codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3b) **CX/MAS 09/30/4**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Thirtieth Session
Balatonalmádi, Hungary, 9 - 13 March 2009

CRITERIA FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS

DRAFT GUIDELINES FOR SETTLING DISPUTES OVER ANALYTICAL (TEST) RESULTS

GOVERNMENT COMMENTS AT STEP 6
(Brazil, Cuba, European Community, New Zealand)

BRAZIL

Item 4 - The Methods of Analysis to be Used by the Laboratory

Substitute: "If the test from two laboratories differ by less than would be expected from measurement uncertainty of results (see annex), the importing country's original assessment of the lot shall stand, and the dispute is thus resolved". by:

"If the analysis result of first reserve sample agrees with one of the two original results, or from importer country or from exporter country, considering measurement uncertainty, the dispute will be solved. Otherwise, if this result does not confirm the original results, it should proceed to the following step".

CUBA (versión en español)

El documento de referencia constituye una herramienta importante para la solución de las disputas que pueden surgir como consecuencia del comercio internacional de alimentos; es también muy importante su contribución a la eliminación de barreras u obstáculos técnicos al comercio.

Cuba desea someter a su consideración los siguientes comentarios en relación con el documento circulado, versión en idioma español:

- Punto 2, pleca 2 y punto 3, pleca 4: sustituir en la versión en español el término “garantía de la calidad” por “aseguramiento de la calidad” que es vocablo correcto y coincide entonces con la versión inglesa.
- Punto 2, pleca 4 y Anexo, línea 3: Sustituir en la versión en español el término “incertidumbre ampliada” por “incertidumbre expandida” que es el término aceptado.
- Punto 2, pleca 5: Falta añadir la referencia recientemente aprobada por la CAC para su inclusión en el Manual de Procedimiento.
- Punto 3, pleca 4: Sustituir en la versión en español el término “datos en blanco” por “datos del blanco”.
- Punto 4.1: Sustituir “el análisis de las posibles muestras de reserva” por “la idoneidad de las posibles muestras de reserva” ya que en el punto 4.3 es donde ciertamente se habla sobre “el análisis de la muestra de reserva”.
- Párrafo que aparece a continuación del punto 4.4: El párrafo hace referencia a “la diferencia entre los resultados de ensayo realizados por los dos laboratorios”, esta redacción es ambigua y se debe precisar a cuáles dos laboratorios específicamente se hace referencia bajo estas nuevas condiciones.
- Punto 5, línea 1: Sustituir en la versión en español la redacción “una tercera reserva de las muestras” por “una tercera muestra de reserva”

- Punto 5, línea 2: Sustituir el término “disconformidad” por “discrepancia”, ya que inicialmente cada laboratorio emite un resultado que para él mismo “es conforme”, pero más tarde se origina una discrepancia.
- Anexo, línea a continuación de la segunda fórmula: precisar si “u_1” y “u_2” se refieren a las “incertidumbres típicas” o a las “incertidumbres típicas combinadas”

CUBA (English version)

The document of reference is an important tool in the settling of disputes that may be started as consequence of the international trade of foods; it is also very important their contribution in the removal of barriers or technical obstacles to the trade.

Cuba wishes to subject to your consideration the following comments in connection with the circulated document, version in Spanish language:

- Item 2, second bullet and item 3, fourth bullet: Change in the Spanish version the term "quality guarantee" for "quality assurance" that is the correct word in Spanish and then it matches with the English version.
- Item 2, fourth bullet and Annex, line 3: Change in the Spanish version the term "enlarged uncertainty" by "expanded uncertainty" that it is the accepted term in Spanish.
- Item 2, fifth bullet: It is really necessary to add the referred reference in the paragraph, recently approved by the CAC for their inclusion in the CODEX Procedure Manual.
- Item 3, fourth bullet: Change in the Spanish version the term "data in blank" for "data of the blank."
- Item 4.1: Change the text "the analysis of the possible reserve samples" for "the suitability of the possible reserve samples" since in item 4.3 is where certainly refers to "the analysis of the reserve samples".
- Paragraph immediately after item 4.4: This paragraph refers to "the difference between the test results carried out by the two laboratories", this writing is ambiguous and it should be necessarily specified to which of the two laboratories we are referring exactly under these new conditions.
- Item 5, line 1: Change in the Spanish version the writing "a third reservation of the samples" for "a third reserve sample".
- Item 5, line 2: Change the term "unconformity" for "discrepancy", since initially each laboratory emits its own result "in conformity" itself, but a discrepancy is originated later.
- Annex, line immediately after the second formula: It is necessary to specify if "u_1" and "u_2" refer to the "typical uncertainties" or to the "combined typical uncertainties".

