CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 8 MAS/38 CRD/11

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Thirty-eighth Session
Budapest, Hungary, 8 – 12 May 2017

PROPOSAL TO AMEND THE *GUIDELINES ON MEASURMENT UNCERTAINTY* (CAC/GL 54-2004)

(Comments submitted by IDF, European Union, Kenya, Peru, Mexico, Ghana)

International Dairy Federation(IDF)

Executive Summary

The International Dairy Federation (IDF) wishes to thank the electronic Working Group (eWG) for preparing this draft and for the opportunity to comment. IDF strongly believes that it is crucial for involved stakeholders to have an adequate appreciation of the principles and the limitations in order to enable proper implementation of the proposed draft Guidelines.

IDF supports the revision of the GL54 guidelines in general. If the Committee decides to revise GL54, IDF sees a definite need for the Committee further clarifying the scope and the role of measurement uncertainty.

General comments

Measurement uncertainty has an important and well-defined role in conformity assessment, to assess whether the true value of a sample actually tested lies within specification. This is a common situation in legal metrology, where a null hypothesis of compliant must necessary be assumed. This importance is reflected in the requirement in ISO17025 for laboratories to estimate measurement uncertainties and to make them available when required.

Conformity assessment does not appear an effective alternative to sampling inspection. Whilst in the proposed draft Guidelines some clarity has been provided concerning the differences between measurement uncertainty and sampling inspection, IDF is of the opinion that the role of measurement uncertainty in sampling inspection has yet to be made clear. The revised draft document suggests that one possible approach to deal with situations where significant measurement error is present would be to classify samples as pass or fail using the “measurement uncertainty approach”, and then use sampling plans based on inspection by attributes. IDF does not consider this approach to be a valid way of proceeding.

In addition, the measurement error adjustment for sampling plans based on inspection by variables, described in Annex O of ISO3951-2 (2013), pertains only to the repeatability component of measurement error, and it would not be appropriate to use measurement uncertainty in the context of multi-sample assessments.

The suggested use of measurement uncertainty appears flawed for product assessment as it allows acceptance of samples having true values lying outside the specification limits, provided test results fall within the allowable range. This means that the procedure does not provide the claimed level confidence (95%) of detecting non-compliant product implied by a coverage factor k=2 or by the quantile of the “T-distribution” used for the assessment.

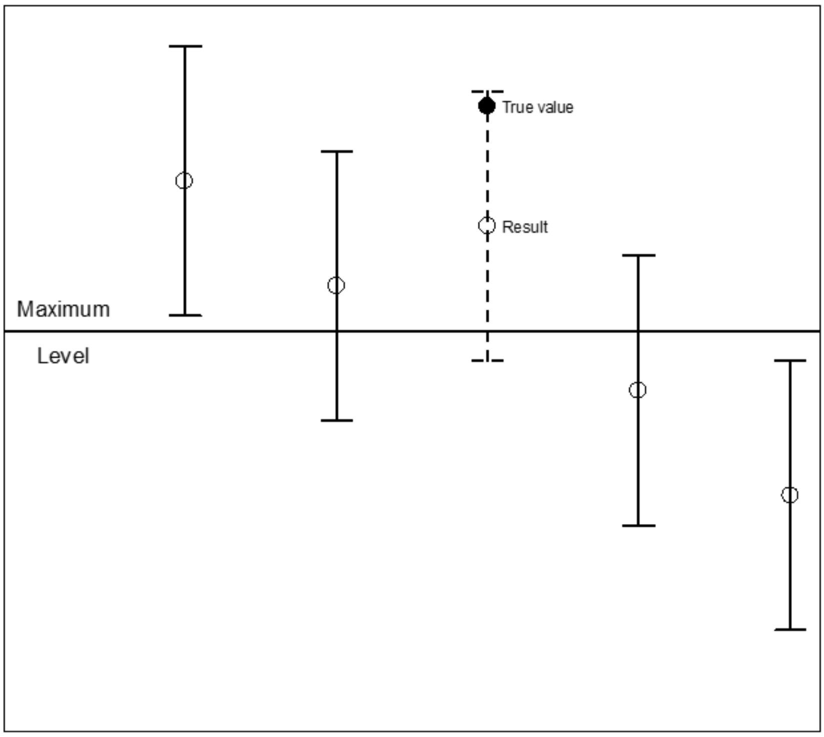
IDF considers that the handling of situations involving significant measurement error is best dealt with through the existing statistical framework for sampling inspection; indeed there are several publications describing solutions or part solutions to this problem (see references). IDF prefers this approach rather than, say, attempting to allow for Uncertainty of Sampling by extension of the measurement uncertainty approach.

