codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/MAS 10/31/4-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Thirty-first Session
Budapest, Hungary, 8 - 12 March 2010

PROPOSED DRAFT REVISED GUIDELINES ON MEASUREMENT UNCERTAINTY
(Comments submitted by Argentina, Brazil, New Zealand, Panama and IDF)

ARGENTINA

VERSION ESPAÑOL

En General se acuerda con el Documento que en forma clara expone los principios básicos para el tratamiento del tema por los laboratorios, no obstante realizamos los siguientes comentarios:

La delegación Argentina considera que el título 9 del Documento CX/MAS10/31/4: Uso de la Medición de la Incertidumbre y Definición en situación de Disputa debe ser eliminado y reemplazado por el siguiente:

“En situación de disputa respecto a resultados analíticos, una vez calculada la incertidumbre del método, se aplicará la "Guía para la Resolución de Disputas sobre Resultados Analíticos” incluida en el Manual de Procedimientos del Codex Alimentarius”.

Además se sugiere agregar las referencias bibliográficas en el Titulo 7

ENGLISH VERSION

In general we agree with the Document that in clear form it exposes the basic principles for the treatment of the topic for the laboratories, nevertheless we realize the following commentaries

“The Delegation of Argentina considers that the title 9 of Document CX/MAS 10/31/4: Use of the Measurement of Uncertainty and Definition in situation of Dispute, must be eliminated and replaced for the following one:

In situation of dispute with regard to analytical results, once calculated the uncertainty of method, "Guide for the Resolution of Disputes on Analytical Results” will apply, which is included in the Manual of Procedures of Codex Alimentarius.

In addition it is suggested the bibliographical references add in the Title7

BRAZIL

Brazil thanks the United Kingdom for the preparation of this document and proposes new wording to:

Annex

Introduction; third paragraph

Most quantitative analytical results take the form of “a ± ku or a ± U” where “a” is the best estimate of the true value of the concentration of the measurand (the analytical result), “k” a coverage factor and “u” is the standard

uncertainty and "U" (equal to ku) is the expanded uncertainty. The range "a ± ku" (where k = 2) represents a 95% level of confidence where the true value would be found (in other cases can be increased as k = 3 (99%)). The value of "U" or "ku" is the value which is normally used and reported by analysts and is hereafter referred to as "measurement uncertainty" and may be estimated in a number of different ways.

Explanatory Notes To The Codex Guidelines On Measurement Uncertainty

1st. Question, 1st. paragraph:

Initiating the sentence with **"Most quantitative analytical results…**

Question 7, 4th paragraph,:

Eliminating the paragraph with the mention to microbiological analysis;

Item 8.1 Measurement uncertainty:

Substituting the title of the figure by: "Assessment of compliance with and Upper Limit"

NEW ZEALAND

General comments

New Zealand wishes to thank the United Kingdom for leading the electronic working group and for redrafting the proposed guidelines and explanatory notes.

Regrettably New Zealand is not able to support the report or the redrafted guidelines and explanatory notes. Although we participated in the working group, we have no information on the comments submitted by other participants, but we note from the report that the comments received were often in conflict with each other. We therefore have no confidence that the revised draft represents an agreement from the group.

We suggest it would be appropriate for all participants to receive comments submitted by other members of the electronic working group as explicitly provided for in the Codex Rules of Procedure. An open and transparent process of engagement is important to facilitate the development of an agreed draft that reflects the various points raised.

For its part, New Zealand has raised serious concerns on substantial matters with both this electronic working group and the previous eWG, and in the committee, which have not been addressed. The concerns we expressed at CCMAS 30 are reported in ALINORM 09/32/23, para. 114. The proposed revision of the guidelines should not proceed until these basic concerns have been resolved.

A key concern is the proposed approach to compliance assessment of food. Codex procedures set out principles for compliance assessment, where the emphasis is on controlling the frequency, or alternatively the cost, of wrong decisions.

Instead, the measurement uncertainty approach seems directed more towards making judgments about the extent to which individual samples have been "proved" compliant or non-compliant, presumably under the impression that a satisfactory alternative for compliance testing can be built on this basis.

Unfortunately this is not possible and could be seriously misleading. For example, it is easy to envisage a scenario in which every single sample that is claimed "beyond reasonable doubt" to be non-compliant is in fact compliant: one need only postulate the presentation of a series of samples just below the limit (a far-from-unlikely scenario for certain types of specification limit and manufacturing processes).

