Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 6

MAS/40 CRD/25

REVISION OF THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXS 54 - 2004)

(Prepared by the EWG led by Germany)

Scope

(i) the use of measurement uncertainty in the interpretation of measurement results

(ii) the relationship between the measurement uncertainty and (given) sampling plans

(iii) Only focusing on laboratory samples incl. sub-sampling

(iv) As simple as possible and not overloaded

(v) Should illustrate above mentioned points

Not included:

(i) Sampling plans

(ii) Conformity assessment

(iii) Homogeneity of the lot (except fundamental variability)

Comments of Member States

15 comments in detail

NO: 5 comments

NZ: 4 comments*

CA: 2 comments

EC: 1 comment

JM: 1 comment

MA: 1 comment

TH: 1 comment

These comments should be discussed in detail.

* Comments of NZ were discussed bilaterally and had been included

Comments of Member States

Comments in detail

In the following only comments gave reason for discussion will be mentioned

1. CA: Appendix I, page 4, Footnote:

The heterogeneity between test portions **is composed of compositional heterogeneity (CH) and distributional heterogeneity (DH). Both of these lead to random errors when selecting a test portion, known as Fundamental Sampling Error – also called Fundamental Variability – and Grouping and Segregation Error. Fundamental variability results from CH and is the variability between test portions that remains even under the best achievable degree of particle size reduction.**

This is an important subject and should be included.

Question to MS: are the terms CH and DH well-known?

Comments of Member States

Comments in detail

In the following only comments gave reason for discussion will be mentioned

2. CA: Appendix I, page 4, Footnote:

The fundamental variability has a dominant effect on total variability when the “target compound” is predominantly located in a specific fraction of the particles (there is a low number of particles with relatively high concentrations of the target compound). **The fundamental variability can be controlled by collecting a sufficient test portion mass. Grouping and segregation error results from DH and is the non-random distribution (spatial or temporal) of the “target compound” within the material from which a test portion is selected. The grouping and segregation error can be controlled through the collection of a sufficient number of random increments to comprise a test portion.**

This is an important subject and should be included.

Comments of Member States

Comments in detail

3. EG: Referring to ISO no. 19036/2006 "Microbiology of food and animal feeding stuffs - Guidelines for the estimation of measurement uncertainty for quantitative determinations" in the clause of Literatures in page No. (22).

Microbiology is not part of CCMAS and the Standard ISO 19036 is very specific for microbiological methods

Referring to "sum of components" as the above mentioned guidelines refer only to "single method".

s. above

Comments of Member States

Comments in detail

4. JM: Jamaica recommends that the two examples on acceptance sampling be excluded as part of the guideline. Taking into consideration paragraph 6 under background, the section "The use of measurement uncertainty in sampling plans" at the start of paragraph 29 should be removed. It may be better placed in General Guidelines on Sampling (CXG 50 - 2004), when this guideline is to be revised.

It was part of the scope: „(ii) the relationship between the measurement uncertainty and (given) sampling plans”

Comments of Member States

Comments in detail

5. MA: **Introduction,** Paragraph 1: Morocco proposes to include sampling uncertainty in this guideline.

It was not part of the scope: „The purpose of the guideline comprises only laboratory samples“

Comments of Member States

Comments in detail

6. NO: Repeatability is used many times throughout the document. The term “repeatability” should be replaced with the more general term “precision” to not exclude intermediate precision or reproducibility

The term repeatability was used very conciuosly and should remain where it was used otherwise the context became wrong

7. NO: Suggest the following clarification to sentence four in para 9 on page 5: Measurement uncertainty is expressed as an interval within which values which can reasonably attributed to the measured quantity will lie **with a stated coverage probability**.

accepted

Comments of Member States

Comments in detail

8. NO: The individual components of measurement uncertainty ~~must~~ **such as precision and bias, should** be identified and quantified~~, especially repeatability and bias~~.

repeatability and bias are necessary for further calculations

An explanatory text can be added

9. NO: There are many procedures available for estimating the uncertainty of a measurement result, notably those described in ISO [13]**,NMKL [xx]** and EURACHEM [12].

To our opinion NMKL procedure of 2003 is too old

Comments of Member States

Comments in detail

10. NO: Propose to delete para 15, on page 6, except the first sentence which should be moved to the current para 16 (see next proposal below)
Rationale: Both top-down and bottom-up approaches have pros and cons and we therefore propose to delete para 15, since it leaves a very biased impression with respect to the trustworthiness of using different approaches. Alternatively, the characteristics connected to using a bottom up approach should also be clearly stated in a new paragraph.
According to EURACHEM/Citac Guide CG 4 the bottom up approach should only be applied when no other method information like valisdation data is available. Therefore the bottom-up approach is of minor importance and was not subject of discussion.

It was important to highlight the importance of the matrix-mismach uncertainty component.

Comments of Member States

Comments in detail

11. TH: second and third note below Figure 1 should be removed

Cf to respose to comment of NZ: These paragraphs are important for the way how measurement uncertainty should be used

Comments of Member States

Question 1: Should the two examples on acceptance sampling be part of the guideline?

- 10 responses
- 7 should be excluded (AU, CA, NZ, MA, JM, MX, EU)
- 3 should be included (EC, NO, ROK *(could also move to an appendix)*)

Question 2: Should Figure 1 be part of the guideline?

- 10 responses
- 9 should be included (NO, AU, NZ (*with considerable changes*), EC, JM, MA, MX, EU, ROK *(could also move to an appendix)*)
- 1 should be excluded (CA)

Comments of Member States

Question 3: New guideline on decision rules in conformity assessment?

- 6 responses
- 4 yes (JM, MA, NO, EU)
- 1 no (NZ)
- 1 not yet (AU)

Question 4: Should an adapted version of GL 59, chapter 4 be included in GL 54?

- 8 responses
- 6 yes (NO, NZ, JM, MA, MX, EU)
- 1 no (TH)
- 1 yes or no? (*answer was not clear*)