CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4 **CX/MAS 18/39/4 Add.2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

39th Session
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COMMENTS ON THE REVISION OF THE RECOMMENDED METHODS OF CODEX STAN 234 / REVIEW AND UPDATE OF CODEX STAN 234

Comments submitted by Ecuador, Egypt, Canada, Guatemala, Kazakstan, Mexico, Norway, Switzerland, USA, AOCS, IUFOST, NMKL

Text	Comment
General comments	
Ecuador	Ecuador considers that in general terms the document is well structured with clear examples that help users to better understand the structure of the document in a better way. Additionally, we believe that the proposed suggestions help users to correctly choose the method they should use to perform a certain analysis.
USA	The United States thanks Brazil and Uruguay for their efforts in chairing and co-chairing the eWG and continues to support the review of previously endorsed methods and updating of CODEX STAN 234. The United States also thanks AOAC, IDF, and ISO for their review of all methods relating to milk and milk products and their identification of edits to be considered by the Committee. The United States continues to support the updating of CODEX STAN 234 and agrees with the general approach. Given the extensive work required and the potential impact on both CODEX STAN 234 and other Codex standards, it is important that changes made should correct errors and inconsistencies, eliminate ambiguities, and maintain the intent of CODEX STAN 234. To that end, the United States has some specific comments for consideration by the Committee. INTRODUCTION Consider replacing “recommended” by either “adopted” or “endorsed” in the title of CODEX STAN 234, in the first and second sentence of the preamble and in PART II. The United States understands this is a change from the current title of CODEX STAN 234, but it is more accurate description of the methods listed. In the sentence, “When confirming compliance to a Codex standard the methods of analysis and sampling contained in this General Standard that relates to the provision identified in the commodity standard shall (highlight added) be used.” Consider replacing “shall” with “should”. “Shall” has some ambiguity, and can be interpreted as may or as must. The use of the methods is not a requirement if trading partners agree on a different method, so replacement with “should” would remove the ambiguity and is more appropriate in a voluntary Codex standard. DEFINITION OF TERMS The definition of “technically equivalent” (below) does not seem appropriate for Type I methods. The way it is written seems to allow two methods with similar, but different procedures be listed as “technically equivalent”. That is not consistent with what has traditionally been accepted for Type I methods. What needs to be captured is that while the formatting of the written procedures may be different and/or the methods may

	have been created independently, the technical aspects of the procedures are identical and therefore the methods are identical. Is it necessary to use and define this term? Any method listed in CODEX STAN 234 can be used in testing, so the creation of a term seems unnecessary to allow use of CODEX STAN 234. Technically equivalent methods: methods that deliver the same result and where several elements of two methods are technically comparable but not identical: e.g. sample preparation, extraction, cleanup, identification technology (e.g. LC-UV). The methods should have validation parameters fit for purpose and meet with equivalent test results, ideally confirmed by the analysis of a series of common samples. Equivalent test results means results with the same metrological traceability and a measurement uncertainty fit for purpose. SECTION II. Methods Performance Criteria The use of the term “Performance Criteria” is not consistent with how this section is named or referred to in the Procedural Manual. Because “criteria” are referred to multiple times in the Procedural Manual, it would be beneficial to make sure the naming is harmonized to avoid confusion. In the Procedural Manual “Method Criteria” or “Numeric Values for Method Criteria” or “Working Instructions on the Criteria approach” are used to discuss this process. This is different and needs to be separated from the “General Criteria for the Selection of Methods”. The latter deals with the general characteristics (accuracy, precision, etc.) of the method, while the former is about establishing specific numeric values. PART II RECOMMENDED METHODS OF ANALYSIS With respect to the sentence “For the same commodity and provision more than one Type I and Type II methods may be used when they are identical or technically equivalent methods.” This could add some confusion to Type I and even Type II. It seems that this sentence is unnecessary; any method listed in STAN 234 can be used. The sentence, “The most updated version of the method should be used in application of ISO/IEC 17025:2005 unless it is not appropriate or possible to do so” is confusing. Better wording might be to say, “The most updated version of the method should be used since it is consistent with the application of ISO/IEC 17025.” Annex 1 The United States supports harmonization and consistency when appropriate, but the commodity name is determined by the commodity standard. Will changes in CODEX STAN 234 require other committees to alter their standards?

