CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3, 4, 6 and 7 **MAS/40 CRD/14**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

40th Session
Budapest, Hungary, 27 – 31 May 2019

Comments of European Union

EUROPEAN UNION

Agenda Item 3: ENDORSEMENT OF METHODS OF ANALYSIS AND SAMPLING PLANS FOR PROVISIONS IN CODEX STANDARDS

Agenda item 3.1 Endorsement of methods of analysis and sampling plans for provisions in Codex Standards

CCNFSDU40

The European Union and its Member States (EUMS) welcome the suggestion of CCNFSDU to replace the current methods for the determination of vitamin K, folic acid and nine minerals and trace elements in infant formula and agrees with the proposed typing of the methods. The following editorial changes in Appendix 1 shall be considered by CCMAS before endorsing them:

Page 2, Vitamin K, HPLC, should be corrected to HPLC-FL (fluorescent detection) as to indicate also the detection principle of the method. In addition, the EUMS suggest to include next to the proposed AOAC 2015.09 / ISO 21446 (Type II) also EN 14148 as Type III.

Page 2, Folic Acid, J. Chromatography A, 928, 77-90 HPLC, should be HPLC-FL instead.

CCSCH4

The methods of analysis listed in the tables of Appendix II refer for several provisions (moisture, ash, volatile oil, etc.) to empirical method (Type I) which have been developed by more than one standard developing organisation. As empirical methods are defining methods only one Type I method can be used for a provision unless a method has been published by two organisations and is technically equivalent. Therefore, CCSCH is invited to clarify which of the multiply listed Type I method shall be retained in the list.

On page 9, Section 9.1 Artificial colorants, the given measurement principle: Chromatography - should also include the detection method (e.g. HPLC-PDA or HPLC-DAD or HPLC-UV-VIS).

CCFO26

Appendix III list different Type I methods for the same provision. As only one Type I method may be endorsed for checking compliance with the provision of the concerned standard, CCFO is invited to select to most appropriate one.

Agenda item 3.2: Dairy workable package

The EUMS would like to thank the USA and New Zeeland for the excellent work done in leading the EWG and for clearly identifying where further discussion in CCMAS is necessary regarding recommendations on the removal of methods, proposed retyping or additional information on the status of the methods listed.

The EUMS would like to suggest the following editorial change on page 7: the measurement principle for Natamycin in Cheese (and cheese rind) where HPLC is mentioned, it should be replaced by HPLC-PDA or HPLC-DAD or HPLC-UV-VIS.

Agenda item 3.3: Cereals, pulses and legumes workable package:

The EUMS would like to thank the AACCI for for submitting the document on this package. The EUMS wish to recall that CCMAS33 discussed proprietary methods and their relationship to the Codex system. The Committee noted the views that caution should be exercised when considering proprietary methods, taking into account that a proprietary method endorsed as Type I or II would give a significant commercial advantage to the manufacturer. The Committee also noted that in the absence of any other method, consideration should be given to adequate proprietary methods as at least one method of analysis should be endorsed to enforce labelling, such as in the case of gluten determination.

The currently endorsed method for gluten refers to a validation study published in a scientific journal, which is not a common way for referencing methods in CXS 234. The proposal to replace the referred scientific publication with a reference to a method standardised by AOAC and AACC is, therefore, appropriate. However, as the AOAC/AACC method builds on the use of just one commercial test-kit (R-Biopharm Catalogue R7001), the possibility for end-users to choose from is severely limited. The current reference includes test-kits from two manufacturers, both using the same antibody. In addition, the precision data reported for the original method reference and the suggested update are equivalent. Consequently, the EUMS are of the opinion that no modification of the existing method reference for gluten in CXS 234 is necessary.

Regarding the proposal to endorse AOAC 2018.15 (Gluten in oat-based gluten free foods) the EUMS believe that this issue should first be referred to CCNFSDU and then be considered by CCMAS under agenda item 3.1 on Endorsement of methods of analysis and sampling plans for provisions in Codex Standards. Therefore, the EUMS are of the opinion that it is pre-mature to endorse this method during CCMAS40.

Agenda item 3.4: Fats and oils workable package

The EUMS would like to thank AOCS for the excellent work done and invites CCMAS to take the discussion points raised into consideration.

In CX/MAS 19/40/3 Add.3 some questions of importance are raised:

- Can two methods be endorsed as Type I, when they are technically identical, but stem from different sources, with their own validation studies and data?

- How to deal with methods, validated for one commodity, but applied to a different commodity. How comparable must such commodities be to allow endorsement as type II. The document suggests endorsement as type III when a commodity is not within the validated scope. As such a method may be tentative in that case, Type IV might be more appropriate.

As these questions are not specific for the fats and oils workable package, but apply to endorsement in general, it is suggested to deal with these aspects in the guidelines for endorsement.

