

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 6

MAS/39 CRD/13

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Thirty-ninth Session

Budapest, Hungary, 7 – 11 May 2018

PROPOSAL TO AMEND THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54 – 2004)

(Comments submitted by New Zealand)

NEW ZEALAND

New Zealand accepts that measurement uncertainty has a role in reporting, as described in ISO17025, and in conformity assessment, to assess whether the true values of the samples tested comply with specification limits, as described in ISO10576. However we question its applicability to sampling inspection as a way of dealing with significant measurement error.

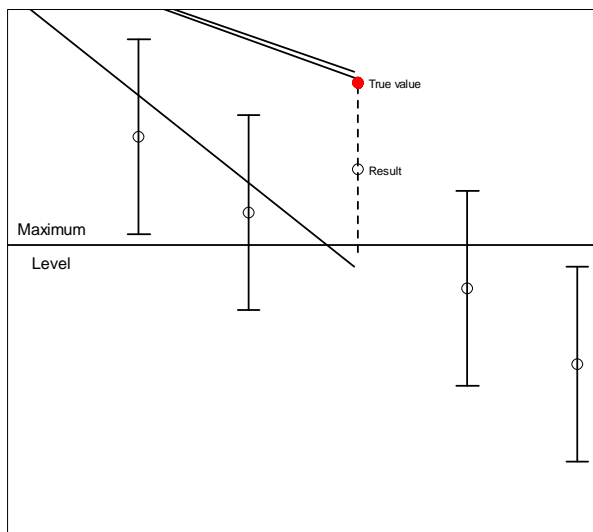
While the GL 54 paper makes some attempt to differentiate between conformity assessment and sampling inspection, the two concepts remain confused, quite possibly because the neither is clearly defined in the document:

- The purpose of conformity assessment is to assess whether the true values of the samples that were actually tested comply with specification limits.
- The objective of sampling inspection is to assess whether the product is of acceptable quality, within allowable levels of risk as it is not possible to provide a 100% guarantee, allowing also for measurement error where appropriate.

On this basis we question the relevance of measurement uncertainty to the activities of Codex; conformity assessment deals only with the compliance of the true values of the samples actually tested, whereas acceptance sampling inspection deals with whether the product complies to specification limits.

Other Points

1. The proposed procedure for conformity assessment seems flawed, as it allows acceptance of product whose true values lie outside the limits, as shown by the diagram below. We do not accept that this procedure provides “95% confidence”, as claimed in the paper.



2. Use of the estimated reproducibility standard deviations, estimated from collaborative studies etc., to represent the measurement uncertainty does not explain or account for differences between bias and precision (as shown on the diagrams in the discussion paper), and between repeatability and reproducibility, and might not provide an appropriate assessment whether the samples comply with the limits.
3. The usual coverage factors ($k = 2$) do not provide 95% confidence [of 95% coverage] when measurement uncertainties are estimated from collaborative studies or proficiency testing. This problem is not overcome by using coverage factors based on the Student's t-distribution - much larger factors are need to provide 95% confidence of 95% coverage. A coverage factor of $k=2$ provides 95% coverage (with 100% confidence), only when the true values of the mean and standard deviation are known.