codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3(a) **CX/RVDF 03/2**
December 2002

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Fourteenth Session

Washington, DC, 4 - 7 March 2003

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

CONSIDERATION OF THE DRAFT STRATEGIC FRAMEWORK, PROPOSED DRAFT MEDIUM PLAN 2003-2007 AND THE CHAIRPERSON'S ACTION PLAN

1. The 50th Session (June 2002) of the Executive Committee of the Codex Alimentarius Commission[1] considered the Draft Medium-Term Plan and agreed that it should be revised by the Codex Secretariat in the light of the comments made at the Session and subsequently circulated for consideration by the Regional Committees and for further consideration by the next (regular) session of the Executive Committee and the Codex Alimentarius Commission, to be held in 2003. The Executive Committee noted that as a result of the Codex Evaluation, further changes might be required to the Draft Medium Term Plan and re-emphasized that the Plan should be flexible enough to allow the introduction of new activities during its operational period.

RISK ANALYSIS POLICIES OF THE CODEX ALIMENTARIUS COMMISSION

2. The 17th Session of the Codex Committee on General Principles[2] (CCGP) (April 2002) agreed to advance the text of the *Proposed Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius* to Step 5 for consideration by the 50th Session of the Executive Committee. It noted that, when finalised, this text would be included in the Procedural manual as general Guidance to the Commission and its subsidiary bodies.

3. The 7th CCGP also agreed to undertake new work on the elaboration of proposed Draft Working Principles for Risk Analysis intended for Governments.

4. The 50th Session of the Executive Committee[3] (June 2002)considered the Proposed Draft Working Principle that had been submitted for preliminary adoption at Step 5 and advanced it at Step 6. The Executive Committee also approved as new work the elaboration of Proposed Draft Working Principles for Risk Analysis intended for governments, as proposed by the CCGP.

5. The 34th Session of the Codex Committee on Pesticide Residues[4] (CCPR) (May 2002) noted that the *Action Plan for Risk Analysis in the Codex System* adopted by the Commission in 1997 foresaw that once the Codex-wide Working Principles had been adopted, relevant Codex Committees would be requested to develop their own specific guidelines for risk analysis for incorporation into the Procedural Manual. It was also noted that some Codex Committees had begun work in this regard. The Committee therefore welcomed the offer of the Codex Secretariat to recruit a Consultant to prepare a document outlining the risk analysis policies used in establishing Codex Maximum Residue Limits for Pesticides. It agreed that this matter should be discussed at the Committee's next Session.

---

1 ALINORM 03/3A, paras. 32-61
2 ALINORM 03/33 paras. 63-72
3 ALINORM 03/3A, paras. 64 and 71
4 ALINORM 03/24, para. 47

CONSIDERATION OF NEW WORK PROPOSALS

The 50th Session of the Executive Committee[5] (June 2002) approved as new work the elaboration of the Proposed Draft Code of Practice to Minimise and Contain Antimicrobial Resistance, of the Proposed Draft Revised Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods and the Priority List of Veterinary Drugs Requiring Evaluation or Re-evaluation as new work.

CONSIDERATION OF PROPOSED DRAFT STANDARDS AND RELATED TEXTS AT STEP 5

6. The 50th Session of the Executive Committee[6] considered the Proposed Draft Standards and Related Texts that had been submitted for preliminary adoption at Step 5. In this regard, the Executive Committee noted that when it was considering the adoption of Codex texts the following decision of the 24th Session of the Codex Alimentarius should be taken into account, namely:

> "When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence".

7. The Executive Committee noted however that there was no guidance on how to interpret or apply this principle, especially in the establishment of maximum residue limits for veterinary drug residues and pesticides and also for microbiological contamination.

8. The Executive Committee[7] adopted the proposed draft maximum residue limits for Clenbuterol, Deltamethrin, Dicyclanil, Melengestrol acetate, Triclorphon (Metriphonate) at Step 5 and advanced to Step 6, as proposed.