	Annex 2 While understanding the need to simplify and harmonize Provisions, in some cases the simplification could create confusion or ambiguity. Specifically: The Provisions should match those listed in the Commodity Standard, to avoid confusion and ambiguity. Some changes to provisions (i.e., fiber) will cause the loss of critical information about the use of the different Type I methods. If changes are made, we may need to capture this detail in some other place. Annex 3 While having a harmonized list is beneficial, the United States suggests some changes to the proposed list. Carbon isotope ratio mass spectrometry should be listed as isotope ratio mass spectrometry, not mass spectrometry. For separation methods (e.g., gas chromatography) followed by a detection method (e.g. flame ionization detection), the detection principle should also be included (e.g. Gas Chromatography Flame Ionization Detection). *Category : TECHNICAL*
Kazakhstan	The European Economic Commission, which is an observer organization of the Codex Alimentarius Commission, uses Technical Regulations of the Custom Union as a legal regulation basis. Technical Regulations contain requirements for food safety. According to the Parts and Sections of the General Standard on the recommended methods analysis and sampling (CXS 234-1999) the following issues are considered and covered: Section I: Standardized methods of analysis on commodity categories: 1. Commodity/product. 2.Provision (measurand or analyt) 3. Method 4. Principle. Section II: Methods efficiency description: 1. Commodity/product. 2. Provision (measurand or analyt). 3. Minimal applicable range. 4. Measurements inaccuracy. 5. Reproducibility. Section III: Full description of the analysis of the method. -Paragraphs of the above-mentioned sections are reflected in the regulations used in Kazakhstan (GOST, ST RK, GOST RK, methodical instructions), are included in the list of standards, which contain regulations and methods of research (tests) and measurements, including sampling regulations, necessary apply and implement the requirements of the Custom Union Technical Regulations.

	Regarding Part III – Standardized methods of analysis on commodity categories and names: mentioned sampling methods are harmonized with the regulations of the Custom Union countries. Taking into account all of the above mentioned, Kazakhstan agrees with the Proposed format to the General Standard on the recommended methods of analysis and sampling (CXS 234-1999).
Canada	Canada thanks Brazil and Uruguay once again, for their continued dedication and effort in re-formatting, reorganising and updating CODEX STAN 234 and for the opportunity to provide additional comments on the Proposed Preamble and Format to General Standard on Recommended Methods of Analysis and Sampling (CXS 234-1999). As we have provided comments on the previous draft, we have only a few comments/questions for consideration which appear below.
AOCS - American Oil Chemists' Society	"Anyone who thinks amino acids analysis “in principle sounds like a valid approach” does not appreciate the extreme problems with doing hydrolyzed amino acids analysis. A nitrogen determination can be done in a few minutes or at most a few hours depending on the method. Complete hydrolyzed amino acids analysis requires a minimum of 3 separate analyses and two days of sample preparation. In addition, when you have completed that AA analysis, it is not as accurate or as precise as nitrogen determination. The technical challenges posed by the hydrolysis are extreme, the loss of some amino acids is difficult to prevent, the need for good controls and corrections makes hydrolyzed amino acid analysis an extremely challenging assay. The hydrolysis time requirement is what makes amino acid analysis impractical. There are a wide variety of acceptable analysis methods for the amino acids once they are hydrolyzed, neither expense of equipment nor training of analysts is really an issue. The time for the hydrolysis is the problem. To say that there is no AOAC Official Method for amino acids in foods is correct but not truthful. AOAC 994.12 Amino Acids in Feeds works correctly with most foods as well, however foods are not specifically listed in the method scope. This is the amino acid analysis method currently most widely used for foods. Concerning nitrogen determination, it is important that the “Jones numbers” are NOT used and are not codified for use. Jones looked at a very limited set of food samples from 1940 and did a moderately poor job on the analysis. Jones numbers are not even

