CODEX ALIMENTARIUS COMMISSION

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Agenda Item 4 **CX/MAS 15/36/4 Add.2**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Thirty-sixth Session

Budapest, Hungary, 23 - 27 February 2015

PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE: EXPLANATORY NOTES AND PRACTICAL EXAMPLES

Comments at Step 3

(Comments of Brazil, India and ICUMSA)

BRAZIL

The document should take into consideration the recommendations of REP14MAS, paragraphs 33 and 35 and described in the CRD 19 presented during the 35th. CCMAS Meeting.

In this way the CX/MAS 16/36/4, for example in section 4, Principle 1, page 5, line 15, must replace "The agreed specifications should not restrict the flexibility of the control program in the importing country and should preferably be done in general terms" with the text, discussed and approved at the 35th CCMAS Meeting, described in the CRD 19 - CX/MAS 14/35/4, CX/MAS14/35/4: "In line with the Principles, the agreed specifications should not restrict the flexibility of the control program in the importing country."

INDIA

General Comments:

1) Bibliography may be updated. Numbering of reference to the foot note in appendix I -CAC/GL83-2013 and integrated text as in shaded grey is confusing needs to be renumbered.

2) Appendix I & II verified- may include details of sampling plan for spices depending on acceptable Quality level that (i.e. finalized) to the Annex on practical examples. May also see document CAC-GL 14-1991.

ICUMSA

General Comments

In the Background to the paper it is stated:

5. The Committee agreed that the electronic working group would take up the development of practical examples taking into consideration the recommendations from the Discussion Paper on Sampling Codex Standards (CX/MAS 14/35/7) and the discussion in the Committee (paragraph 83). The electronic working group would:

- Provide a brief explanation of the use of sampling and analytical measurement uncertainty in product control and testing compliance;
- Develop examples, including case-by-case advice of consideration of sampling uncertainty;
- Fruits/vegetables, fats/oils, fish/fishery products, milk/milk products, meat/meat products, natural waters, cereals;
- Sensory inspection, food additives, food hygiene, pesticide residues, contaminants, residues of veterinary drugs;
- Packages/bulk material/foodstuff for consumption;
- Develop procedures for determining uncertainty of measurement results including sub-sampling, sample processing and analysis;

- Consideration of importing and exporting countries including control of production and testing compliance.

To take the first bullet point, the explanation of sampling and analytical measurement uncertainty in product control and testing compliance is scarcely addressed. In particular the issue regarding sampling measurement uncertainty is not developed. At this time it is this issue that may be considered critical. It must be appreciated that it was the preparation of papers considering of uncertainty derived from sampling which was the precursor to these Principles.

It would have been useful to have incorporated the sentiments given in the Codex Procedure Manual and in particular the section dealing with "The Use of Analytical Results: Sampling Plans, Relationship Between The Analytical Results, The Measurement Uncertainty, Recovery Factors and Provisions In Codex Standards"

There it is stated that:

It is recommended that when a Codex Commodity Committee discusses and agrees on a commodity specification and the analytical methods concerned, it states the following information in the Codex Standard:

1. **Sampling Plans**

The appropriate sampling plan, as outlined in the Guidelines for Sampling (CAC/GL 50-2004), Section 2.1.2 Guidelines on Sampling to control conformity of products with the specification. This should state:

- whether the specification applies to every item in a lot, or to the average in a lot, or the proportion non-conforming;
- the appropriate acceptable quality level to be used;
- the acceptance conditions of a lot controlled, in relation to the qualitative/quantitative characteristic determined on the sample.

2. Measurement Uncertainty

An allowance is to be made for the measurement uncertainty when deciding whether or not an analytical result falls within the specification. This requirement may not apply in situations when a direct health hazard is concerned, such as for food pathogens.

The phrase "The Measurement Uncertainty" is not defined as referring to measurement uncertainty derived from (only) "analysis" or to also include uncertainty derived from "sampling". As there is much international opinion that "measurement uncertainty" should apply to the whole process when considering lots, sampling uncertainty should be addressed by the principles.

It is therefore important that the critical issue of whether uncertainty derived from sampling should be included in the paper.

At the present time the Explanatory Notes to Principle 5 states:

The exporting country and the importing country should make available clear statements on how the analytical measurement uncertainty is taken into account when assessing the conformity of a measurement against a legal limit. This agreement should cover all situations where a limit or specification level is to be met, including limits for potential health hazards if such characteristics are to be assessed under the agreement.

ICUMSA considers that it is important to expand this statement either here, or in Principle 4, to state that:

"The exporting country and the importing country should make available clear statements on how the measurement uncertainty derived from both sampling and analysis is to be taken into account when assessing the conformity of a measurement against a legal limit. This agreement should cover all situations where a limit or specification level is to be met, including limits for potential health hazards if such characteristics are to be assessed under the agreement."

Specific Comments

Annex on Practical Examples

Table 1: Code of Examples

Here it is useful to see reference to various plans that have been adopted by Codex. It is also interesting that for 3 of the four Codex Committees given in the Code of Examples, the responsibility for methods of analysis and sampling for these Committees does not extend to the Codex Committee on Methods of Analysis and Sampling. Some clarification would be welcomed here.

