codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 4 **CX/MAS 04/4**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Twenty-fifth Session
Budapest, Hungary, 8 – 12 March 2004

DRAFT GUIDELINES ON MEASUREMENT UNCERTAINTY GOVERNMENT COMMENTS AT STEP 6 (Finland, Ireland, Japan, New Zealand)

FINLAND

The **Draft Guidelines on Measurement Uncertainty** have been prepared mainly from the viewpoint of chemical analysis and do not to a sufficient degree take into account the principles of the estimation of measurement uncertainty in microbiological and sensory analysis (identification of error sources and their assessment).

It is not clear from the Guidelines whether the measurement uncertainty due to sampling is included or not. It appears that only analytical uncertainty is included, even if it is generally recognised that in practise the collection of samples gives rise to the largest uncertainty.

In the guidelines it is noted that the measurement uncertainty should be made available to the customer on the customer's request. This approach has in the experience of the laboratory assessors in Finland led to the practise that laboratories do not report measurement uncertainty on the basis that the customer does not ask for it. In the official control of foods it is of great importance that the measurement uncertainty of an analytical result is known to the user who has to interpret the result and/or compare it to a legal norm. In the ISO/IEC standard 17025 it is stated that the measurement uncertainty must be provided with the analytical result if the result is compared to a limit ("when the uncertainty affects compliance to a specification limit").

It would be an advantage if the guidelines contained clearer instructions regarding the way in which the measurement uncertainty is to be reported. When laboratories have the possibility of choosing themselves the method for estimating the uncertainty, it should for example be stated on what confidence (e.g. 95% or 99%) it is based.

IRELAND

Ireland wishes to make the following comments of a largely editorial nature regarding the above CL:

1. Terminology

"The accepted definition for measurement uncertainty" should read "the international definition for measurement uncertainty". It should be referenced to the ISO document where the term quoted is defined i.e. the International vocabulary of Basic and general Terms in Metrology, ISO, 1993 ,2nd Edition.

2. Recommendation number 3, second half of line 1

"may be estimated in a number of procedures" should read "may be estimated by a number of procedures"

JAPAN

We wish to propose to add the use of proficiency testing in footnote 2 and to amend slightly the text of the footnote. The resulting footnote will read as follows (added words are underlined):

> "Where inter-laboratory studies are not possible, a satisfactory substitute for reproducibility must be found. Such substitutes include reproducibility derived from the results of proficiency testing, the intra-laboratory reproducibility, or an approximation, such as the Horwitz criterion.

NEW ZEALAND

General comment

The Proposed Draft Guidelines do not provide information on the important issue of how measurement uncertainty is to be used, particularly in assessing compliance as outlined in the Eurachem document (Reference 2) for example. To this extent the document does not achieve the goal of standardising the interpretation of test results to harmonise trade, as discussed in CX/MAS 02/13, The Use of Analytical Results.

We contend that both Measurement Uncertainty and Sampling Plans are used to assess conformance of product to specifications, and we feel that their roles need to be clarified To address this issue, we support the proposal made by the Delegation of Ireland (para. 51 of Alinorm 03/23) that an over-arching document be prepared explaining the relationship between measurement error and other issues that affect the use of analytical results. This would cover the points:

- assessments of compliance must take account of measurement uncertainty;
- assessments of compliance need take account of only measurement uncertainty when sampling error, i.e. product variation, is or is assumed negligible in comparison with measurement error;
- sampling plans such as those appearing in the Draft General Guidelines on Sampling are used in situations where measurement error is negligible in comparison with sampling error, i.e. product variation. Measurement uncertainty does not need to be considered in these cases;
- in cases where the sampling error and measurement uncertainty are comparable special sampling plans must be used. These are currently outside the scope of the Draft General Guidelines on Sampling.

Note that sampling error is considered negligible in comparison to measurement error if the standard deviation representing the product variation does not exceed 30% of the total measurement error standard deviation

Specific comments

NZ questions how bias is to be handled in terms of measurement uncertainty. Bias can cause a significant difference in the interpretation of results but not being a component of dispersion, it does not enter into measurement uncertainty.

Does this mean, for example, that all results reported are corrected for bias or that measurement uncertainty is generalised from the current style "±a" to the interval "-a to +b"?

Note 1

We feel there needs to be standardisation of the way in which measurement uncertainty is expressed to avoid ambiguity in the interpretation of quoted values. We recommend that such expressions be based on "the 95% confidence interval".

Note 3

The intent of this note is unclear but it suggests that a single result is the best estimate of a measurand. A single result may be the best estimate available but it is not necessarily the best estimate, as a result from a retest of the same sample, or of a different sample, will invariably be different, and there would be no means to judge which is superior.