	very good for the types of food products Jones analyzed as the varieties grown today are far different from those grown in 1940. Jones numbers are not appropriate for a great many modern food ingredients, this is especially true of protein isolates and concentrates, where there is almost no non-protein nitrogen. Use of the Jones numbers for soybeans when analyzing soy protein products results in an incorrect underestimation of protein. This exact problem has already been encountered in China when they banned import of soy protein products for being below label claims because they used the Jones number of 5.71 instead of 6.25 for the nitrogen conversion. This is the reason the latest version of the AOCS protein methods via nitrogen list only 6.25 as the conversion, the Jones numbers were removed from the method due to the problems they cause. If the concern is adulteration, other rapid methods such as NIR can be used to be certain products are not adulterated. There is no possibility at this time or in the near future of a rapid complete amino acids analysis. The hydrolysis requirements for proteins are such that this is not likely to improve sufficiently to make this a viable alternative. It is possible alternative rapid methods will become available in the future, but they are not available today."
Guatemala	At this time, Guatemala has not comments on this document.
IUFOST	IUFoST finds the proposed document to be fully acceptable.
SPECIFIC COMMENTS	
This Standard is intended to provide a single reference to Codex recommended methods of analysis and sampling for food.	**Switzerland** Place in the scope *Category : EDITORIAL*
The recommended methods are primarily intended to allow competent national and/or regional authorities to select appropriate methods of analysis and ~~sampling~~ sampling for ~~food, as appropriate for their purpose, as acceptable methods for~~ the verification of commodities and provisions found in Codex standards.	**Norway** With regards to the preamble it gives a good introduction to the intended use of CODEX STAN 234. However, we think that the second sentence could be edited for increased readability. We propose the following amendments and deletions. Native English speakers may be able to improve the sentence further *Category : EDITORIAL*
This Standard contains definitions, lists of methods of analysis, methods performance criteria, descriptions of some methods and a list of methods of sampling which are recommended by the Codex Alimentarius Commission (CAC) to verify the provisions in Codex standards to be applied to commodities moving in international trade.	**Switzerland** Should be placed in the introduction. *Category : EDITORIAL*

2.2 Identical methods and/or collaboratively developed: when the same method was published by several Standards Development Organizations (SDO), each SDO using its own format. The only difference between these methods is the fact that they were formatted ~~and written~~ differently.	**Switzerland** Looks confusing to the reader 'written differently' as it was explained first that they are identical… *Category : SUBSTANTIVE*
2.2 Identical ~~methods and/or collaboratively developed~~methods: when the same method was published by several Standards Development Organizations (SDO), each SDO using its own format. The only difference between these methods is the fact that they were formatted and written differently.	**NMKL** "and/or collaboratively developed" may be deleted, as the methods should be identical as described *Category : TECHNICAL*
2.3 Technically equivalent methods: methods that deliver the same result and where several elements of two methods are technically comparable but not identical: e.g. sample preparation, extraction, cleanup, identification technology (e.g. LC-UV). The methods should have validation parameters fit for purpose and meet with equivalent test results, ideally confirmed by the analysis of a series of common samples. Equivalent test results means results with the same metrological traceability and a measurement uncertainty fit for purpose. All methods listed in this standard are elegible for any purpose, can also be used in cases of disputes, if it was agreed between the respective competent authorities, according to the Guidelines for Settling Disputes on Analytical (Test) Results (CAC/GL 70-2009). There is also an option for two countries to agree on an acceptable method. Type II methods are the recommended methods to chouse.	**Mexico** *Category : TECHNICAL*
2.4 Method of Analysis Principle: The science-based analytical principle of the method of analysis, described concisely, focusing on the technique.	**Canada** It may be helpful to build-in additional criteria for consistency because currently the definitions of individual method principles are variable. *Category : EDITORIAL*
The year of endorsement by CCMAS;	**Canada** Is bullet point g) required at this point? Is this information needed? *Category : EDITORIAL*
SECTION II. METHODS PERFORMANCE CRITERIA	**Canada** Is it possible to include the link to the NMKL Excel-based spreadsheet for calculating the performance criteria for any proposed Maximum Level? (http://www.nmkl.org/index.php/en/spreadsheet-excel) *Category : EDITORIAL*
Codex Standard to which the method is directed;	**Canada** Should the relevant Codex Committee, in addition to the applicable Codex Standard, be included? *Category : EDITORIAL*

