

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 2

**CX/PR 04/2-Add.1
April 2004**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

**Thirty-sixth Session
New Delhi, India, 19 - 24 April 2004**

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES

FIFTY-THIRD SESSION OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION, WHO Headquarters, Geneva, 4 - 6 February 2004

New work proposals

The Executive Committee recommended that all Committees proposing new work should prepare a project document following the format proposed by the Committee on General Principles (ALINORM 04/27/33, Appendix III).

Scientific advice related to pesticide MRLs

73. The Committee noted that the improvement of the Methodology for Point Estimates on dietary exposure assessment was part of a general effort to standardize the methodology for exposure assessment in order to improve MRL setting and that training courses for developing countries participants were also planned. It was however noted that training activities should not be considered as part of requests for scientific advice.

74. The Committee noted that the Zoning Report on minimum data requirements for establishing MRLs and Import Tolerances would be the object of an expert consultation with the objective of decreasing the workload of JMPR.

Scientific advice

84. The Representative of WHO informed the Committee of the status of the consultative process for the provision of scientific advice to Codex and member countries. The FAO/WHO Workshop on the Provision of Scientific Advice, held 27 - 29 January 2004 at WHO headquarters, had considered the proposals to improve the current procedures and to achieve better coordination in the provision of scientific advice. The Representative underlined the importance of basic guiding principles such as transparency and the need for a new integrated management function, including the establishment of an independent advisory group. The Workshop had considered the issues related to the selection of experts and the specific problems of developing countries, and had identified the gaps where further work was needed.

85. The recommendations of the Workshop would be circulated for comments to member countries of FAO and WHO. These comments would be collated by FAO and WHO for consideration by the expert

consultation, which would be convened towards the end of 2004 to finalize the recommendations on the provisions of scientific advice, if funding was available. The Committee noted that a progress report on the consultative process would be presented to the 27th Session of the Commission for discussion.

Antimicrobial Resistance

67. The Member for North America expressed strong concern at the process followed for convening the FAO/WHO/OIE expert workshops, including the selection of experts, the transparency of the process, the lack of separation between risk assessment and risk management, and inadequate risk communication. The Member pointed out that most of the recommendations of the first FAO/WHO/OIE workshop were not directed to Codex and that the result of the workshop should be reported to the Executive Committee and the Commission, and then to the relevant Codex Committees before convening a second workshop.

68. The Representative of WHO recalled that FAO and WHO had applied the same procedures and criteria for the selection of experts as in the case of JEMRA in order to ensure transparency and geographical balance. Two separate workshops had been organized in order to ensure the separation between risk assessment and risk management issues. The Representative pointed out that the workshops had been organized jointly with OIE and addressed the need for a multidisciplinary approach to coordinate the work of all organizations involved, in order to carry out a comprehensive risk analysis specifically based on the Codex Working Principles for Risk Analysis. The Representative also pointed out that because of the multidisciplinary nature of the meetings, the advice would also be aimed at the managers other than Codex, i.e. OIE, FAO (IPPC) and WHO. The Committee noted that the report of both workshops would be presented to the Commission and the Committees concerned.

69. The Chairperson informed the Committee that IFAH (International Federation of Animal Health) had sent him a letter expressing its concern with the process and recommendations of the expert workshops on antimicrobial resistance and that WHO had provided its comments to the Chairperson on behalf of FAO and WHO. Both letters were made available to the Committee for information.

Additional Information from FAO/WHO

In accordance with Codex Risk analysis principles – FAO/WHO/OIE decided to organize and separate the considerations in two workshops, i.e. a 1st workshop on scientific issues and a 2nd workshop on management options.

The 1st Workshop in Geneva, December 2003 conducted a preliminary scientific assessment considering all non-human uses of antimicrobials in animals (including aquaculture) and plants, and their role in antimicrobial resistance; the workshop was only attended by independent scientists selected after evaluation of their CVs by a panel composed of representatives from FAO, OIE and WHO and external independent reviewers. Based on the outcome of this Workshop the 2nd Workshop in Oslo, March 2004 considered the broad range of possible risk management options. All major stakeholder groups (e.g., pharmaceutical industry, farmers¹, food processors, consumers, regulatory agencies) participated in this 2nd meeting.

The combined outcome of the two workshops represents the consultative effort by the three Organizations involved and is hoped to be a relevant and timely input for the official standard setting process of Codex. Furthermore, the outcome should also be of interest to FAO, OIE and WHO for planning their own future activities in dealing with this multi-sectoral issue.

The workshop process resulted in two reports representing a coherent picture describing both risk assessment and risk management considerations. It was stated that Antimicrobial agents are essential drugs for human and animal health and welfare and that Antimicrobial resistance is a global public and animal health concern that is impacted by both human and non-human antimicrobial usage. Antimicrobial agents are used in food animals, aquaculture, companion animals and horticulture to treat or prevent disease and sometimes used in food animals to promote growth. The risks associated with non-human antimicrobial use and antimicrobial resistance should be part of the human safety assessment.

