

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4b)

CX/MAS 02/5-Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Twenty-fourth Session
Budapest, Hungary, 18-22 November 2002

CRITERIA FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS FOR CODEX PURPOSES

PROPOSED AMENDMENT TO THE PRINCIPLES FOR THE ESTABLISHMENT OF CODEX METHODS OF ANALYSIS IN THE PROCEDURAL MANUAL

GOVERNMENT COMMENTS (France, EC)

FRANCE

A. General

France generally agrees with the content of the proposed text on "Working Instructions for the Implementation of Criteria Approach in Codex", as in document CX/MAS 02/5.

It especially considers that the document should remain, as it is now, sufficiently general in order to be applied in all cases to be encountered by CCMAS when implementing the "criteria approach". Meanwhile, the document should also include some more precise guidance for the use of the criteria, as well as sufficient number of worked examples in the annex in order to represent a true practical guide.

B. Specific comments

pp. 3/4 : In the two articles "*Conversion of Specific Methods of Analysis to Method Criteria by the CCMAS*" and "*Additions to Analytical Terminology for Codex Use*", we have comments on :

- the **choice and definition of the criteria** to be included into the minimum list of criteria required to enable the conversion,
- to which extent the **application of the criteria** is general.

Proposals of France (comments in italics):

- Accuracy
general criterion (if possible, use certified reference materials)
- Applicability
general criterion, specify the meaning of "satisfactory" in the definition -recalled below in brackets- by adding a note in the definition as follows :
[**Applicability:** The analytes, matrices, and concentrations for which a method of analysis may be used satisfactorily to determine compliance with a Codex standard.

Note 1 : "satisfactorily" means that the method is used in such a way that the performance criteria set by Codex are met".

Note 2 :...]

- Limit of detection
- criterion needed only for qualitative method
- concerning the definition, we appreciate that an alternative to the field blank has been introduced, that is the reproducibility relative standard deviation. But we would favour, as already suggested by several countries, the use of an inter-laboratory estimation of σ_R .

- Limit of quantification
 - *criterion needed only for quantitative methods -in particular trace analysis.*
 - *concerning the definition, same comment that for LOD.*
- Precision: *general criterion*
- Recovery: *general criterion (certified reference materials are the privileged means for establishing the recovery rate).*
- Selectivity: *criterion to be excluded from the list, as it is redundant with the specificity.*
- Sensitivity
 - general criterion, delete Note 3 of the definition -recalled below.*
 - [Change in the response divided by the corresponding change in the concentration of a standard (calibration) curve; i.e., the slope, s_i , of the analytical calibration curve.]

Notes:

1. This term has been used for several other analytical applications, often referring to capability of detection, to the concentration giving 1% absorption in atomic absorption spectroscopy, and to ratio of found positives to known, true positives in immunological and microbiological tests. Such applications to analytical chemistry should be discouraged.

2. A method is said to be sensitive if a small change in concentration, c , or quantity, q , causes a large change in the measure, x ; that is, when the derivative dx/dc or dx/dq is large.

~~3. Although the signal may vary with the magnitude of c_i or q_i , the slope, s_i , is usually constant over a reasonable range of concentrations. s_i may also be a function of the c or q of other analytes present in the sample.]~~

- Specificity (equivalent of selectivity): *general criterion*
- Linearity : *criterion needed for quantitative methods.*
We appreciate that this criterion, together with its definition, proposed in 2001 by France, has been incorporated.

EUROPEAN COMMUNITY

The EC would like to propose that the text presented to the CAC 2001(Alinorm 01/10 add 1) will be agreed upon at the 24th CCMAS 18-22 november 2002.

A FURTHER PROPOSAL IS THE FOLLOWING :

The criteria approach is proposed to be applied for type III methods only.

The EC however is in favour of applying the criteria approach also for type II methods. The EC is of the opinion also type II methods could be selected using the Criteria Approach. This would need an addition to the text in the Codex Procedural Manual page 66 under “*General Criteria for the Selection of Methods of Analysis using the Criteria Approach*”

The text would read:

“In the case of Codex Type II and III methods, method criteria may be identified and values quantified for incorporation into the appropriate Codex commodity standard. Methods.....factors.”

The present situation in Codex concerning methods of analysis is problematic for several committees. The work on establishing e.g. maximum levels for veterinary drugs has almost come to a stop. The demand for intercollaboratively tested methods has not been possible to meet. A collaborative test is very costly and few countries are prepared to be responsible for such work. Reliable methods which are intralaboratively tested are succesively used. Applying criteria would facilitate the Codex work and make it possible to adopt MRL:s for several substances.