CONSIDERATION OF DISCONTINUATION OF WORK

9. The 50th Session of the Executive Committee[8] approved the proposal to discontinue the work on Proposed Draft Guidelines for Residues at Injection Sites.

ANTIBIOTICS USED ON AGRICULTURAL COMMODITIES AND ANTIMICROBIAL RESISTANT BACTERIA IN FOOD

10. The 34th Session of the Codex Committee on Food Hygiene[9] (CCFH) (October 2001), generally supported the conclusions of the 48th Session of the Executive Committee, especially as related to convening a multidisciplinary expert consultation to address antimicrobial resistance. It noted that regardless of whether or not *ad hoc* Task Force was established, a comprehensive and multidisciplinary approach to these risk assessments would be required. The Committee agreed that the emergency of pathogen-specific antimicrobial resistance such as fluoroquinolone-resistant *Campylobacter* in poultry be examined as data are available for future risk assessments.

11. The Committee also supported the following recommendations contained in document CX/FH 01/12.

- This risk profile acknowledges the public health risks associated with antimicrobial-resistant bacteria in the food chain, but the magnitude of the risk is not established. Therefore it is recommended to further address this problem in the various committees involved.
- Based on the current risk profile it is recommended that the CCFH should commission risk assessments for selected specific scenarios relating to antimicrobial-resistant bacteria in food (e.g.,

---

5 ALINORM 03/3A, para. 64 and Appendix III.
6 ALINORM 03/3A, paras. 69-70
7 ALINORM 03/3A, para. 71 and Appendix II.
8 ALINORM 03/3A, para. 68 and Appendix IV.
9 ALINORM 03/13, paras. 158-162

bacterium/antimicrobial/food combinations). It is suggested that member countries be requested for proposals for the bacterium/antimicrobial/food combinations that are a priority for risk assessment.

- The principles of "reservation for human medicine" of certain antimicrobial substances need international consideration.

12. The 50th Executive Committee[10] (June 2002) noted that FAO, WHO and OIE were in the process or organising an expert consultation on antimicrobial resistance and that further action in the framework of Codex would depend on the results of the scientific advice provided by the Consultation. The Committee also recalled that a multidisciplinary approach was necessary and agreed with the view of the Vice-Chair (Professor Slorach) that coordination between concerned Committees should be pursued and that all sources of antimicrobial resistance related to animal or plant production should be taken into account.

RESIDUES OF CHLORAMPHENICOL IN SHRIMP

13. The 13th Session of the FAO/WHO Regional Coordinating Committee for Asia[11] (CCASIA) (October 2002), considered a document presented by the Delegation of Indonesia (CRD 18) that outlined problems facing exporters of shrimp due to the detection of residues or traces of chloramphenicol. The Delegation questioned the scientific basis for imposing a zero tolerance (including the reported association with aplastic anaemia) and stated that neither JECFA nor the Codex Committee on Food Additives and Contaminants (CCFAC) had established maximum residue limits for chloramphenicol especially in shrimp. The Delegation stated that there was an urgent need to establish a MRL for chloramphenicol in shrimp to avoid such technical barriers to trade.

14. In this regard, the Delegation of Vietnam stated that a major question to be addressed was the progressive reduction of the limit of analytical detection that resulted from the use of new techniques and equipment in the importing countries without adequate advice, forewarning or technical assistance to exporting countries. The Delegation of India stated that since this was a problem not exclusively associated with chloramphenicol in shrimp but concerned other antibiotics and contaminants and in respect of other products also and it needed to be addressed more widely and urgently.

15. The Coordinating Committee recommended that the Committee on Residues of Veterinary Drugs in Foods (CCRVDF) take up this matter and in relation to the matter of analytical methodology for determination of residues of substances not permitted or severely restricted in foods, the Committee requested that relevant Codex Committee (CCMAS, CCRVDF, CCFAC, CCPR) give urgent attention to the resolution of the problem of abrupt changes in analytical techniques, and changes in detection limits (levels determination).

