CODEX ALIMENTARIUS COMMISSION E

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Agenda Item 4 **CX/MAS 14/35/4-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Thirty-fifth Session

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PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE: EXPLANATORY NOTES – Comments at Step 3

(Comments of Brazil, Ghana, Japan, Kenya, New Zealand)

BRAZIL

SCOPE

Brazil agrees with the chair of the EWG to include other interested parties in the scope of the document to align with CAC\GL 50- 2004 that mentions other users. However, considering these explanatory notes are intended to assist governments in understanding the principles of the CAC\GL 83-2013, it cannot go beyond the scope of the main document. We suggest include other interested parties in the scope of the CAC\GL 83-2013 not just governments.

It is also necessary to define if this document will be part of CAC\GL 83-2013, e.g as an annex, or it will be other document. We prefer the first option, otherwise always there is a reference to "main document" it should be replaced by CAC\GL 83-2013.

Principle 1: Transparency and agreements before initiating trade

Before starting trading activities, or **when introducing or modifying an import testing program,** the parties concerned should reach agreement related to the sampling and testing procedures that will be applied to assess whether the food in trade meets the specifications of Codex or the importing country. This agreement should also specify the sampling and testing procedures to be followed.

The phrase "*The agreed specifications should not restrict the flexibility of the control program in the importing country and should preferably be done in general term"* should be deleted, because it is in disagreement with it is stated in principle 1 (in bold).

Principle 4: Selecting appropriate sampling and testing procedures

It is not necessary to mention examples, just state to follow relevant Codex standards and other international references agreed by the parties.

ANNEX : Practical Examples of Sampling Plans

Considering that there is a specific agenda item to deal with sampling, we suggest deleting the annex of this document. The annex can be discussed on the agenda item 7 in conjunction with **CX/MAS 14/35/7- DISCUSSION PAPER ON SAMPLING IN CODEX STANDARDS.**

GHANA

General Comments

Ghana welcomes the opportunity to provide comments on the Proposed Draft Principles for the use of Sampling and Testing in International Food Trade: Explanatory Notes and appreciates work carried out by the Electronic Working Group (eWG).

Specific comments

Comments: Principle 3

Ghana supports Principle 3 and has no comments on the sentence in square brackets.

Rationale:

This principle is unavoidable. They are always bound to happen, though importing and exporting countries can have similar or agreed procedures, nonetheless environmental factors can impact the final results. Thus the suggested methods to resolve these probabilities via methodology spelt out in internationally recognized standards are laudable.

Comments: Principle 4

[*Without selecting an appropriate sampling and testing procedure, it is difficult to reach an agreement between the exporting and importing country*.]

Ghana suggests the amendment of the sentence in the square brackets to read as:

"[*Without selecting an appropriate sampling and testing procedure,* ***there is a probability of wrongfully accepting or rejecting a consignment which may lead to disputes between the importing and exporting parties.]"***

Rationale

When sampling and testing procedures are not appropriate, countries may wrongfully accept or reject a consignment/ lot which can lead to disputes between the countries involved. This could also lead to either the importing or exporting country from being disadvantaged / advantaged at the expense of the other.

JAPAN

Japan would like to submit the following comments on the Proposed Draft Principles for the Use of Sampling and Testing in International Trade: Explanatory Notes (CX/MAS 14/35/4).

General Comment

Japan greatly appreciates the efforts of the electronic working group in preparing the discussion paper. Japan basically agrees with the draft explanatory notes but the term "sampling uncertainty" should not be used in this explanatory notes, especially referring to the contents of the section 2.4 of GL50-2004.

The term "sampling uncertainty" should be replaced by "sampling error" as stipulated in the section 2.4 of GL50. Although the term "sampling error" is often confused with the term "sampling uncertainty", these two terms should have different meaning because "error" and "uncertainty" are essentially different concepts. Japan is of the opinion that it is premature at this point to stipulate "sampling uncertainty as well as analytical measurement uncertainty should be quantified and combined". If it is necessary to refer to the section 2.4 of GL50-2004 in this explanatory notes, the phrase should not be modified and whole sentences should be correctly referred as below. "It is desirable that the sampling errors associated with any sampling plan, as well as the measurement errors associated with the analysis should be quantified and minimised……" (Please also see the specific comments).

Japan recognizes that CCMAS have not yet decided how to treat sampling uncertainty including whether any estimated uncertainty from sampling should be taken into account when assessing compliance, and CCMAS have not yet developed any general guidance documents for estimation of sampling uncertainty. Japan also recognizes that the Inter-Agency Meeting (IAM) prepared a discussion paper about sampling issues.