Table 2: Example Sampling Plans

These are taken from published standards. However it would have been very useful to have seen how the plans were built up and the considerations that attached to aspects within them.

It is also suggested that "Instructions" in simple language would appreciated by delegates to Codex Committees – part of the problem is that the whole issue of analysis, and particularly sampling, is considered to be too complex by non-specialists.

To some extent this issue was discussed in the paper CX/MAS 14/35/7 from the 35th Session of CCMAS. That paper stresses that it is important that the selection of values of mathematical parameters for the operation of the sampling plan are considered.

To extract from that paper, the following should be noted when setting up plans:

(Note: for Tables, Appendices referred to below, please see original paper)

Choice between variables and attribute plans

Where inspection of an item in a lot is made by recording whether it is defective or non-defective (or by counting the number of defects in the sample) it is necessary to use an attributes plan. Where inspection involves making a measurement of some kind on each item, on a continuous scale, and the distribution of these measurements can be verified to be at least approximately normal form, it is appropriate to use a variables plan, although an attributes plan may be used if desired. In the latter case the item is deemed to be defective or non-defective according to whether or not the numerical measurement lies beyond the specification for the product.

A variables plan is more economic than an attributes plan to operate as it requires a smaller size of sample for the same acceptable quality level (AQL) and consumer risks of accepting poor quality.

Acceptable Quality Level

The initial parameter to be considered is the acceptable quality level (AQL). The AQL may be considered as the maximum percentage of defective items (or the maximum number of defects per hundred units) in the lot which is satisfactory as a process average in continuous production. Lots of AQL quality will be accepted most of the time (i.e. more than 90%) that they are submitted for sampling. For a given sample size the lower the AQL of the plan the greater is the protection given to the consumer and buyer against accepting lots with defective items. Equally, the greater is the onus on the producer to manufacture to a sufficiently high standard of quality. Any value of AQL which is selected must be one which is practically realisable and economically viable.

The sampling plan for defective units in prepackaged foods uses an AQL in the region of 6.5% with an associated lot acceptance of 95% or more. There is a tendency for this plan to be misapplied to compositional characteristics, and for the specified AQL to be taken as the 'norm' whenever Codex sampling plans are discussed. However, it should be recognized that the selection of the value of the AQL to be used is dependent on the specific characteristic under consideration and its relevance (economic or otherwise) to the standard as a whole. In other words some weighting should be given to certain characteristics (e.g. in critical, major or minor defects).

It is suggested that Codex Commodity Committees consider one of eight values of AQL, namely in the region of 0.1, 0.25, 0.65, 1.0, 2.5, 4.0, 6.5 or 10.0% as appropriate to the characteristic in question. Characteristics which may be "health-risk" associated should attract a low value AQL (i.e. 0.1 to 1.0%) whereas those for compositional characteristics such as fat, moisture etc, could attract a higher value AQL (e.g. 6.5% and 10% is often used for milk products.

The sampling plans and associated quality levels, as given in Appendix V, are referenced, as far as is possible to the right AQL values indicated above. It should be appreciated that, due to derivational limitations, not all of the above suggested AQLs are possible for each referenced sampling plan.

Size of sample to be taken

The effect of the numbers of items taken on the chance of accepting a lot is given in Appendix V. Particular attention should be paid to the quality of a lot which has a 10% chance of acceptance as this is indicative of the risk of reducing the sample size for analysis.

Consideration must be given to the nature of the items forming the sample. Where the produce is pre-packed this does not normally present a problem since each package will constitute an item for the purpose of sampling. If the product is supplied in bulk it will be necessary to take an increment and each increment will constitute a sample item (unless two or more increments are blended together).

For this reason, in order to reduce the risk of accepting large numbers of defective items, it is usual to increase the sample size as the lot size increases.

Note that it is not necessary to continue to inspect the units in a sample after a decision is certain from the items already inspected. Thus, in inspecting to the plan n=13, c=2, if the first three items are found to be non-conforming, the lot may be rejected without necessarily inspecting the remaining 10 units. Similarly, inspection could cease after 11 conforming units are found.

Inspection Level

The risk of accepting examined lots with a given percentage of defective items is determined by the sampling plan chosen. Clearly, however, the actual number of defective items in the lot will depend on the size of the lot. Tables (1, 3) showing recommended sample sizes to be taken for different lot sizes, corresponding to different levels of inspection, are shown in Appendix V. These are intended as a guide and it is not mandatory to use either the precise values quoted for lot sizes or as many range sub-divisions. Two opposing factors need to be considered in deciding on the inspection level to use. These are the consequences of passing lots with a higher number of defective items and the overall cost of the total sampling operation, including analysis.

The inspection level numbers (1 to 5) correspond to similar risks in the operation of attribute and variable plans. For a given AQL the lower the inspection level number the greater is the risk of passing poor quality lots. It is suggested that, depending on the implication, levels 2 to 4 be regarded as the normal levels for sampling lots. If health risks are not involved and sampling costs are a major consideration, a lower level may be used. Where health risks are of major concern inspection level 5 may be adopted.

Whatever plan is selected, the actual quality of lots (in percent defective items) which, if submitted, would be passed 95%, 50% and 10% of the time, is given in Appendix V.