

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 5

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ORIGINAL LANGUAGE ONLY

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

42nd Session  
Budapest, Hungary

13 – 16 June 2023, with report adoption on 20 June 2023 (virtual)

### INFORMATION DOCUMENT: GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54-2004)

*(Comments of Chile, Ghana, Nigeria, Peru and Uruguay)*

#### Chile

##### Contexto:

Se presentan mejoras al documento de incertidumbre de la medición.

##### Posición país:

Observaciones en respuesta a CL 2023/14/OCS-MAS

Se considera que el documento es adecuado en su contenido, sin embargo, no se tiene claridad si el documento podría ser comprendido con claridad por todos los que recurran a él debido a que se utiliza terminología, que requiere para su mejor comprensión dirigirse a la normas o bibliografía anexa, para una mejor comprensión.

Se sugiere, distinguir en el documento claramente lo que hace referencia al Método de Monte Carlo (MCM); ya que esto facilitaría su comprensión. Ejemplo:

*“...where  $u_c$  denotes the combined uncertainty,  $u_i$  denotes the uncertainty associated with input variable  $i$  and  $c_i$  denotes the corresponding sensitivity coefficient, usually obtained via partial differentiation ( $c_i = \left(\frac{\partial f}{\partial x_i}\right)^2$ ), see 5.1.2 and 5.1.3 in GUM **Error! Reference source not found.***

##### **2.1. Monte Carlo method (MCM).**

*The second option consists in applying a Monte Carlo method (MCM). This can briefly described as “repeated sampling from the PDFs of the  $X_i$  and the evaluation of the model in each case,” see 5.9.1 in **Error! Reference source not found.** This option is also referred to as the propagation of distributions. In practice, the implementation of this option requires software, since the number of simulation runs (i.e. the number of times each input variable is sampled) is typically on the order of  $10^6$ .*

“

Sería importante, que tras la aprobación del documento el CCMAS pudiera organizar un taller on-line para su divulgación y mejor comprensión entre los distintos países miembros.

Por otro lado en el documento se mencionan versiones obsoletas de normas ISO en las referencias, que sería importante corregir.

[5] ISO 5725-2:~~1994~~, **2019** Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method.

[14] ISO 3951-1:~~2016~~ **2022**, Sampling procedures for inspection by variables — Part 1: Specification of single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL.

[16] ~~ISO/WD 3951-6:2019, Sampling procedures for inspection by variables — Part 6: Specification for single sampling plans indexed by limiting quality (LQ)~~. ISO me aparece ISO/DIS 3951-6 Sampling procedures for inspection by variables — Part 6: Specification for single sampling plans for isolated lot inspection indexed by limiting quality (LQ) y que está en desarrollo , es decir aún no es oficial: <https://www.iso.org/standard/78827.html>

[20] ISO TS 23471:**2022**, Experimental designs for the evaluation of uncertainty – Use of factorial designs for determining uncertainty functions.

[22] ISO 13528:~~2015~~**2022**, Statistical methods for use in proficiency testing by interlaboratory comparison.

## Ghana

**POSITION 1:** For the introduction, Ghana proposes that the statement “A measurement result should always be accompanied by information regarding its uncertainty” is replaced with “A measurement result should ideally be accompanied by information regarding its uncertainty”.

**RATIONALE:** With reference to the ISO 17025 standard, under Clause 7.6, there is the need to identify contributions to MU. We need to evaluate MU or an estimate based on an understanding of the theoretical principles or practical experience of the performance of the method. As per Clause 7.8.3.1, test reports shall however, **where necessary** for interpretation of test results, include, where applicable, the measurement uncertainty presented in the same unit as the measurand or in a term relative to the measurand when;

- it is relevant to the validity or application of test results
- a customer’s instruction so requires, or
- MU affects conformity to a specification limit.

In view of the above, we are proposing alternate wording.

**POSITION 2:** Ghana supports the changes made on the Guidelines on Measurement Uncertainty document (Appendix I) and agrees with the proposal to publish the information document on the Codex website, however we request the working group to come up with an additional guidance document to address;

- i) Estimation of Measurement Uncertainty due to Sampling.
- ii) Measurement uncertainty for qualitative methods in microbiological analysis/ molecular biology.

**RATIONALE:** According to the Guidelines on Measurement Uncertainty CXG 54-2004, “Analytical measurements in food control are often quantitative, but qualitative test results are also performed and relevant. Qualitative analysis are sometimes used in molecular biological and microbiological methods for food control. Provision of guidance on measurement uncertainty for qualitative results could contribute to improving the robustness of result.

## Nigeria

Nigeria commends Germany for preparing the updated document.

Nigeria agreed that the revised document is an improvement of the former and proposes more discussion of the reviewed document prior to endorsement.

### Peru

#### Comentario General:

El Perú agradece a Alemania, por el esfuerzo emprendido en la revisión y redacción del Documento de información teniendo en cuenta los comentarios y las decisiones realizados en el CCMAS41.

Luego de la revisión realizada al documento de información de las Directrices sobre incertidumbre en la medición (CXG 54-2004) circulado, el Perú no tiene comentarios/observaciones al mismo y se muestra a favor de que el documento sea publicado en la página web del Codex.

### Uruguay

Uruguay appreciates the document INFORMATION DOCUMENT: GUIDELINES ON MEASUREMENT UNCERTAINTY prepared by Germany and thanks the opportunity to present the following comments:

Comment / Page 4: Uruguay would like to suggest to include additional guidelines related with the GUM uncertainty method and the MCM considering the recommendation described on the JCGM 101:2008 Evaluation of measurement data — Supplement 1 to the “Guide to the expression of uncertainty in measurement” — Propagation of distributions using a Monte Carlo method

8.1.1 The GUM uncertainty framework can be expected to work well in many circumstances. However, it is not always straightforward to determine whether all the conditions for its application (see 5.7 and 5.8) hold. Indeed, the degree of difficulty of doing so would typically be considerably greater than that required to apply MCM, assuming suitable software were available [8]. Therefore, since these circumstances cannot readily be tested, any cases of doubt should be validated. Since the domain of validity for MCM is broader than that for the GUM uncertainty framework, it is recommended that both the GUM uncertainty framework and MCM be applied and the results compared. Should the comparison be favourable, the GUM uncertainty framework could be used on this occasion and for sufficiently similar problems in the future. Otherwise, consideration should be given to using MCM or another appropriate approach instead.