EUROPEAN COMMUNITY

The Draft Guidelines in ALINORM 08/31/23, Appendix IV, were the outcome of the in-session working group. The European Community and its Member States (ECMS) therefore fully support the text of the document. With regard to the Annex the ECMS suggest to delete the second formula. Please find the detailed comments below:

The second formula mentioned in the Annex of the Draft Guidelines (ALINORM 08/31/23, page 52) is based on the presumption that reproducibility R and repeatability r have a relation of 2:1.

That means that the used uncertainties u_1 and u_2 of the individual labs are corrected by the reproducibility and the repeatability rate of the methods and it additionally presumes that the standard uncertainty only comprises of these two measurement uncertainty components.

Firstly, the used rate of 2:1 cannot be fixed in a formula since it is not constant as the results of many method comparison studies show. The rates vary between 2 up to 8 or 9. Therefore the use of the fixed rate 2:1 leads to an increase of the error probability of making false rejections of the lots from normally underlying 5% to twice as high or even more which may lead to severe consequences for the importers.

Secondly, the exclusive consideration of the two uncertainty components R and r is underestimating the real situation. Other factors like matrix influences and when different methods were applied, the method error, are also contributing to the combined measurement uncertainty. This again underestimates the combined uncertainty which is used in the formula.

Thirdly, correcting the standard uncertainty of the laboratories (u_1 and u_2) for the number of repeated analyses presumes that the measurement uncertainty is dependent on the number of repetitions of the particular analysis. According to our understanding, the measurement uncertainty is not simply a standard

deviation, but an uncertainty figure assigned to a measurement result, and this concept is – at least in general – not consistent with the concept of reproducibility and repeatability: there is no automatic reduction of measurement uncertainty in case of repeated measurements. So, it is not comprehensible that the random error (repeatability) should influence the difference of the two measurement results and with that the judgment on rejection.

Consequently, the formula should be deleted completely. There is no simple formula to settle disputes generally, but there is a worst-case approach available which resembles the already given formula in the ALINORM paper: If

$$1.96 * \mathrm{sqrt}(u1^2+u2^2)$$

exceeds the difference between the measurement results, it can be concluded that there is a significant difference. However, this requires appropriate determination of the respective uncertainties.

NEW ZEALAND

New Zealand supports progress on these draft Guidelines, and makes the following comments on the sections in square brackets, and to improve and clarify the text.

SECTION 2. PREREQUISITES/ASSUMPTIONS

The introductory statement should make it clear that the prerequisite points are conditions with which the parties are expected to comply in order that it is possible for disputes to be resolved. We propose the following wording:

> "The procedure described in these guidelines is operable and effective only when the conditions listed below are met. Competent authorities should therefore ensure that these are satisfied wherever possible."

Bullet 4

This bullet point should be retained, since the information on measurement uncertainty is needed when comparing results from two laboratories in section 4 of the Guidelines. Measurement uncertainty needs to be reported only when requested. The words "when requested" should be inserted in the first sentence.

