

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 3a)

CX/MAS 06/27/3-Add.1

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING  
Twenty-seventh Session  
Budapest, Hungary, 15-19 May 2006**

**DRAFT GUIDELINES FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS  
GOVERNMENT COMMENTS AT STEP 6**

**EUROPEAN COMMUNITY**

**General comments**

The draft *Guidelines for Evaluating Acceptable Methods of Analysis*, circulated in CL 2005/44-MAS, have been redrafted in a generally satisfactory manner, according to the work undertaken in the drafting Working Group. In particular, the presentation of the new draft is very easy to follow and helps its understanding, with the modifications underlined, the explanations to the changes in a right column and the explanatory notes after each annex. Moreover, comments from EC have been generally taken into account.

These Guidelines give the possible estimation methods for performance characteristics of candidate methods, but these should be considered as suggestions rather than prescriptions. As written in the Draft Guidelines (Requirements point 11): "The data from the method performance study should be analysed as described in Annex A. An adequate method description and verifiable performance data should be available for peer review." Thus, the peer review will decide on the acceptance. These Guidelines are an important and useful help both in the assessment and at the acceptance of a candidate method. An extensive list of bibliography with reference numbers is necessary at the end.

**Specific comments**

• **Background**

- Para. 7: The ECMS would prefer including the definitions in these guidelines, since without them available in the same document, it would be difficult to understand and follow the estimation of the parameters. But in that case, a clear warning should be inserted at the beginning of these guidelines to stress that part of these definitions come from the Manual of Procedures, and that any changes to these should be reported in these Guidelines. Or/and inversely, the clause of the Manual of Procedures providing definitions should mention that some of these definitions are reproduced in these guidelines, and that any change to these definitions should be reported in the guidelines. Still in the case of maintaining the definitions in the guidelines, they should not be finalized before the completion of the revision of analytical terminology by CCMAS.
- Para. 11: The ECMS fully support the recommendation to include in these Guidelines the document currently prepared by another CCMAS Working Group on conversion of validation data into criteria.

• **Draft Guidelines**

- Scope, 3: The guidelines apply not only to methods of Type III, but also to Type II, according to the Manual of Procedures regarding the criteria approach.

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- Requirements, 9
  - The ECMS support the deletion of the characteristic “accuracy”, and its replacement by “bias” and “precision”.
  - Limit of quantification: this should be included, as already stated in EC comments on analytical terminology (CX/MAS/ 05/26/6).
- Definitions
  - Repeatability/reproducibility standard deviation: for a better understanding, the notes under the within-laboratory reproducibility standard deviation, applying to both terms, should be referred to.
  - Standard deviation for reproducibility net of repeatability: the usual denomination is “interlaboratory standard deviation”, in accordance with ISO 5725-2, para. 7.4.5.1, for example. This should be indicated between brackets.
  - Within-laboratory reproducibility conditions: The ECMS propose the following text, to be consistent with other definitions, to correct a mistake (identical or different test items could be used) and to add the notion of time of analysis: “Observation conditions where independent test/measurement results are obtained with the same method, on specified test material (identical or different test/measurement items), in the same laboratory by different operators using different or the same equipment, possibly on different days.”
- Annex A: Estimation of Characteristics
  - It is good for the reader that the definitions of characteristics and their estimation are given in the same para. We suggest to give definitions rather from VIM than ISO Draft 3234, VIM is more connected to measurements. Note the current work of Inter-Agency Meeting „Harmonisation of Analytical Terminology in Accordance with International Standards”
  - Reference values, 3: reference values of samples – even artificials – always have uncertainty. No need to emphasise here the difficulties originated from uncertainty, it will be exposed later in Explanatory Notes for Annex A
  - The definitions of Limit of Detection (8) / Quantification (9) do not correspond to the ones proposed by EC for the analytical terminology (see CX/MAS/ 05/26/6). It is understood that these definitions should not be further discussed here, but by the Working Group in charge of the analytical terminology.
- Annex B: Conditions for Acceptance of Methods
  - While this new annex provides useful guidance on how to consider that analytical performances can be considered as satisfactory for the intended purpose, there are some points that surely need further discussion. (e.g. page 24 and 25: the fixation of 14% as maximum deviation that is acceptable, by which the repeatability standard deviation of the ‘new’ method may exceed the corresponding standard deviation of the standard method). Meanwhile, this is introduced for the first time at CCMAS level, and the ECMS are of the opinion that the draft guidelines could not be finalized without further development and consensus on this annex.
- Explanatory Notes for Annex B: It is really an extensive statistical discussion of acceptance conditions. Too much attention is paid to sampling problem, it would be better to separate from the assessment of a new method.