin, 22-24 March 2004, established three working groups to address the questions posed by Codex with regard to setting up maximum levels of biotoxins and reference analytical methods for the Draft Standards for Live and Processed Bivalve Molluscs, and to provide scientific information that can be used for Section 7 - Live and [raw] bivalve molluscs - of the Code of Practice for Fish and Fishery Products with respect to hazard identification and to technical guidance for classification and monitoring of growing areas.

32. Technical working papers prepared by these working groups were reviewed at the joint FAO/IOC/WHO expert consultation from 27 September to 1 October 2004 in Norway. The final report will be posted on both WHO (<http://www.who.int/foodsafety/chem/meetings/biotoxin/en>) and FAO websites (http://www.fao.org/es/esn/food/risk_biotoxin_en.stm) as it becomes available.

Safety assessment of foods derived from genetically modified animals

33. A joint FAO/WHO Expert Consultation on the safety assessment of foods derived from genetically modified animals (GM animals), including fish, was held from 17 to 21 November 2003. The consultation indicated that the food safety assessment of GM animals and derived products can largely be performed along the lines that have already been established for the evaluation of GM plants and derived products on a case-by-case basis. This means that the initial step of the food safety assessment will be a comparative safety assessment of the GM animal with its conventional counterpart, including a food intake assessment, followed where appropriate, by a full risk characterization. The Consultation also concluded that rigorous pre-market safety assessment of foods derived from GM animals should provide sufficient safety assurances.

34. The final report of the expert consultation is now available from: ftp://ftp.fao.org/es/esn/food/gmanimal_report_en.pdf. The report will also be available in French and Spanish and in print format as an FAO Food and Nutrition Paper in the future. The working papers and executive summary are also available from: http://www.fao.org/es/ESN/food/risk_biotech_animal_en.stm

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

Guidance document on Obstacles to the Application of HACCP, Particularly in Small and Less Developed Business (SLDBs) and Approaches to Overcome them.

35. The 35th session of the CCFH (27 January - 1 February 2003) accepted the offer of FAO/WHO Representatives, to elaborate a guidance document on "Obstacles to the Application of HACCP, Particularly in Small and Less Developed Business (SLDBs) and Approaches to Overcome Them" using as a basis the CCFH discussions, in particular those related to discussion of paper CX/FH 03/4-Add.1 (December 2003). An electronic working group has been established by FAO/WHO to contribute to this document which will be available for the next session of the CCFH. FAO has also supported the preparation of four case studies on application of HACCP in Brazil, Chile, India and Thailand. The information obtained will also be considered in the preparation of the guidance document.

Preparedness for response to nuclear emergencies.

36. FAO has established a network of technical experts on preparedness for response to nuclear emergencies in relation to food and agriculture. This group is charged with implementation of the cooperative arrangements between IAEA and FAO. Ongoing activities include the development of an on-line information system (including data on soil types, nutrition patterns, land use etc.), setting up an internal crisis management team to deal with nuclear emergencies affecting agriculture, and strengthening working relations with IAEA on this issue.

37. WHO's Radiation and Environmental Health Programme (RAD) has established a network of collaborating centers on Radiation Emergency Medical Preparedness and Assistance (RENPAN), that includes 14 institutions. Additionally, 13 more institutions are currently undergoing the WHO Collaborating Centre designation process. According to the Conventions on Early Notification and Assistance, regarding public health aspects of radiation emergency, WHO and IAEA co-operate closely in order to provide any requesting Member State or State Party with verified information on real or perceived risks to public health. Jointly with the IAEA, RAD is developing a document on public health guidance for preparedness and response to radionuclear accidents.

Expert consultation on community based veterinary public health

38. FAO held an Expert Consultation on Community Based Veterinary Public Health (VPH) in Rome on 27-28 October 2003 with OIE and WHO participation. Among the recommendations, the experts suggested that FAO should provide support to countries for identifying and solving problems especially relating to endemic, persistent zoonoses and food borne diseases with specific recommendations for prioritization of such VPH hazards based on risk analysis, burden assessment and socio-economic factors. Zoonoses and other VPH hazards should also be considered in the context of poverty alleviation. Support should include the development of practical guidelines for the delivery of VPH services at the community level to support new or existing human and animal health services.

Guidelines for Good Agricultural Practices

39. FAO is developing guidelines for Good Agricultural Practices (GAP) along the food-chain in the context of Sustainable Agriculture and Rural Development (SARD). To this effect, an Expert Consultation was held in Rome from 10 to 12 November 2003, to obtain advice on the relevance, validity and next steps of the proposed Good Agricultural Practices Approach. Participants discussed examples of application and methodology of a GAP approach based on stakeholder priorities with a focus particularly on developing country settings. The meeting resulted in initial strategies for implementing the GAP approach and the design of several pilot activities for testing the approach. There has been a joint initiative with Empresa Brasileira de Pesquisa Agropecuária (EMBRAPA), Brazil, to define GAPs for a number of animal production systems within selected agro-ecosystems which resulted in a publication.