We are also concerned that the procedure does not warn against evaluating more than one sample from the same lot by the measurement uncertainty approach.

In particular therefore New Zealand considers that sections 8.1 and 9 should be deleted from the Explanatory Notes at this time.

New Zealand also has a number of other concerns, which may be summarised as follows:

- The status of the text is unclear. The Explanatory Notes go considerably beyond explaining the Guidelines, since they cover matters that are not mentioned in the Guidelines; they go beyond explanation, since they include specific procedures recommended for governments; and they include embedded text from the Procedural Manual, provide lists of references and quote text from the references. We assume all of this will have the normal status of a Codex text, that is, it is covered by the definition of "international standard" contained in the WTO/TBT Agreement, and all of it may be applied by governments or any other party even though it is described as "explanatory" and "written not for metrological experts but routine providers of analytical data, customers of laboratories reporting analytical data and delegates to Codex Commodity Committees."
- The procedures recommended for applying measurement uncertainty to product compliance are somewhat unclear, but they appear to require that ALL results should fall more than U away from the limit, in order to avoid risk that a single sample (and therefore a lot) may be found non-compliant. If the procedures were applied to measurands of economic value, such as protein, this could result in very substantial costs to food manufacturers and exporting countries. On the other hand, the protection afforded to the importing country by the recommended single-sample assessment is very poor.
- We have noted previously that there are deficiencies in the recommended procedures for estimating measurement uncertainty; that the estimates of measurement uncertainty are likely to be considerably too small to achieve the expected nominal coverage rates; and that the procedures do not adequately account for bias. We also note that there is no verification procedure for the estimated measurement uncertainty.
- The procedures do not take account of uncertainty from sampling. In many cases uncertainty from sampling is as large as or larger than analytical uncertainty. The two must therefore be considered in conjunction when assessing product conformity (but without perpetuating the flaws in the present paper).

New Zealand recommends that CCMAS should:

1. Adopt a concept of compliance assessment that is based on the idea of controlling the frequency of wrong decisions rather than 'reasonable doubt', and

2. Develop guidelines that simultaneously address both sampling uncertainty and a suitable concept of measurement uncertainty.

PANAMA

Estamos de acuerdo con el documento del Codex que dicta la directriz de la forma de estimar la incertidumbre de los resultados, requisito importante para las normas ISO 17025 necesarias para la acreditación de laboratorios de ensayo.

Esta directriz permitirá armonizar los procedimientos que actualmente usan los laboratorios en los diferentes países.

Opinamos que entre más claro sea el mismo facilitará a los laboratorios que no tienen acreditación con las normas ISO 17025 y que no están relacionados con el termino de incertidumbre entender con más claridad la naturaleza del mismo.

IDF

IDF acknowledges the work of the delegation of the United Kingdom in preparing the Proposed Draft Revised Guidelines on Measurement Uncertainty and the accompanying explanatory notes (CX/MAS 10/31/4).

IDF has also noted the dispatch of a document on Guidance on Uncertainty of Sampling (CX/MAS 10/31/06).

GENERAL REMARK

In our opinion, it is essential to apply clear and unambiguous terminology. In line with the approach mentioned in CX/MAS 10/31/06, and noting that the term "measurement uncertainty" is used in a restricted sense in this

document, we have, for clarity, considered the *total or measurement uncertainty* of a measurement or measurements to consist of both *sampling uncertainty* and *analytical uncertainty*, in short:

Measurement uncertainty = sampling uncertainty + analytical uncertainty

SPECIFIC REMARKS

Recommendation 2 of "Proposed draft revised guidelines on measurement uncertainty and explanatory notes on the significant of the guidelines (Revised CAC/GL 54-2004)"

1. IDF supports the approach taken to not recommend procedures for the estimation of measurement uncertainty as this is not the objective of the draft Guidelines. Hence, so as not to give any preference to any procedure, we recommend rewording CX/MAS 10/31/4, p.5 (and CX/MAS 10/31/6, p.6), recommendation 2 as follows, "The measurement uncertainty of an analytical result may be estimated by a number of procedures, such as those described …."