Specific Comments

The aim of sampling inspection is to ensure that the product as a whole complies with specification, within allowable risks set by consumers and producers when sampling plans are designed. This is an important use of test results, which is commonly employed, that is not reflected in ISO17025.

The proposed procedure for assessing compliance of samples based on measurement uncertainty is not consistent with the principles of sampling inspection. Compliance of results or of individual samples allowing for measurement uncertainty does not necessarily mean compliance of product, or vice versa.

The suggested procedure allows acceptance of samples whose true values lie considerably outside specification limits, provided test results fall within the acceptable range (see diagram). While the procedure might deliver the desired level of confidence in respect of not penalising truly compliant samples, whose true values lie within specification, it provides poor protection against truly non-compliant samples.



The formula for the combination of standard deviations of different uncertainty components assumes that the different components are statistically independent, which will often not be the case.

The procedures for estimating measurement uncertainty for defining methods and for methods subject to Single Laboratory Validation do not reflect actual inter-laboratory variation and might lead to under-estimation of the measurement uncertainty.

The use of a coverage factor k=2, implying 95% confidence, assumes that the measurement errors are normally distributed and that the measurement uncertainty standard deviation is known. This will not be the case where standard deviations are estimated from data, including values adopted from collaborative studies. In this case, there are two factors to be controlled:

-The proportion of the distribution of possible results that the range claims to cover [known as the coverage], and

-The confidence with which we can say that this coverage is achieved.

Coverage factors based on the Student's t-distribution will not satisfactorily resolve matters as these provide 50% confidence that the interval provides 95% coverage, less than what might be expected under a 'beyond reasonable doubt' approach. To overcome the problem, to achieve, say, 95% confidence that an interval provides 95% confidence, it is necessary to resort to tolerance intervals based on the non-central t-distribution for normally distributed data.

Conclusions and Recommendation
IDF supports the revision of the Guidelines. However, the revised Guidelines must clearly describe the purpose of conformity assessment and of sampling inspection, outline the differences between them, and clarify the role of measurement uncertainty with each activity.

References

ISO3951-1 (2013)
Sampling procedures for inspection by variables —

Part 1: Specification for sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL.

Owen DB & Chou Y-M (1983)
Effect of Measurement Error and Instrumental Bias on Operating Characteristics for Variables Sampling Plans. Journal Quality Technology 15 pp107-115.

K. Govindaraju & G. Jones (2014)
Fractional Acceptance Numbers for Lot Quality Assurance and Control Charting. Proceedings, Workshop on Intelligent Statistical Quality Control, Sydney, 2013.

European Union

The European Union and its Member States (EUMS) acknowledge the excellent work of the eWG under the lead of Germany.

The current version of CAC/GL 54-2004 is a lean document which describes in plain language what measurement uncertainty is, why it has to be determined, how to use to assess conformity of an inspected lot with provisions of a STAN, and how it can be determined (by way of references to published guidance/standards).

The main assignment for the work of the eWG was to identify areas in CAC/GL 54-2004 which need improvement, in particular with a view to procedures for the determination of measurement uncertainty including uncertainty contributions from sub-sampling and sample processing.

The proposed revision goes well beyond this and takes additionally into account the plenary discussion at CCMAS in 2010. It does not only identify areas of improvement but provides a revised guideline. The proposal of the eWG integrates the main text CAC/GL54-2004 and its explanatory notes into a comprehensive document, with additional explanation on sampling and subsampling issues in connection with conformity assessment. It gives rather detailed procedures for estimating measurement uncertainty which can affect the readability of the proposed draft standard. These detailed explanations on how to estimate measurement uncertainty, including sources such as sub-sampling and sample processing, are needed instead of references to published guidance. However, the more technical details, especially with respect to the estimation of the measurement uncertainty, may impart the readability. They should be summarised in an information document outside of a revised CAC/GL 54-2004. With such a restructuring the main text highlights the important aspects without distraction by the detailed description of estimation of the measurement uncertainty.

The EUMS propose to forward the draft, after restructuring at step 5 for member state comments.

