

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 9 (b)

CX/PR 05/37/10

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-seventh Session

The Hague, The Netherlands, 18-23 April 2005.

Comments on the Proposed Draft Guidelines on the Estimation of Uncertainty of Results at Step 3 submitted by Australia and the United States of America

The 36th Session of the Committee on Pesticide Residues decided to circulate the Proposed Draft Guidelines on the Estimation of the Uncertainty of Results at Step 3 of the Codex Procedure. Comments were received from Australia and the USA, both showing general support for the document, but recommending some editorial and technical changes. The detailed comments are given below:

Australia:

The first part of the first sentence in the first paragraph of the Introduction can be deleted so that the sentence commences as follows 'It is a requirement under ISO/IEC 17025 that....'

Section 2, last paragraph Insert the following sentence "It should be noted that a laboratory is normally only required to estimate the uncertainty associated with those processes for which it has control, that is, only those processes that take place in the laboratory if field sampling is not the responsibility of laboratory staff"

Section 3, paragraph 4, line 3 Change recommended to suggested

Section 3, paragraph 4, line 7 Change *instead* to *rather than* and insert the following sentence at the end of paragraph 3: 'The selection of the representative range of analytes and matrices to provide an uncertainty estimate should be supported by validation data and studies on the selected matrix/analyte combination'.

Section 3.1, last line of paragraph, delete 'and should be consulted where necessary'.

It is recommended that the draft document include some guidance on the application of uncertainty estimates in the assessment of compliance with MRLs.

United States of America:

Footnote 7, second sentence:

Change "time of sampling, Incorrect labeling decomposition of analytes" to "time of sampling, *incorrect* labeling, decomposition of analytes" *Insert a comma between labeling and decomposition.*

Page 80, GUIDANCE VALUES FOR ACCEPTABLE UNCERTAINTIES, first sentence:

Change "a series of tests ran by a single laboratory," to "a series of tests *run* by a single laboratory" and "the results a large data-set" to "the results *of* a large data-set"

Page 81, Table 4, row 2, Sampling of Animal Products:

Change the statement in the middle column to: The relation between the number of samples (n) to be taken for detection of a specified percentage of violations (β_p) with a given probability (β_t), *both expressed as fractions, not percentages*, is described by: $1 - \beta_t = (1 - \beta_p)^n$.

The equation given, $1 - \beta_t = (\beta_p)^n$, is incorrect.

The Committee is invited to review the above recommended changes to the draft Guidelines through its ad-hoc Working Group on Methods of Analysis. The Netherlands will prepare a modified version of the document taking into account the written comments received as well as observations from the floor for further advancement in the Codex Procedure.