The workshop process has resulted in suggestions for a recommended way forward in this area, for Codex, as well as for OIE, WHO and FAO. The outcome of the consultative process described will be discussed in

¹ In the context of this report, farmers include individuals, groups and companies involved in food production.

detail at the Codex Alimentarius Commission meeting in June 2004 in Geneva, based on the full publication and distribution of both reports to all Member States.

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING (ALINORM 04/27/23)

The 25th Session of the Codex Committee on Methods of Analysis had considered various issues relevant to methods of analysis and sampling. For full information, please see the above ALINORM which is available from the following web:

<http://www.codexalimentarius.net/reports.asp>

Single laboratory validated methods of analysis

14. The Committee recalled that following the request of its 24th session, the Codex Committee on Pesticide Residues (CCPR) had proposed criteria of a general nature for the selection of single-laboratory validated methods of analysis, to be included in the Procedural Manual after the General Criteria in order to recognize that inter-laboratory validation of methods of analysis was not always available and applicable for multi-residue analysis purposes.

15. After some discussion regarding the applicability of criteria, the Committee concluded that the proposed criteria should be of a general nature and should be incorporated into the Procedural Manual. It therefore amended the first bullet (i) by deleting the specific reference to the CCPR Guideline on Good Laboratory Practice.

16. In bullet (ii), the Committee deleted the reference to “assurance” in quality system in order to be consistent with the decision of the 24th Session and clarified that the use of the method was embedded in a quality system in compliance with the ISO/IEC 17025 document. It also clarified that the principles of Good Laboratory Practice were those established by OECD.

17. The Committee amended the last bullet to indicate that the verification of results with other validated methods was applicable “where available”.

19. The Committee agreed to forward the proposed General Criteria for Selection of Single-Laboratory Validated Methods of Analysis to the Committee on General Principles for endorsement and subsequent adoption by the 27th Session of the Commission and inclusion in the Codex Procedural Manual after the section on General Criteria (see Appendix attached).

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS (ALINORM 04/27/12 to be issued in April 2004)

CONSIDERATION OF THE CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS (GSCTF) (Agenda Item 13)

Inclusion of Schedule II in the General Standard for Contaminants and Toxins in Food (GSCTF)

122. The Committee noted that Schedule II presented a list of maximum levels for contaminants and toxins arranged by food category. In this regard, the Committee noted that the current food categorization system used in the GSCTF was based on a system developed by the Codex Committee on Pesticide Residues (CCPR). The Committee further noted that CCPR developed this list mainly for primary food commodities although some processed foods such as fruit juices were already included. However, further work was required for processed, derived and multi-ingredient foods.

123. The Committee agreed with the recommendation of the *ad hoc* Working Group³⁹ that, in view of the lack of commodity codes for some existing commodities with contaminant maximum levels, it would not be advisable at this stage to include Schedule II in the GSCTF. Meanwhile, it was agreed that the Committee should enter into consultations with CCPR to determine the best approach to be followed for further development of the food categorization system, in order to allow inclusion of Schedule II in the GSCT at sometime in the future.

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL**1. GENERAL CRITERIA FOR THE SELECTION OF SINGLE-LABORATORY VALIDATED METHODS OF ANALYSIS (TO BE INCLUDED AFTER THE GENERAL CRITERIA)**

Inter-laboratory validated methods are not always available or applicable, especially in the case of multi-analyte/multi substrate methods and new analytes. The criteria to be used to select a method are included in the General Criteria for the Selection of Methods of Analysis. In addition the single-laboratory validated methods must fulfill the following criteria:

- i. the method is validated according to an internationally recognized protocol (e.g. those referenced in the harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis)
- ii. the use of the method is embedded in a quality system in compliance with the ISO/IEC 17025:1999 Standard or the OECD Principles of Good Laboratory Practice;

The method should be complemented with information on accuracy demonstrated for instance with:

- regular participation in proficiency schemes, where available;
- calibration using certified reference materials, where applicable;
- recovery studies performed at the expected concentration of the analytes;
- verification of result with other validated method where available

2. Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts**Principles for the Establishment of Codex Methods of Analysis****AMENDMENTS TO ANALYTICAL TERMINOLOGY FOR CODEX USE*****Specificity: deleted***

Selectivity: Selectivity is the extent to which a method can determine particular analyte(s) in mixtures or matrices without interferences from other components of similar behaviour.

Selectivity is the recommended term in analytical chemistry to express the extent to which a particular method can determine analyte(s) in the presence of interferences from other components. Selectivity can be graded. The use of the term specificity for the same concept is to be discouraged as this often leads to confusion.

Accuracy (as a concept) and Accuracy (as a statistic) to be replaced with the following definition:

Accuracy: The closeness of agreement between a test result and the accepted reference value.

Note:

The term accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component.

Trueness: The closeness of agreement between the average value obtained from a series of test results and an accepted reference value.

Notes:

- 1 The measure of trueness is usually expressed in terms of bias.
- 2 Trueness has been referred to as “accuracy of the mean”. This usage is not recommended.

TERMS TO BE USED IN THE CRITERIA APPROACH

Selectivity: Selectivity is the extent to which a method can determine particular analyte(s) in mixtures or matrices without interferences from other components of similar behaviour.

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