KENYA

Kenya fully supports the work to amend the guidelines on the measurement of Uncertainty. We propose that the continuation of the work to the next stage taking into the considerations of the discussions that evolved within the EWG which Kenya actively participated.

PERU

Observaciones generales:

Perú en el marco del Codex Alimentarius tiene los siguientes comentarios generales al documento CX/MAS 17/38/8:

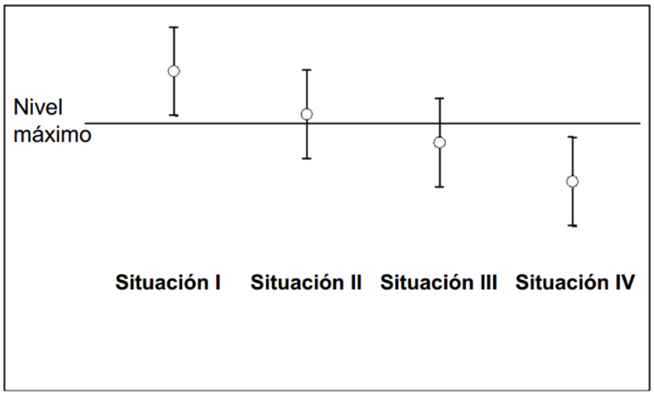
1. Estas Directrices deberían indicar las ventajas y desventajas de aplicar un modelo de estimación de incertidumbre sobre otro(s). Si bien el laboratorio define qué procedimiento utilizar, las directrices deben proponer al menos un procedimiento por tipo de ensayo.

2. El documento es denso por la cantidad de fórmulas, por lo que se sugiere optimizar la redacción indicando el documento de referencia. La Directriz debería indicar qué hacer para cada procedimiento de estimación de incertidumbre, si se va a basar en el enfoque global o por componentes. Se recomienda presentar las fórmulas en un anexo.

Observaciones Específicas:

En relación con la Figura 1, la descripción literal (pág. 5) de las situaciones I, II, II y IV no aclara lo observado en dicha figura, y se recomienda dar una conclusión al respecto. Asimismo, por encontrarse en la parte introductoria, se debería ser más claro en describir esta Figura, con el fin de que el lector entienda la relación entre resultados, incertidumbre expandida y límite máximo de especificación.

En ese sentido se propone lo siguiente:



Situación I

Dice:

El resultado analítico menos la incertidumbre expandida en la medición da un valor superior al nivel máximo. El resultado indica que el analito medido en la muestra de ensayo supera la especificación.

Se sugiere colocar:

El resultado analítico menos la incertidumbre expandida en la medición es igual a un valor mayor que el nivel máximo. Por tanto, esta situación representa que el valor “real” del analito medido en la muestra de ensayo supera la especificación, con un nivel razonable de confianza.

Situación II

Dice:

El resultado analítico supera el nivel máximo en medida menor que la incertidumbre expandida de la medición

Se sugiere colocar:

El resultado analítico supera el nivel máximo, pero el resultado analítico menos la incertidumbre expandida es igual a un valor menor al nivel máximo. Por tanto, esta situación representa ambigüedad debido a que el valor “real” del analito medido en la muestra de ensayo puede no exceder la especificación, con un nivel razonable de confianza.

Situación III

Dice:

El resultado del análisis es inferior al nivel máximo en medida menor que el valor de la incertidumbre expandida de la medición.

Se sugiere colocar:

El resultado analítico es menor que el nivel máximo, pero el resultado analítico más la incertidumbre expandida es igual a un valor superior al nivel máximo. Por tanto, esta situación representa ambigüedad debido a que el valor “real” del analito medido en la muestra de ensayo puede exceder la especificación, con un nivel razonable de confianza.

Situación IV

Dice:

El resultado del análisis es inferior al nivel máximo en medida mayor que el valor de la incertidumbre expandida de la medición.

Se sugiere colocar:

El resultado analítico más la incertidumbre expandida en la medición es igual a un valor menor que el nivel máximo. Por tanto, esta situación representa que el valor “real” del analito medido en la muestra de ensayo no excede la especificación, con un nivel razonable de confianza.

MEXICO

Comentarios
Se considera que la estructura presentada en el anteproyecto es adecuada. Se apoya a que se continúe en el trámite del documento.

GHANA

Ghana welcomes the proposal to amend the Guidelines on Measurement Uncertainty to ensure ease of use and clarity.