

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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Agenda Item 10 (a)

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-eighth Session

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#### COMMENTS ON THE PROPOSED DRAFT GUIDELINES ON THE ESTIMATION OF UNCERTAINTY OF RESULTS AT STEP 6

##### ARGENTINA (Submitted at Step 5 for the 28<sup>th</sup> Session of the Commission)

Argentina considers this a very useful document as it provides information on the different sources of uncertainty in analytical results.

Argentina wishes to state that EURACHEM recommends using a coverage factor of 2, which implies working with a level of confidence of 95%, which is a common criterion in most statistical analyses and is in fact a universally accepted Codex Alimentarius criterion suggested for the design of samples. However, there is a contradiction in the document as para 5.2.1 on the testing of commodities for *the domestic market adopts a level of confidence of 95%, and also considers as certain situations ii y iii of figure 1*; while para 5.2.2 on *commodities to be exported applies a level of confidence of 99%, thus rejecting all commodities approved for the domestic market. This suggests a double standard for foods determined by their market, and two categories of consumer, when evaluation of a monitoring plan considers the adoption of a single criterion as serious and responsible.*

This discrimination in sampling and the laboratory would also oblige food exporting countries to apply a special system of application of this double standard, with its associated cost.

##### CHINA (Submitted at Step 5 for the 28<sup>th</sup> Session of the Commission)

The Delegation of China expressed its concern regarding the estimation of uncertainty and indicated that the global food trade was impeded by the absence of internationally agreed value of confidence and compliance levels.

## UNITED STATES OF AMERICA

1. The USA supports the principle of developing information on “uncertainty” as one of the performance measures to determine to the utility of a method in enforcing Codex Maximum Residues Limits (MRLs). However, the USA Delegation has reservations regarding the *application* of “uncertainty” to modify an analytical result obtained from a monitoring or enforcement effort. Appendix XII, Section 5- “The Use of Uncertainty Information” describes the application of method variability to express an analytical result as a range of values with an upper and/or lower limit. The upper limit or boundary may result in a theoretical value exceeding the MRL. The closer the analytical test result is to the MRL, the greater the probability that the sample tested when applying this “uncertainty” calculation may produce an upper limit value exceeding the MRL.

2. Using the example in Section 5.2.2 Appendix XIII, a test value of 0.55 mg/kg when applying a 99% confidence interval based on the method’s uncertainty, predicts a possible upper limit of 1.26 mg/kg, exceeding the 1 mg/kg MRL. This can be interpreted as a violation, although there is no direct measurement of the result exceeding the MRL. Applying different confidence intervals, e.g. 90% or 95%, around the test result or using analytical methods having different performance characteristics will change the lower and upper limit of the measurement range when “uncertainty” is applied.

3. Therefore, the U S objects to the adoption of Section 5, based on the following reasons:

a. In estimating an MRL, the JMPR already includes safety and rounding factors, i.e., the MRL is proposed at a value *greater* than the maximum value obtained in a series of supervised field trials where the pesticide is applied at the maximum GAP. Adopting the principles of Section 5 artificially changes an MRL. An analytical value at half the MRL can produce value at the maximum upper bound of “uncertainty” which theoretically exceeds the MRL.

b. Codex Alimentarius document CAC/GL 33 describes the “Recommended Methods for the Determination of Pesticide Residues for Compliance with an MRL.” Section 3- “Sampling Procedures” defines a collection of primary samples and their preparation for analysis. In Section 4, “Criteria for Determining Compliance,” Section 4.3 states: —“The lot complies with the Codex MRL where the MRL is not exceeded by the analytical result.” It is this homogenized bulk sample derived from primary samples representing the lot that determines compliance with an MRL. The definitions for sampling terms can be found in Annex 1 of this document.

c. The US strongly adheres to the principles of sampling and lot representation described in CAC/GL33 and to the concept that the analytical test result and not a theoretical potential upper limit determined by “uncertainty” calculations is used to determine compliance with the established MRL.

## JAPAN

Concerning the uncertainty of analytical research, we wish to recall that the Codex Alimentarius Commission at the 27<sup>th</sup> session adopted the Guidelines on Measurement Uncertainty at Step 8 as final text on the basis of recommendation of the Codex Committee on Methods of Analysis and Sampling (CCMAS). The Guidelines are applicable to issues related to measurement uncertainty throughout Codex as a horizontal guidance document.

The Draft Guidelines on Estimation of Uncertainty of Results currently under development at the Codex Committee on Pesticide Residues (CCPR) contain descriptive text about general aspects of uncertainty which is helpful for readers to understand the concept of uncertainty. However, the section on how the analytical results should be reported does not contain information to what has

already been included in the Guidelines on Measurement uncertainty. In order to make the Draft guidelines more useful, practical instructions or worked example on the estimation of measurement uncertainty should preferably be included.

We therefore propose that the Draft Guidelines should be divided into two parts: one for practical instructions/examples on the estimation and reporting of uncertainty; and the other for explanation of the concept and importance of uncertainty as an annex. A reformatted guidelines should be structured as below:

1. Introduction
2. Estimation of uncertainty – practical instructions and worked examples
3. Reporting of uncertainty

Annex: General Aspects of Uncertainty

1. Identification of uncertainty sources
2. Existing procedures for estimating measurement uncertainty
3. Guidance values for acceptable uncertainties

Glossary of terms used in the text.

## CANADA

At the request of the last session of the Committee document (CX/PR 05/37/11), draft guidelines on the estimation of uncertainty of results were prepared by the Netherlands. The draft guidelines cover the estimation of uncertainty and demonstrate how enforcement authorities can use this information. However, the guidelines do not address how this information may be used in a practical way. At this time, there is still no international agreement or nationally declared value for acceptable violation rates other than the 99% compliance required by the United States.

In Canada, the Canadian Food Inspection Agency (CFIA) does not, at this time, report uncertainty associated with its methods. However, it does intend to determine the measurement of uncertainty as new methods are developed. This activity would require validation of 300+ pesticides and approximately 50 matrices on the 3 multi-residue screening methods presently in place. It has been communicated that CFIA scientists are working on developing a unified practical approach using the EURACHEM model described in The CXPRO 05/37/11.

Canada, will provide additional comments on this issue upon receipt of additional information from the Canadian Food Inspection Agency.