Specific Comments

Principle 1

1. Clarification of the meaning of the first sentence in the 7th bullet point is needed for further discussion.
   - *If the assessment procedure requires an estimate of lot inhomogeneity (e.g. a standard deviation), the method that should be used to estimate it. If the standard deviation is treated as "known", the assumed value should be scientifically based and accepted by both parties*
2. Examples in the 8th bullet point should be revised as shown below because guidelines for establishing

numeric values for these criteria are already shown in the Procedural Manual.

- *The specification of analytical methods including criteria of appropriateness in order to ensure equivalent measurements (e.g. applicability, limit of detection, limit of quantification ~~sensitivity and~~, precision, recovery and trueness)*

Principle 3

The 3rd paragraph from the bottom of page 3 should be modified as follows because values of probabilities of wrongly accepting or wrongly rejecting a lot or consignment depends on sampling plan, which is one of desirable contents of the agreements between parties.

As mentioned in Principle 1, the specification of acceptable probabilities of wrongly accepting or wrongly rejecting a lot or consignment should have regard to principles of fairness towards the consumer and towards the producer respectively. This means making sure that a compliant product is not exposed to an unduly high probability of rejection. The probability of wrongly reject or wrongly accept depends on selected sampling plan. Practically ~~Typically~~, sampling plans are sometimes set to wrongly reject with probability 5% and wrongly accept with probability 10%.

Principle 4

1. The 6th bullet point of the body of Principle 4 should be deleted because it is not stated in the original "PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIOAL FOOD TRADE (CAC/GL 83-2013)".

~~- characteristic of samples and the objective of control~~

2. The sentences relating to “sampling uncertainty” in paragraphs in the square bracket in page 5 and the 1st paragraph in page 11 should be modified as follows because accurate quotations from the GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004) Section 2.4 is needed.

- [*Unless other conventions or regulations (e.g. for testing compliance with MRLs of pesticide residues and several other chemical contaminants) exclude sampling ~~uncertainty~~ errors from the assessment, it is desirable that the sampling ~~uncertainty~~ errors (expressed by the sampling standard deviation) associated with any sampling plan, as well as the measurement ~~uncertainty~~ errors associated with the analysis~~,~~ should be quantified and ~~combined~~ minimised, as stated in the GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004), Section 2.4, and in the GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006), Section 2, when setting up a sampling plan.*

The sampling ~~uncertainty~~ errors to be used when setting up a sampling plan can be based on an estimate of standard deviation obtained from experimental data during an extended period of production, made available by the professionals (σ-method), or can be estimated by testing a number of primary samples (s-method) if there is insufficient product experience.]

[DE: Setting up a sampling plan, in principle, it is desirable that the sampling ~~uncertainty~~ errors (expressed by the sampling standard deviation as a measure of the dispersion of sample characteristics in the lot), as well as the measurement ~~uncertainty~~ errors (expressed by the analytical standard deviation as a measure of the dispersion of single analytical results) should be quantified and ~~combined~~ minimised according to GENERAL GUIDELINES ON SAMPLING, CAC/GL 50-2004, Section 2.4, although the Guidelines cover only the most frequent case where the analytical error is negligible compared to the sampling error.

The sampling ~~uncertainty~~ error can be based on an estimate of the standard deviation obtained from experimental data on an extended period of production, made available by the professionals (σ-method) or can be estimated by testing a number of primary samples (s-method) in case of nonsufficient product experience.

This sampling ~~uncertainty~~ error must not be confused with the uncertainty which is associated with the sampling as part of the testing procedure (e.g. the dispersion of sample characteristics in the test samples caused by selection of sampling position, time of sampling, decomposition of analyte or contamination of the sample) as quoted in the GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS(CAC/GL 59-2006). It is the latter of which concerns testing for compliance.]

- *This estimator is a simple approach based on the prerequisite that the analytical measurement*

uncertainty should be less than or equal to one-third of the sampling ~~uncertainty~~ error and therefore contributes less than 5% to the standard deviation of the observed results~~combined uncertainty~~.

KENYA

Scope

~~[~~These explanatory notes are intended to assist governments in understanding the principles, and in the establishment and use of sampling and testing procedures for determining, on a scientific basis, whether foods in international trade are in compliance with particular specifications~~.]~~

Specific comment

We note the comments given by AU, NZ and Chair of electronic working group on the scope of CAC/GL 83-2013 and are in agreement on the details as given in the document by the different parties. We propose to delete the opening and closing brackets as indicated above under the scope.