Finally, a general question comes to mind: does STAN 234 currently contain methods with different typing, depending on the commodity involved?

Agenda Item 4: GUIDANCE ON ENDORSEMENT

The European Union and its Member States (EUMS) would like to thank the United States of America for their excellent work in leading the eWG and for preparing a very well structured and thorough document for consideration at the 40th CCMAS session.

The EUMS would like to submit the following comments to the outstanding questions highlighted in the document:

1. The Definition of Identical

When two methods have identical steps, rather than the same steps, it is acceptable to consider methods as identical and both can be listed. If validation studies carried out by different organisations using different representatives of matrices identified in the scope of the method exist and the resulting method performance pararmeters are equivalent, ruggedness of such a method is clearly demonstrated.

2. Type III Method when no Type II exists (Table 2.2)

Following Codex rules, Type II methods should be fully validated, whereas Type IV methods are considered as tentative when not fully validated. Therefore, the EUMS support the second option to use Type IV for those cases.

4. Section 3.2 iiia

The EUMS agree that it is primarily the task of committees and SDOs to propose methods, however, we support the notion that it is the responsibility of CCMAS to assess whether a proposed method is appropriate for checking compliance of the relevant provision(s) with a Codex standard.

6. Section 3.8 Changing Type I methods to Type IV

Competent authorities should be able to rely on Codex methods. Type I methods should be fully validated, whereas Type IV methods may give tentative results. The revision process of STAN-234 may be the opportunity to review validation status and typing.

7. Interaction between commodity committees and CCMAS

The EUMS believe it would be more efficient if commodity committees can submit methods to CCMAS for endorsement. When CCMAS endorses the methods according to the commodity committee proposal, these should then be forwarded to the CAC for adoption without a further consultation of the commodity committee.

Finally, the EUMS recommend to use this guidance as an internal guidance document for CCMAS.

Agenda Item 6: REVISION OF THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54-2004)

The European Union and its Member States (EUMS) would like to thank Germany for the excellent work done in leading the eWG.

Concerning the questions raised under paragraph 21, the EUMS have the following comments:

Should the two examples on acceptance sampling be part of the guideline?

As this aspect is more related to sampling and the relevant ISO standards where detailed information can be found are referenced the EUMS suggest deleting the examples from the guide and moving the examples to the information document (Appendix II).

Should the Figure 1 (former Figure 5) be part of the guideline?

Figure 1 is a simple visualization of the possible use of measurement uncertainty for comparing a measurement result with a limit. Furthermore, the following explanations (situation i to iv) build on the visualization. Therefore, it is suggested to maintain the figure.

During the revision of the first draft it became more and more obvious how complex the decision making process is. Furthermore, ISO 17025 attaches great importance to the decision making process. It requires that decision rules applied in conformity assessment must be based on the uncertainty of measurement and sampling. Therefore it might be reasonable to think of a guideline to explain the several ISO standards, guides and publications.

The EUMS welcome the suggestion to develop a discussion paper on the interplay of measurement uncertainty, decision rules and conformity assessment procedures as described in different ISO standards, guides and publications.

It should be considered whether an adapted version of GL 59, chapter 4 could be included in GL 54

The EUMS wish to recall that CCMAS38 agreed that the revised version of CAC/GL 54-2004 shall avoid overlapping with the Guidelines on Estimation of Uncertainty of Results (CAC/GL 59-2006). Therefore, including a reference in CAC/GL 54-2004 to the relevant parts of CAC/GL 59-2006 should suffice and an adapted version of table 3, chapter 4 of GL 59 could be included in the Information Document.

Concerning Appendix I, the EUMS have the following comments:

Section 8:

The definition of “lot” may need to be further expanded to be in line with the one given in other Codex texts, including major characteristics (same origin, producer etc.).

Section 18.b:

The notion of "properly perform" may need to be expressed in a more specific way. The EUMS suggest the following wording: “… verifies that the within laboratory performance parameters concord with the official standardized method”.

Section 28, Figure 1

Situations ii and iii could be reinforced. It is suggested that CCMAS invites commodity committees to declare the applicable decision rules (acceptable percentage of non-compliance with specific limits) for individual commodities or group of commodities, as the commodity committees are in the best placed to do so.

Situation iv: The wording could be improved. The EUMS would like to suggest to replace the expression (This follows from □−2·□=2.5 □□−2·0.3·2.5 □□=□□) by (This follows from: X-2*0.3X>ML; X(1-2*0.3)=0.4X>ML; X>2.5 ML; ML/0.4=2.5).

Agenda Item 7: REVISION OF THE GENERAL GUIDELINES ON SAMPLING (CXG 50-2004)

The European Union and its Member States (EUMS) would like to thank New Zealand for the excellent work done in leading the eWG.

