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Agenda Item 6.2 **CX/MAS 25/44/9**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

44th Session

Virtual

5 – 8 May and 14 May 2025

REVIEW OF SAMPLING PLANS IN CXS 234

(Prepared by the EWG led by New Zealand and co-chaired by Germany)

Introduction

1. CCMAS43 (2024) agreed to establish an electronic working group (EWG), chaired by New Zealand and co-chaired by Germany, to develop a discussion paper on the review of all sampling plans in the *Recommended methods of analysis and sampling* (CXS 234-1999), to determine what information should be included in CXS 234-1999, and the format of this information. This discussion paper would:

   - provide a review of current procedures for the inclusion of sampling plans in CXS 234-1999; and
   - consider sampling plan information that may be included in CXS 234-1999 for sampling plans that will be developed under the *General guidelines on sampling* (CXG 50-2004) and sampling plans from other sources noting that sampling plans are subject to endorsement by CCMAS prior to inclusion in CXS 234-1999.[1]

2. This paper focuses on the review of sampling plans as per the term of reference for the EWG indicated in paragraph 1. The other terms of reference for the EWG related to the information document are addressed in CX/MAS 25/44/8.

3. This working document contains the following:

   a. A summary of the process since CCMAS43 including the EWG process and recommendations to CCMAS44

   b. **Appendix I: Discussion Paper: Inclusion of sampling plan information in CXS 234-1999**. Sampling in this context refers to acceptance sampling. It does not refer to physical sampling processes.

   c. **Appendix II**: **Proposal to develop a discussion paper on sampling plans for bulk materials including mycotoxins**

EWG process

4. The discussion paper on the inclusion of sampling plan information in CXS 234-1999 was not sufficiently progressed to send to the EWG for consideration. The discussion paper was developed by the Chair and co-Chair of the EWG and as part of their review of sampling plans, options for further work were identified. These options are set out in Appendix I. In summary, the options are to:

   - include sampling plan information in CXS 234-1999 noting a review of the current format is needed;
   - include sampling plan information in each individual standard;
   - develop a new standard to include sampling plan information (in parallel to CXS 234-1999) that only contains sampling plan information and remove Part B of CXS 234-1999; and
   - develop a standard for each commodity group that describes the sampling plans for that commodity group.

5. On the proposal to develop a discussion paper on sampling plans for bulk materials including mycotoxins this work was not sufficiently progressed to send to the EWG for consideration. Although there was considerable interest expressed by CCMAS participants to have sampling plans for bulk materials, and a sampling plan app

[1] REP24/MAS, paragraph 39 (ii-iii)

for this during discussions on the revision of the *General guidelines on sampling* (CXG 50-2004) and the development of the related information document, this area would be complex. The investigation undertaken so far identified that the current sampling approaches, e.g. the sampling plans for mycotoxins described in the *General standard for contaminants and toxins in food and feed* (CXS 193-1995), should be reviewed.

Conclusions

6. Based on the investigations undertaken since CCMAS43, the options for inclusion of sampling plan information in CXS 234-1999 or elsewhere should be developed further to consider the recommendations.

7. The proposal for a discussion paper on sampling plans for bulk materials should also be considered.

Recommendation

8. CCMAS44 is invited to:

- recommend that the discussion paper on the inclusion of sampling plan information in CXS 234-1999 continues to be developed for consideration at CCMAS45 (2026), to expand on the options for further work as set out in paragraph 4 and Appendix I; and
- consider the development of a discussion paper on sampling plans for bulk materials including mycotoxins and including Bayesian approaches as set out in Appendix II, to be considered at CCMAS45.

Appendix I

Discussion paper: Inclusion of sampling plan information in CXS 234-1999

Introduction

1. The 43rd session of the Codex Committee on Methods of Analysis and Sampling (CCMAS43, 2024) agreed to establish the electronic working group (EWG), chaired by New Zealand and co-chaired by Germany, to develop a discussion paper on the review of all sampling plans in the *Recommended methods of analysis and sampling* (CXS 234-1999), to determine what information should be included in CXS 234-1999, and the format of this information. The discussion paper would:

   - include a review of current procedures for the inclusion of sampling plans in CXS 234-1999; and
   - consider sampling plan information that may be included in CXS 234-1999 for sampling plans that will be developed under the *General guidelines on sampling* (CXG 50-2004) and sampling plans from other sources noting that sampling plans are subject to endorsement by CCMAS prior to inclusion in CXS 234-1999.[2]

Background

2. Sampling in this context refers to acceptance sampling. It does not refer to physical sampling processes.
3. Information on sampling plans is included in Codex to ensure complete harmonization of Codex standards, to facilitate trade and to avoid disputes by ensuring fair and valid sampling plans are used. To achieve this, a single, designated sampling inspection plan should be specified for each provision, in the same way there is a single, designated analytical test method for each provision.
4. The inclusion of sampling plan information in Codex standards is needed to ensure harm and facilitate trade and to avoid disputes. A single, designated sampling inspection plan should be specified for each provision, similar to how a single analytical test method is designated.

Principles for sampling inspection plans

5. Sampling inspection plans should align with Codex principles:

   - Validity: Based on sound statistical principles, accounting for measurement error and within-lot product variation
   - Fairness/Fitness for Purpose: Procedures should have acceptable probabilities of wrongly accepting or rejecting a lot, ensuring they are fit for purpose.

Requirements for sampling plans (*Principles for the use of sampling and testing in international food trade* (CXG 83-2013))

6. A sampling plan must specify:

   - the number of samples and sampling method
   - the test method for analyzing samples
   - how results are used to assess compliance with the provision.