16. The 24th Session of Codex Committee on Methods of Analysis and Sampling[12] (CCMAS) (November 2002) noted the referral from the 13th CCASIA that there was a need to give attention to the resolution of the problem of abrupt changes in analytical techniques, and changes in detection limits at the level of determination and was informed that the comments of India presented in CRD 6 could be taken into consideration from a general point of view on the relevant Agenda Items of this Committee.

SINGLE LABORATORY VALIDATION: CONSIDERATION OF HARMONIZED IUPAC GUIDELINES FOR THE IN-HOUSE VALIDATION OF METHODS OF ANALYSIS

17. The 24th Session of the Codex Committee on Methods of Analysis and Sampling[13] (November 2002) agreed to recommend to the 26th Session of the Commission to adopt the IUPAC *Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis* by reference for Codex purposes. It also agreed to initiate the revision of the definitions contained in the Codex Procedural Manual (Analytical Terminology for Codex Use), subject to the approval of the Commission as new work.

---

10 ALINORM 03/3A, para. 90
11 ALINORM 03/15, para. 151-155
12 ALINORM 03/23, para. 6
13 ALINORM 03/23, para. 96 and Appendix III

REQUIREMENTS FOR SINGLE LABORATORY VALIDATION FOR CODEX PURPOSES

18. The 24th Session of Codex Committee on Methods of Analysis and Sampling[14] recalled that its last Session had considered the use of single-laboratory validation for the purposes of Codex, taking into account the activities of international organizations and the work underway in other Codex Committees, and had agreed that the Delegation of the Netherlands would further develop general requirements for single-laboratory validation for Codex purposes. The Committee agreed that the single-laboratory validated method should be embedded in a "quality system" rather than a "quality assurance system". After some discussion, it was also agreed to delete the reference to accreditation and to specify that the system should comply with ISO/IEC 17025.

19. As a result of these discussions, the Committee agreed that the following text would be acceptable:

> *General Criteria for the Acceptance of Single-Laboratory Validated Methods of Analysis*
>
> Especially in the case of multi-analyte-multi-substrate methods and new hazards, interlaboratory validated methods may not be available or appropriate. Criteria used to select a method include the General Criteria for the Selection of Methods of Analysis, where appropriate. In addition, the single-laboratory validated methods must fulfil the following criteria:
>
> i the method is validated according to an internationally recognized protocol (e.g. those referenced in the *Harmonized IUPAC Guidelines for the Single-Laboratory Validation of Methods of Analysis*)
>
> ii the single-laboratory validated method is embedded in a quality system complying with ISO/IEC 17025

20. However, the Committee could not agree on the modalities of its incorporation into the Procedural Manual. It was recalled that these *General Criteria* had been proposed for inclusion after the *General Criteria for the Selection of Methods of Analysis using the Criteria Approach* and had not been associated with a specific Type of method in earlier discussions. However, some delegations expressed the view that these recommendations could not be included in the Manual as General Criteria, but should be restricted to Type IV methods because Type II and III methods should be collaboratively tested.

21. Other delegations recalled that the purpose of single-laboratory validation was to allow the use of reference methods that would not otherwise be available and that the current requirements for the type of methods would have to be amended accordingly. It was also pointed out that there was no need to apply additional requirements to Type IV methods and that the inclusion of criteria for single-laboratory validation was not relevant if they were not generally applicable.

22. The Committee could not come to a conclusion on an amendment to the Procedural Manual and agreed to inform the Committee on Pesticide Residues, the Committee on Residues of Veterinary Drugs in Foods and the Committee on Food Additives and Contaminants of the above discussion as the use of single-laboratory validation was especially important for their work.

---

14 ALINORM 03/23, paras. 96-104