Bullet 5

This bullet point should be redrafted to focus on the specific points that are relevant to settling the case at issue, since the recommendations that are referenced are intended for a different purpose, i.e. general procedures for drafting Codex commodity specifications. We propose as follows:

> "Laboratories report the sampling plan (including acceptance criteria) that was used and the analytical results that were used to determine the acceptance status, including any information necessary to interpret the results such as:
>
> a) whether analytical results are expressed on a recovery-corrected basis (and if so the method by which recovery was taken into account and the recovery rate),
>
> b) the units in which results are expressed, and
>
> c) the number of significant figures."

Bullet 6

Bullet 2 already covers this point, since GL 27 states, "The following quality criteria should be adopted by laboratories involved in the import and export control of foods: … Whenever available, use methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission." Bullet 6 should therefore be deleted to avoid duplication and possible confusion.

SECTION 3. THE RESULTS AND PROCEDURES OF THE LABORATORY OF THE EXPORTING COUNTRY AND ITS COUNTERPART IN THE IMPORTING COUNTRY ARE COMPARED

The procedures in this section will very likely be time consuming, and the results may be inconclusive. In cases where dispute resolution is needed quickly, for instance where perishable food is in question or where demurrage costs are high, it would be much better to proceed immediately to section 4, which will generally provide a speedy conclusion. A footnote to the first sentence should therefore be included as follows:

"In cases where a dispute needs to be resolved quickly, for instance where perishable food is in question or where demurrage costs are high, it is recommended that the competent authorities should proceed immediately to section 4, which will generally provide a speedy conclusion. The procedures given in section 3 can then follow later."

Bullet 1: The term "method-specific" should be hyphenated.

Bullet 2: Since this is a list of information items rather than a list of actions, the words, "are assessed and are in order" should be deleted.

Bullet 4: Similarly the words, "assessment of" should be deleted.

The second paragraph is ambiguous as it may be taken to imply that the procedure will necessarily result in only one laboratory's results being recognised, whereas it is also possible that both laboratories' results may be recognised, or neither. It should be rewritten for clarity as follows:

"Each competent authority reviews its initial assessment on the basis of the additional information received from the other. This may lead to agreement on conformity or agreement on non conformity, e.g. by recognising the validity of the results of only one of the two laboratories."

SECTION 4. ANALYSING RESERVE SAMPLES

The drafting of the first paragraph should be improved to make its meaning clearer. Firstly, the sequence of events in the first sentence needs to be stated clearly: that is, the first set of reserve samples is analysed, subject to certain conditions, and the results are compared. Secondly, the prerequisites have established that there is at least one sample, which is split into three to provide for two reserves. In Section 4 the laboratory is analysing the <u>first</u> of the reserve samples. Thirdly, it needs to be clear that the results being compared are those arising from the sample(s) on which the finding of non-conformity was based and the corresponding reserve sample(s).

We propose the following rewording:

"The first set of reserve sample(s) is analysed, subject to it being established that sample integrity and their chain of custody have not been compromised and agreement between the respective competent authorities on the following procedures for analysis of the sample(s):

1. The timeline, and the time of availability of the sample(s)[6];
2. The analysis of the reserve sample(s) by either

   The importing country's laboratory in the presence of an expert from the exporting country

   OR

   A laboratory chosen by the exporting country;
3. The methods of analysis to be used by the laboratory.

The test results from the samples on which the finding of non-conformity was based are compared with results from the reserve sample(s). If the test results … (etc)"

SECTION 5. ANALYSIS OF REMAINING RESERVE SAMPLES

The 3rd prerequisite bullet has established that there is at least one sample, which is split into three to make two reserves. In Section 5 the laboratory is analysing the second of the reserve samples. The first sentence should therefore read:

"The second reserve(s) of the sample(s) on which the finding of non-conformity was based should be analysed …"

ANNEX

It is pleasing that both formulas are included in the Annex, to allow for the possibility that more than one sample might be involved in the procedure in section 4.

First line: Only the laboratory selected in section 4 is testing a reserve sample. The word "reserve" should therefore be deleted. The expression "limit Δ" needs a few words of explanation. The line should therefore read:

"When each laboratory tests only a single sample giving one result the limit Δ for the difference between the two is …"

The word "where" following each formula should be lower case.