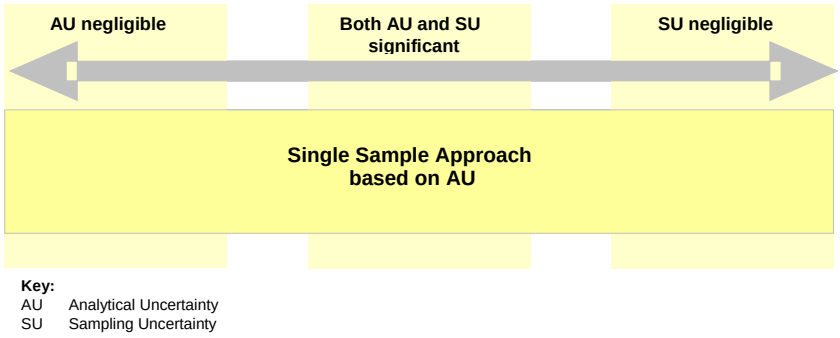
Sections 8 and 9 of the explanatory notes (CX/MAS 10/31/04)

2. IDF notes the approach advocated in Sections 8 and 9 of the explanatory notes. These suggest that an adequate compliance assessment of a lot can be performed by testing a single sample and comparing the analytical result with a specification limit taking only analytical uncertainty into account. IDF has serious reservations concerning this approach, because it appears to compromise one of the objectives of Codex, namely to ensure fair practices in trade. This is because the proposal outlined in Section 8 fails to provide adequate protection to either the importer or exporter, particularly for dairy products where sampling error is of similar magnitude as analytical error, or where sampling uncertainty is significantly larger than analytical uncertainty.

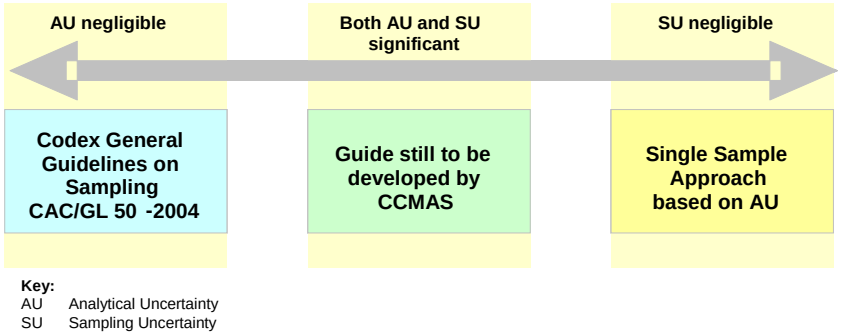
3. The sampling plans in CAC GL 50 are designed to control risks of incorrect decisions, specified by the *Acceptable Quality Limit* or the *Limiting Quality* and operating characteristics are provided to allow users to select plans to allow no more risk than required. However, no such demonstrations have been provided for the scheme proposed in Sections 8 and 9 to assure importers that it will provide them with sufficient protection against non-compliant product, or to assure exporters that it will not lead to unjustifiably high levels of rejection of compliant product.

4. The sampling plans appearing in the Codex General Guidelines on Sampling CAC GL 50-2004 do not contain plans based on samples of size n=1, yet Sections 8 and 9 imply that schemes based on single sample assessments are universally applicable for compliance assessment. The approach implied in Sections 8 and 9 is represented in the first scenario in the diagram below, whereas IDF believes the *correct* approach depends on the relative sizes of sampling uncertainty and analytical uncertainty, as shown in the second scenario.

Approach suggested by Section 8



Correct approach according to IDF



5. IDF also believes Section 9 is too prescriptive especially towards exporters/producers as it concentrates only on one possible form of product assessment.

   IDF proposes to replace the text of section 9 with the following text:

   Where the results of the importer indicate non-compliance of a lot and a dispute between the importer and exporter arises, the dispute may be resolved by using the Codex Guidelines for Settling Disputes on Analytical (Test) Results

6. In summary, IDF has serious reservations about the material in Sections 8 and 9. IDF notes that with any sampling plan there will be risks of making an incorrect decision about the compliance status of the lot, that is, of (i) accepting product that should be rejected, or (ii) rejecting product that should be accepted. These risks can be evaluated using statistical methods. Sampling plans can then be chosen to allow no more risk than is required. However no such evaluation has been provided for the single sample proposal outlined in Sections 8 and 9. Therefore, to avoid giving users a false sense of security, the explanatory notes should *at the very least* outline the limitations of compliance assessments on the basis of single sample analyses. IDF is of the view that the effectiveness of this (in fact, "any") procedure, to control the risks of making incorrect decisions about compliance of a lot, *must* be transparent to its users.

   However, IDF's strong preference is that CCMAS addresses its guidance on "measurement uncertainty" in a *holistic manner* by taking an integrated approach, i.e. by dealing with *both* analytical uncertainty and sampling uncertainty.