The EUMS would like to make the following general remarks:

Excessively general frameworks for the design of acceptance sampling plans allowing for a large variety of choices may easily overwhelm the average user. In particular, the selection of an adequate sampling scheme under operational, contractual, and business constraints, and the specification of values for a variety of statistical parameters may be difficult for users with few statistical skills. The interpretation and suitable quantification of parameters such as AQL, LQ, AOQL, and associated risk parameters require expertise in statistical methodology. In many cases, users are better served by design frameworks that restrict attention to selected representative parameter combinations to a concise class instead of allowing for the full variety of combinations.

Sampling plans and the underlying methodology should be unambiguously defined and documented, should be legally robust, clearly understood and unconditionally recognised by all parties involved. In particular, numerical algorithms and their software implementations need to be accessible to make results reproducible and traceable.

The EUMS appreciate that the aim of these Guidelines is to be user friendly; however, information to address all sources of uncertainty within the Acceptance Sampling approach could overly complicate the end product. The Guidelines could include a statement that a pragmatic approach to measurement uncertainty has been taken, still making clear the factors that have and have not been included.

Concerning the specific questions of CL 2019/17-MAS mentioned in the key outcomes from the EWG consultation the EUMS have the following comments:

In what context is it that Codex sampling plans are intended to be used?

Codex sampling plans have to ensure that fair and valid procedures are used when food/feed is being inspected for compliance with a particular Codex standard (or requirements provided by a Codex standard)

What do Codex sampling plans hope to achieve?

Codex sampling plans or sampling plans developed on the basis of the Codex guidelines on sampling should ensure that the samples are representative for the sampled lot to verify compliance with Codex standards (or requirement established in Codex standards).

How Codex sampling plans can be used by exporting and importing countries in real situations?

Prescriptive or defined Codex sampling procedures associated with Codex standards (or requirements provided in the Codex standard) are recommended to be applied to check compliance of lots/consignments with Codex standards (or requirements provided in the Codex standard)

In case there is no prescriptive or defined Codex sampling procedure associated with the Codex standard (or requirements provided in the Codex standard) food surveillance authorities should elaborate/design appropriate sampling procedures based on the general guidelines for sampling provided for in CAC/GL 50-2004., also for checking compliance with national standards in the absence of Codex standards.

Are Codex sampling plans intended for use in international trade disputes?

Codex sampling procedures or Codex guidelines for sampling could be considered for use in international trade disputes. However, in these cases it must be ensured that the balance producers' risk and consumers' risk related to the Codex sampling procedure is equivalent to the balance producers' risk and consumers' risk related to the sampling plan applied by the importing country. For the control of compliance with feed/food safety standards it is important that the consumers' risk is minimized combined with an acceptable producers' risk.

What situations where Codex sampling plans are used, are covered or not covered?

Sampling inspection is widely used to control and regulate the interface between two distinct parties, e.g., producer and consumer, vendor and buyer, trader and regulatory authority. Currently, Codex sampling plans refer closely to ISO 2859 and ISO 3951 series. These standards have limited practicality and are not accessible via a simple app and they have further limitations as significant measurement uncertainty and significant bias are not taken into account. Therefore, the responsible ISO working group TC 69 SC 5 is working on a revision of these standards. The EUMS strongly recommend aligning the procedures to establish Codex sampling plans with ISO standards of the 3951 and 2859 series as soon as the revised versions become available.

The scope of the CAC/GL 50-2004- General Guidelines on Sampling (section 1.4 of CAC/GL 50-2004) provides explicitly that the guidelines do not cover the control of non-homogeneous goods, situations where the measurement error is not negligible compared to sampling error, the control of qualitative characteristics in bulk material.

It is the view of the EUMS that it would be appropriate to consider if also for these situations guidelines on sampling could be elaborated. In particular, it is of major importance that in case of control of compliance with a food safety standard of a substance non-homogeneously distributed in the lot, that the sampling procedure ensures a minimisation of the consumers' risk combined with an acceptable producers' risk.

In the point 2 of the Recommendations to CCMAS 40 on page 3 of CX/MAS 19/40/7, the following question (in addition to the questions above) is put forward for consideration to guide further work:

Is it practical to achieve a perfectly balanced producer/consumer risk, based on statistical theory will rarely ever be practically achieved, as there is not a single producer for a commodity, or a single consumer (importing country), or single testing authority who are importing and testing at the boarder all the producer product?

The EUMS are of the opinion that in the development of sampling procedures the producers' risk and consumers' risk have to be taken into account but on a pragmatic basis and not to ensure a "perfectly balanced producer/consumer risk based on a statistical theory"

It is thereby important to underline that for the control of food safety standard, the elaborated sampling plan should ensure a minimisation of the consumers risk combined with an acceptable producers' risk.

For the control of compliance with standards, not related to food safety, the elaborated sampling plan should aim at ensuring a fair balance of the consumers' risk and producers' risk on a pragmatic basis.