Explanatory Notes to Principles

Principle 1: Transparency and agreements before initiating trade

Specific comment

The explanatory notes as provided in the italicized section of the document will serve to further understand principle 1 on transparency and greements before initiating trade, the explanatory notes comprehensively describes examples of what should be contained in the agreement between trading parties.

We therefore support retaining of the explanatory notes as they are in this document.

Principle 2: Components of a product assessment procedure

Specific comment

Kenya is in agreement of the three components of product assessment as given in the document, and we propose it be retained as it is.

Principle 3: Probability of incorrect decisions

Specific comment

We agree with the comments as proposed by New Zealand, on random variations in measurement errors and effects on limits of compliance assessment.

Principle 4: Selecting appropriate sampling and testing procedures

Specific comment

We agree on the explanatory notes as given by New Zealand and the examples given on sampling on milk and milk products also the provision that other scientifically based testing procedures can be employed.

Principle 5: Analytical measurement uncertainty

Specific comment

We agree the need to consider measurement uncertainty for product assessment using, *GUIDELINES ON MEASUREMENT UNCERTAINTY (CAC/GL 54-2004)* and *GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006).* However there are other ways of establishing measurement uncertainty .In this regard we propose inclusion of "…..and Eurachem /CITAC guide ", at page 6 paragraph 2, line 2 of the explanatory note guidelines.

Principle 6: Fitness for purpose

Specific comment

We agree with the explanatory notes in particular the emphasis on quality control aspects of analysis in the laboratory; the information is useful to be read together with the guidelines.

Principle 7: Review procedures

Specific comment

We support the review procedures as stated.

Annexe:

Specific comment

The worked out examples should be retained in the explanatory notes guidelines, they will enable further elaboration of the document, thus assist in understanding of the guidelines.

NEW ZEALAND

General comments

New Zealand appreciates the efforts of Germany and other working group members in producing helpful Explanatory Notes to the Principles. We have a few comments on points in the paper as follows.

Specific comments

Introduction and later text

In the context of acceptance sampling, the phrase "lot or consignment" can lead to confusion.

In acceptance sampling a "lot" is the product to be accepted or rejected (in its entirety) and sampling schemes such as those in CAC/GL 50-2004 (GL 50) presuppose a random sampling of the entire lot. If a consignment is to be accepted or rejected, then that consignment is the "lot". The phrase "lot or consignment" is confusing in that it suggests a distinction that does not exist, or it creates the impression that the term "lot" in this document is being used in a different sense.

We therefore recommend that the term "lot" alone should be used wherever the *Explanatory Notes* are dealing with acceptance sampling.

It would be useful to add a further footnote to the first paragraph of the Introduction to explain this terminology. It would also be advisable to emphasise that if a consignment is to be accepted or rejected in its entirety, the sampling should be carried out over the entire consignment.

Scope

The parent *Principles* are addressed to governments, so it seems appropriate that the *Explanatory Notes* should be addressed to the same audience. It is reasonable to have regulators agree and control the principles and commercial parties understand and apply them. "Trading partners" widens the scope to commercial transactions, which are outside the scope of Codex.

Principle 1, penultimate paragraph

We suggest that the second part of this sentence should be deleted, as it appears to negate the intention of the rest of the section. It should read:

> *The agreed specifications should not restrict the flexibility of the control program in the importing country.*

Principle 3, square bracketed text

New Zealand has proposed alternative wording for the first 2 paragraphs. The second paragraph could perhaps be interpreted as suggesting (wrongly) that all compliance tests consist of comparing individual results to a specification limit. Consistent wording would make it easier to read and understand. However some language is unclear: "*analytical results encompassing an agreed level of variability".* The results do not "encompass" the agreed level of variability, but follow a probability distribution whose standard deviation is determined by the TRUE level of variability.

The term "conformity assessment" should be replaced by "sampling inspection" in paragraph 2 and elsewhere. Following ISO 10725, the term "conformity assessment" relates to the conformity only of the item inspected, or possibly to the mean level within a lot. The sampling plans in GL 50 are more appropriately described by the term "sampling inspection". Conformity assessment is a subset of sampling inspection (but not the other way around) – the plans for bulk materials in GL 50 are conformity assessment.

Principle 4, 3rd bullet point

The bullet point that reads "characteristic of samples and the objective of control" is not part of Principle 4 and should not appear in the document.

Principle 4, paragraph beginning "Unless other conventions ..."

We are cautious concerning "combining" the sampling uncertainty with the analytical measurement uncertainty. Often this will not be appropriate, particularly where between-laboratory variation is significant.

