

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

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Agenda Item 8a

CX/MAS 02/ 10-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**

**CONSIDERATION OF HARMONIZED IUPAC *GUIDELINES FOR THE IN-HOUSE VALIDATION OF METHODS OF ANALYSIS*
GOVERNMENT COMMENTS**

UNITED STATES

General Comments

The U.S. supports the adoption of the IUPAC Guidelines as a Codex reference document. However, we believe that the guidelines should not be forwarded for adoption until agreement is reached on the clarifying document in Agenda Item 8b, CX/MAS 02/11, Requirements for Single-Laboratory Validation for Codex Purposes. It is also important that requirements be instituted to prevent the Single-Laboratory Validation approach from being used except in exceptional circumstances where there are no fully validated methods available or justify not to fully validate methods in an inter-laboratory study.

Below are some more specific comments that could be considered for future revisions of the IUPAC Guidelines or for clarification in the Codex requirements for their use.

Specific Comments

It is to be noted that “single laboratory validation” is used in two senses:

- (1) Validation of the performance of a new method by a developing laboratory;
- (2) Validation of the performance of a method previously validated in a collaborative study by a specific laboratory.

The requirements in each of the two validation processes above are sometimes different. The guideline has failed to consistently include or point out the differing requirements, as shown in Section 6 on the Extent of Validation Studies.

The guideline includes several subjective statements such as “this needs to be taken into account” and “that needs to be taken into account,” and the guideline also contains several vague statements without any guidance: “There may be unmeasurable sources of uncertainty associated with such techniques.” (last sentence of 5th paragraph of section 4.4), and “although in some instances they are suspected of being very large” (last sentence of 6th paragraph of section 4.4). The U.S. recommends that the above statements be replaced with specific or objective requirements or deleted from the document as they fail to provide the reader with any useful information.

Section 4.3, 3rd footnote:

Footnote “detection should be ‘determination’ as a concentration 10 times below a detection limit is quite unmeasurable, if not inconceivable.

Section 6, sixth bullet, last sentence:

The Horwitz function does not usually apply to empirical methods where the analyte is often ill-defined thus, requiring an empirical method.

A7, Range, paragraph 4:

The term " c_L " is not defined.