

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 8 (a)

CX/PR 01/11  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-third Session

The Hague, The Netherlands, 2-7 April 2001

### MATTERS RELATED TO METHODS OF ANALYSIS

#### PROPOSED DRAFT AMENDMENTS TO THE GUIDELINES ON GOOD LABORATORY PRACTICE IN PESTICIDE RESIDUE ANALYSIS

*(Prepared by the Netherlands)*

#### BACKGROUND

1. The Codex Committee on Pesticide Residues in its thirty-second session discussed recent developments of principles and practices of method validation. The Committee agreed that methods appropriately validated in a single laboratory can be considered suitable for the determination of compliance with Codex MRLs in addition to methods that have been validated to through collaborative trial. It was noted that the current texts in Volume II of the *Codex Alimentarius* would need an up-date to accommodate for single laboratory validated methods. The Executive Committee in its 47<sup>th</sup> session approved new work on amendments to the *Guidelines on Good Laboratory Practices in Pesticide Residue Analysis, Codex Alimentarius, Volume 2A, Part 1, Pesticide Residues in Food, Methods of Analysis and Sampling, Second edition, Rome 2000, pages 37-47, also available at the following URL: [ftp://ftp.fao.org/codex/standard/volume2a/en/vol2a1\\_5.pdf](ftp://ftp.fao.org/codex/standard/volume2a/en/vol2a1_5.pdf)*

#### PROPOSED AMENDMENTS

2. Amendments will be based on the report of a Joint AOAC/FAO/IAEA/IUPAC Expert Consultation on Single Laboratory Validation on Analytical Methods for Trace-level Concentrations of Organic Chemicals<sup>1</sup> held in Miskolc, November 1999. The process of method validation cannot be separated from subsequent ongoing method performance as long as the method is in operation, as a consequence the concept of the Lowest Calibrated Level (LCL) has been introduced by the Miskolc Consultation.

3. The Committee in its previous session also stressed the importance of harmonizing method validation requirements with those that are formulated by other Codex Committees. An important alternative document that, together with the Miskolc Report, is also under consideration by the

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<sup>1</sup> Report of the AOAC/FAO/IAEA/IUPAC Expert Consultation on Single Laboratory Validation on Analytical Methods for Trace-level Concentrations of Organic Chemicals, in Principles and Practices of Method Validation, A.Fajgelj and A. Ambrus (editors), The Royal Society of Chemistry, London, 2000, ISBN 0-85404-783-2, pages 179-252 also available at this URL: [http://www.iaea.org/trc/pest-qa\\_val2.htm](http://www.iaea.org/trc/pest-qa_val2.htm)

CCMAS is the Draft IUPAC harmonized guidelines on single-laboratory validation of analytical methods<sup>2</sup>, while the CCRVDF is also considering including the Report of the Miskolc Consultation in appropriate parts of the *Codex Alimentarius*. The Committee should review the differences between both documents through its ad-hoc Working Group on Methods of Analysis, a process which should consequently lead to a solid basis for a revised text for the present *Guidelines on Good Laboratory Practices in Pesticide Residue Analysis*.

4. The Committee decided that a paper should be prepared by drafting group (Australia, Brazil, Canada, France, Germany, The Netherlands, United Kingdom, the United States and GCPF), led by the Netherlands describing appropriate parameters and criteria for the assessment of the suitability of analytical methods for Codex purposes. Noting that a similar paper would be prepared for consideration by the CCRVDF, the Committee invited those drafting countries involved in the drafting groups of both Committees to ensure harmonization and coordination between both Committees. Two draft papers have circulated in the drafting group, a proposed text for the introduction section of the Recommended Methods of Analysis for Pesticide Residue Analysis is given in Annex to CX/PR 01/12. A first working draft for the Guidelines to Good Laboratory Practice in Pesticide Residue Analysis will be made available at the meeting for consideration by the ad-hoc working group on methods of analysis and subsequent elaboration by the Committee.

5. The Committee will be invited to consider a document to be prepared by the ad-hoc Working Group on Methods of Analysis that includes a bridge between method validation and ongoing quality control (method verification).

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<sup>2</sup> Draft IUPAC harmonized guideline on single-laboratory validation of analytical methods.