CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **MAS-CRD/11**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Comments of Nigeria, Thailand and AAFCO

Nigeria

Nigeria supports the advancement of the guidelines on measurement uncertainty to CAC44 for adoption at step 8.

Thailand

General Comments

Thailand agrees in principle for advancing the Draft Revised Guidelines on Measurement Uncertainty (CXG 54 – 2004) (Appendix I) to the 44th session of CAC for adoption at Step 8. However, we have comments for specific sections as follows:

Specific Comments

- **Section: Procedures for estimating measurement uncertainty**

- According to ISO17025:2017 (Section 7.6 :Evaluation of measurement data), the term "evaluation" is currently used, so in these guidelines, the term "estimation"/"estimating" should be replaced by "evaluation"/"evaluating" for the whole document.

- Para24

We note that ISO/IEC 17025:2017 specifies the requirements for any laboratories to use validated methods, however regardless of involving in food import/export. While, the Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods (CXG 27-1997) requires that the laboratories which are a part of food import/export control should comply with ISO/IEC 17025.

So, we would like to propose revising para 24 to read:

"According to CXG27-1997, laboratories involve in import and export control of food should comply with ISO/IEC17025. ISO/IEC 17025:2017 requires laboratories ~~***involved in the import/export of foods***~~ to use validated methods (see Section 7.2); thus, data from the interlaboratory or single-lab validation study can be used for the estimation of measurement uncertainty following the top-down approach."

AAFCO

REVISION OF THE GUIDELINES ON MEASUREMENT UNCERTAINTY April 2021		
Clause/ Subclause/Paragraph/ Figure/ Table	**Comment**	**Proposed change**
Appendix 1. 1.	Editorial	Analytical measurement results in food control are used to assess whether food products meet relevant specifications. The accuracy of measurement results is affected by various error contributions, and it is important that errors are known and considered. All measurement results have an associated uncertainty; the non-estimation of measurement uncertainty does not mean that there is no uncertainty. The evaluation of measurement uncertainty is required to establish the reliability (or confidence) of measurement results. Accordingly, measurement uncertainty is of utmost importance in analytical testing and subsequent decision-making.
Terms and Definitions: Increment	Reword definition for clarity	Material collected by a single operation of a sampling device and combined with other increments to form a sample. OR A group of material elements collected by a single operation of a sampling device and combined with other increments to form a sample.
Terms and Definitions: Laboratory sample	Reword definition for clarity. Delete “from the lot”. Actually, it would be prepared from the primary sample, unless the primary sample and the laboratory sample were identical. The purpose (inspection, testing) for sampling is not critical to the definition, so delete.	sample as prepared for sending to the laboratory
Terms and Definitions: Lot	Reword definition for clarity. The uniformity of the lot can NEVER be assumed. If every lot were perfectly uniform, sampling would never be needed, eh?	a lot is a definite quantity of some commodity manufactured or produced under similar conditions,
Terms and Definitions:	Reword definition for clarity	A mass or volume of material selected from a large mas or volume (using principles of Theory of Sampling)

Sample		
Terms and Definitions: Sampling plan	Reword definition for clarity (sample size is an ambiguous term; use "sample mass or volume")	Minimum sample mass or volume, methodology for the selection of samples and lot acceptability criteria
Terms and Definitions: Sample size	Delete definition. Using this term only adds confusion. Replace sample size with "sample mass or volume" when referring to mass or volume. When referring to number of increments, say "number of increments"	
Terms and Definitions: Test portion	Reword definition for clarity	Mass or volume of material drawn form the test sample for a single test
General considerations 12.	Editorial. Suggest adding analyst technique to the list of changes.	….e.g. effects which arise in connection with changes in temperature, pressure, humidity, matrix variability, analyst technique, or with the judgment of the analyst
General considerations 17.	Check grammar. This section is very confusing. Too much information, and not clearly stated.	
General considerations 18.	I really can't figure out what this first sentence is supposed to be saying. For one thing, there are too many words, excess verbage, and the point is missing. For clarity, just delete it.	Both the chosen approach for estimating measurement uncertainty (in-house validation, collaborative study, bottom up etc.) and the estimated level of confidence of the measurement uncertainty should be available on request.
General considerations 19.	Editorial. The word uncertainty is used twice in two different contexts in the same sentence. Reword.	Almost all uncertainty data are expressed as standard deviations or functions of standard deviations. If a standard deviation is calculated using a small amount of data there is considerable lack of statistical confidence in the estimate of measurement uncertainty obtained.
General considerations 21.	Delete this section. Intention is unclear and adds confusion to the document.	Delete the entire section 21
General considerations 22.	Editorial. Delete "in order to". Unneeded words.	To demonstrate that a laboratory is competent in the application of a validated method, there are two possible approaches:
General considerations 23.	This statement is not true for procedures used to obtain the test portion from the laboratory sample.	

	This is a large gap which should be noted.	
Uses of measurement uncertainty. 25	Suggest deleting this section entirely. It only adds confusion. Most of this is covered in the scope. The purpose of the estimation of measurement uncertainty is to know the error associated with a test results (thus know the confidence in the test results). This section only adds confusion. Obviously, there are many occasions when it is important to know the error associated with a test result. In fact, any time a test result is used, it is important to know the associated uncertainly.	Delete the entire section 25.
How to report measurement uncertainty in test results. Section 26	The decision is ultimately being made about the lot or decision unit, not the laboratory sample.	
How to report measurement uncertainty in test results. Section 27	Section 27 is confusing. Adds no clarity, only confusion. Delete.	Delete the entire section 27
Examples of situations occurring when measurement uncertainty is considered, Section 28	Editorial	Figure 1 illustrates how measurement uncertainty can affect the decision about how the test result conforms to a specification limit. The procedure illustrated in Figure 1 is not always suitable and is merely intended to illustrate the basic principle.
Examples of situations occurring when measurement uncertainty is considered. Section 29	Editorial	The decision whether the test result meets the specification or not depends on the rules which the different parties involved have agreed to apply.
End of comments		