Current state of CXS 234-1999 Part B

7. The current format of CXS 234-1999 Part B includes three columns:

   i. Commodity categories
   ii. Method of Sampling
   iii. Notes

8. Currently, CXS 234-1999 contains only sampling information for three commodity groups (Cereals, Milk and Milk Products, and Processed Fruit and Vegetables), leading to confusion between physical sampling and sampling inspection plans. A review of 272 standards showed: - 63% had no sampling information. - 13% referred to ISO sampling plans with an AQL (PRQ) of 6.5%. - 1% referred to CXG 50-2004.

Options for including sampling information

9. The following options can be considered:

   - Include sampling plan information in CXS 234-1999, noting a review of the current format is needed

[2] REP24/MAS, paragraph 39

- Include sampling plan information in each individual standard
- Develop a new standard to include sampling plan information (in parallel to CXS 234-1999) that only contains sampling plan information and remove Part B of CXS 234-1999
- Develop a new standard for each commodity group that describes the sampling plans for that commodity group

Guidance from Section 3.2.4 of the CXG 50 information document

10. Commodity committees can either:

- propose specific sampling plans for provisions; or
- propose outcomes for sampling plans in terms of maximum allowable producer's and consumer's risks.

11. The latter approach is preferred when measurement uncertainty is significant, as it caters for different variability of producers' processes (noting that some commodities are unprocessed and others minimally processed).

Proposed table format for Part B of CXS 234-1999

12. The table should include:

Heading	**Information**
Commodity Category or Provision	Clearly defined
Reference to Physical Sampling Procedure	Such as an ISO standard or a section in the commodity standard
Sampling plan details	A sampling plan or outcomes for the sampling plan expressed in terms of the PRQ and CRQ quality levels
Notes	Including values of producer's and consumer's risks if default values are not used

Example: Proposed format for specification of sampling plan information

Commodity	**Provision**	**Physical sampling procedure**	**Sampling plan details**	**Notes**
Butter	Salt	ISO 707|IDF 50	PRQ = 5%, CRQ = 10%	

Default values

13. Producer's Risk: 5% chance of rejection at the PRQ.

14. Consumer's Risk: 10% chance of acceptance at the CRQ.

Application of sampling plans

15. The same sampling plan could be used for multiple provisions provided that designers of plans consider that it is appropriate that the same producer's and consumer's risks apply to each of the characteristics.

16. It is noted that sampling plans specified in Codex are intended for use by 'consumers' including importing country regulatory agencies and customers and are not necessarily suitable for use by producers.

Examples

17. Examples should be provided to illustrate how the proposed table format and sampling plans would be applied in practice.

18. An example of the proposed format is included in paragraph 12.

Conclusion

19. Incorporating sampling plan information in CXS 234-1999 will support the harmonization of Codex standards, facilitate trade, and ensure fair and valid sampling practices. The proposed table format and guidance will help achieve these goals. However, the other options in paragraph 9 need to be considered.

Appendix II

Proposal to develop a discussion paper on sampling plans for bulk materials including mycotoxins

Introduction

1. CCMAS participants have expressed considerable interest in having acceptance sampling plans for lots consisting of bulk material / heterogeneous lots, along with a corresponding App.

2. During the work on the *General guidelines on sampling* (CXG 50-2004) and the information document, CCMAS delegates expressed interest in a review of the current sampling approaches used - for example the sampling plans for mycotoxins described in the *General standard for contaminants and toxins in food and feed* (CXS 193-1995) and consideration of other approaches for sampling plans for these commodities. If undertaken, the Codex Committee on Contaminants in Food (CCCF) would be advised. The review should address the following issues:

   - The sampling plans in CXS 193-1995 are based on data from lots previously found to be contaminated but might not be applicable to lots in general.
   - For some matrix/analyte combinations (e.g. Aflatoxin A in Brazil nuts) no acceptance sampling plan is currently provided in CXS 193-1995.
   - It is unclear to what extent the Mycotoxin Sampling Tool can be used to determine suitable plans. For example, it is not clear how to take the number of increments into account in the Mycotoxin Sampling Tool.
   - The plans have been developed using an experimental/empirical approach and although statistical distributions have been used, the approach is not consistent with the usual statistical approach, such that that presented in ISO 10725.
   - The number of increments in CXS 193-1995 (e.g. 100 increments) may lead to pockets of possibly harmful contamination being missed.
   - Usually, a single composite sample is tested, meaning that the levels of contamination within the lot are averaged out. The final result may thus be less than the acceptance limit, and possibly below the detection limit of the test method, even if potentially harmful pockets of contamination are present in the lot.
   - It is possible that Bayesian approaches may be more appropriate than a risk-based approach, nonetheless, an updated method for the calculation of various (Bayesian) risks is also required.

3. In the time between CCMAS43 (2024) and CCMAS44 (2025), New Zealand and Germany have already started looking at these issues. In particular, there were very productive discussions with the United States of America (USA) and Canada, the available literature (e.g. article by Whitaker and Tittlemier) has been reviewed, the plans described in CXS 193-1995 have been compared with the plans provided in EU legislation (e.g. CIR 2023/2782 and CIR 2023/2783) and the statistical modelling in the Mycotoxin Sampling Tool have been looked at. New Zealand and Germany have received data from Canada and may soon receive data from USA.

4. New Zealand and Germany propose a discussion paper on sampling plans for bulk materials / heterogeneous lots (with a focus on the inspection of lots for mycotoxin contamination), including Bayesian approaches, to be considered at CCMAS45.

Appendix III

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