CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5, 6 and 7 **MAS/39 CRD/6**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Thirty-ninth Session
Budapest, Hungary, 7 – 11 May 2018

Comments submitted by European Union

AGENDA ITEM 5 : DISCUSSION PAPER ON THE CRITERIA FOR ENDORSEMENT OF BIOLOGICAL METHODS USED TO DETECT CHEMICALS OF CONCERN

The European Union and its Member States (EUMS) would like to thank Chile and Mexico for the work done and for leading the eWG.

CCMAS 38 agreed to continue the work on criteria for the endorsement of biological methods and to establish an eWG chaired by Chile and Mexico with the following ToR:

- to use the General Criteria for the Selection of Methods of Analysis laid down in the Procedural Manual and other related Procedural Manual referenced documents for the validation of methods of analysis to assess methods in which potency of a substance is measured by the response of living organisms or living systems,
- to determine which criteria would not apply and propose some other criteria that might be necessary for biological methods which are currently endorsed by Codex.

The Committee further agreed that the work should be discontinued if the eWG does not produce a concrete result for consideration by CCMAS39.

The Discussion Paper CX/MAS 18/39/5 produced by the eWG invites the Committee to consider:

- A procedure to save or protect or track the scientific information to make decisions regarding new methods listed in CXS 234;
- Regarding biological methods, to discuss a way to proceed, using the current criteria on a case-by-case basis; or to develop specific criteria for biological methods.

The first recommendation, although not being part of the ToR, is worthwhile to consider by the WG revising CXS 234.

The second recommendation reflects the discussions held at CCMAS37 and CCMAS38. At the latter meeting several delegations were of the opinion that the *General Criteria for Selection of Methods of Analysis* in the Procedural Manual were applicable also to biological methods and therefore additional criteria were not necessary; and if numerical criteria were needed, these could be considered on a case-by-case basis.

The proposed considerations put forward by the eWG do not substantially progress the state-of-play. Therefore, the EUMS suggest to discontinue the work on the development of criteria for endorsement of biological methods used to detect chemical of concern.

AGENDA ITEM 6 : PROPOSAL TO AMEND THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54 – 2004)

The European Union and its Member States (EUMS) would like to thank Germany for the work done and for leading the eWG.

The EUMS welcome the recommendations made by the eWG and support the project document for the new work on the revision of CXG 54-2004 with the general aim to improve the readability for the intended audience

of the current version of the standard. The EUMS also agree and the proposed changes of the current version. Measurement uncertainty, selection of sampling plans, and lot conformity assessment are interlinked particulars and the proposed amendments illustrates well those links.

The EUMS would like to propose the following suggestions for editorial changes to the Proposed Draft of the Revised Guidelines on Measurement Uncertainty.

The EUMS propose to condense the information document and make more use of published guidance documents and standards just by referencing them (e.g. ISO 13528, ISO 5725, EURACHEM Guideline, etc).

Proposed editorial changes:

It is unclear whether the uncertainty given in Figure 2 (and the associated text) is the standard uncertainty (u) or the expanded uncertainty (U). If it is u, than the expanded uncertainty (U, k=2) will amount to +/- 36 which is larger as the reported value (27). As this seems to be confusing, it is recommended to choose a more appropriate value for u.

The incomplete definition of the measurand is not an uncertainty source (page 9) but a shortcoming of the work instruction or the analyst.

"Sampling, e.g. selecting …. from a huge lot of samples" (Figure 3) should be rephrased (… from a lot).

CCMAS agreed to use only the last edition/revision of standards; therefore, ISO/IEC 17025:2005 should be cited as ISO 17025 (page 9).

In Figure 4 the Commission Decision 2002/657/EC should be deleted and replaced by CAC/GL 49-2003 (Harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis).

AGENDA ITEM 7 : PROPOSAL TO AMEND THE GENERAL GUIDELINES ON SAMPLING (CXG 50-2004)

The European Union and its Member States (EUMS) would like to thank New Zealand for the work done and for leading the eWG.

The EUMS welcome the recommendations made by the eWG and support the project document for the new work on the revision of CXG 50-2004 with the general aim to improve the readability for the intended audience of the current version of the standard. In particular, the development of an electronic sampling plan tool/app has great potential to foster the appropriate design of sampling plans by Codex Commodity Committees.

The examples given in the document illustrate very well the aims the revision of the Guideline shall work towards.

Concerning the project document, the EUMS would like to stress that under that Point (a) as regards criteria applicable to general subjects, the improved guidelines should enable the development of more suitable sampling plans for all relevant Codex standards and not only for Codex Commodity standards.

Furthermore the EUMS are of the opinion that it would be appropriate to make specific reference in the project document (Appendix I, under ongoing work) or in the outline of a new CXG 50 (Appendix III) to:

The FAO mycotoxin sampling tool (http://tools.fstools.org/mycotoxins/)

The FAO/WHO microbiological sampling plan analysis tool
(http://tools.fstools.org/Samplingmodel/)

The FAO/WHO histamine sampling tool
(http://tools.fstools.org/histamine/)