Principle 4, final paragraph (Germany's wording)

In the examples of sources of uncertainty, variation due to the positions of the individual samples can be regarded as sampling uncertainty, whereas variation due to the other factors seems to be part of the measurement uncertainty. These also seem to be likely sources of bias.

Correct classification of the sources of uncertainty is important to avoid a difficulty in comparing sampling with measurement uncertainty to judge whether it is "negligible" and to avoid complicating the treatment of sampling uncertainty.

Principle 5, second paragraph

In the last sentence, we are not clear what is meant by a "representative" measure of the overall error of the result. We suggest "a probable upper limit to the overall error of the result" would be appropriate, but at present the procedures for measurement uncertainty do not deal with such a quantity.

Annex, Example A

1) The example must consider Acceptable Quality Level (AQL) and producers' risk. Visible defects are not a health hazard for which these do not need to be considered.

2) We have recalculated the characteristics of the recommended sampling plans and find that they do not provide the protection desired. We speculate that in 1985 the computational burden involved in producing the ISO tables was much larger than it is today and that approximate procedures were used that now turn out to have been inadequate.

Lot size 151 to 280

To give a producers' risk of 5% at an AQL of 6.5% and a consumers' risk of 10% at a Limiting Quality (LQ) of 12.5% requires large sample sizes, and the best scheme varies markedly with the size of the lot. E.g. for a lot size of 151 one should sample 81 fruit and accept 7 defective fruit; for a lot size of 250 one should sample 100 fruit and accept 9 defectives.

Lot size 3201 to 10,000

To have a producers' risk below 5% at an AQL of 6.5% and a consumers' risk of below 10% at a LQ of 12.5%, the scheme varies again with lot size. But to take 195 samples and allow 18 defectives satisfies both conditions throughout the whole range of lot sizes.

Example B1, Sampling and decision

According to our calculation, which we have double checked, the correct number of allowed non-compliant items is 4, not 5, for a sample of 32, an AQL of 6.5% and a lot size between 151 and 280. For the larger lot sizes (3201 to 10,000) the correct number should be 19, not 21.

Example B2, Agreement before trading activities

The reason for the NZ recommendation after point 1 is that there seems no reason to delete it. Both the sigma method and the s method are possible assessment methods. The remainder of the example in fact considers both methods.

Example B3, paragraph 2

Example B2.1 doesn't exist.

It is not the dispersion that is assumed normally distributed, but the characteristic values. The proposed test (a t-test) is reasonably robust against moderate degrees of non-normality. Normality is not required for s to be a valid estimate of σ.

The sentence should read:

> The recommended procedure is similar to example (…) in that the dispersion of the analyte is unknown and must be estimated.

Example B3, paragraph 3

The lot standard deviation (σ) is estimated, the sample standard deviation (s) is calculated. The term "ad hoc" should be deleted: considerable study has been devoted to the properties of s as an estimator of σ.

The sentence should read:

> The standard deviation σ, (a measure of dispersion) is estimated by measuring a number *n* of randomly taken samples *i* (*i=1....n*) and calculating the sample standard deviation s.

Example B3, Sampling and decision

The rounding (0.97 and 0.02) is premature and too heavy. The t percentile used must be given to at least two significant figures. Therefore the thing that it is multiplied by (0.02) should be given to at least two significant figures. The fact that the sample mean and standard deviation may not be accurate (as estimates of the true mean and standard deviation) to better than 2 decimal points or 1 significant figure respectively is not relevant: the t-distribution allows for sampling variation in these quantities, and use of the t-distribution would in fact be inappropriate if the sample mean and standard deviation were known to be equal to the true mean and standard deviation to the number of places quoted.

Example B4, Agreement before trading activities

It would be advisable to include the acceptance and non-acceptance quality limits in the agreement before trading activities. The second point could read:

> Probability α of wrongly rejecting a conforming lot and probability β of wrongly accepting a nonconforming lot, the acceptance and non-acceptance quality limits m_A and m_R as discussed below.

Example B4, Sampling and decision

The second paragraph should be amended to avoid confusion between AQL and producers' risk, and LQ and consumers' risk, as follows:

> The following four quantities are chosen:
>
> the acceptance quality limit for the lot mean m_A (corresponding to AQL),
>
> the probability α of rejecting a lot with true mean m_A (corresponding to producers' risk),
>
> the non-acceptance quality limit for the lot mean m_R (corresponding to LQ), and
>
> the probability β of accepting a lot with true mean m_R (corresponding to consumers' risk).

From these are deduced ...