PART II - RECOMMENDED METHODS OF ANALYSIS	**Canada** Section I – Standardized methods of analysis by commodity categories: The year of endorsement is not included in the examples given. Should it be included in this section or should this information be considered as part of Section II? Section II – Methods Performance Criteria: Would it be beneficial to identify which Codex group and which year under the heading 'Applicable Codex Stan'? *Category : EDITORIAL*
The most updated version of the method should be used in application of ISO/IEC ~~17025:2005~~ 17025 unless it is not appropriate or possible to do so.	**Mexico** *Category : TECHNICAL*
The most updated version of the method should be used in application of ISO/IEC ~~17025:2005~~ 17025 unless it is not appropriate or possible to do so.	**Switzerland** Outdated, the newest version is 2017: Do not state the year. *Category : SUBSTANTIVE*
Each line of the standardized methods list corresponds to one method of analysis or more than one if they are necessary to reach a result, in this case they are called complementary. When the methods are in the same line separated by a vertical bar "|" they are considered identical or by a forward slash "/" when they are considered technically equivalent. Alternative methods are listed in different lines. When more than one method is needed to verify the provision, the methods ~~be~~ are listed with an "and" between the methods required. When a method is determined by calculation it can be used ~~one line~~ one line? with the method and a brief description of the calculation in the principle column.	**NMKL** Consider wording of the sentence: " When a method is determined by calculation. Can a method be determined? Please clarify, what is meant by "it can be used on line"? *Category : EDITORIAL*
Each line of the standardized methods list corresponds to one method of analysis or more than one if they are necessary to reach a result, in this case they are called complementary. When the methods are in the same line separated by a vertical bar "|" they are considered identical or by a forward slash "/" when they are considered technically equivalent. Alternative methods are listed in different lines. When more than one method is needed to verify the provision, the methods ~~be~~ are listed with an "and" between the methods required. When a method is determined by calculation can be used one line with the method and a brief description of the calculation in the principle column.	**NMKL** *Category : EDITORIAL*
Each line of the standardized methods list corresponds to one method of analysis or more than one if they are necessary to reach a result, in this case they are called complementary. When the methods are in the same line separated by a vertical bar "|" they are considered identical or by a forward slash "/" when they are considered technically equivalent. Alternative methods are listed in different lines. When more than one method is needed to verify the provision, the methods ~~be~~ are listed with an "and" between the methods required. When a method is	**NMKL** *Category : EDITORIAL*

determined by calculation can be used one line with the method and a brief description of the calculation in the principle column.	
Type II methods could be used for any purpose in line with the Procedural Manual, for reference, in calibration of methods in use or introduced, for routine examination and control purposes.	**NMKL** Consider rewriting. This sentence is not easily understood. *Category : EDITORIAL*
Annex 1: LIST OF COMMODITIES CATEGORIES AND NAMES	**Egypt** Egypt agrees on the preamble and structure proposed in the (Appendix 1) and recommends adding a special column for uncertainty to the table mentioned in PART II - RECOMMENDED METHODS OF ANALYSIS - SECTION II - METHODS PERFORMANCE CRITERIA *Category : TECHNICAL*
Annex 1: LIST OF COMMODITIES CATEGORIES AND NAMES	**Switzerland** The criteria used to build this hierarchy should be clearly stated. We assume these commodities are all available in CODEX standards? *Category : TECHNICAL*
Annex 2: LIST OF PROVISIONS	**Egypt** It is necessary to add annexes 1,2 and 3 to facilitate the work by the above mentioned standard. *Category : TECHNICAL*
Annex 2: LIST OF PROVISIONS **Annex 3:List of Principles of the Methods**	**Norway** Concerning the proposed structure and the need for the annexes, we think the proposed structure is clear and well written, but we are unsure whether or not the annexes should be included. The reason for this is that ambiguities may arise following the suggested harmonization of specific provisions (annex 2) and principles (annex 3). Care must be taken when harmonizing provisions and principles so that important information is not lost. This harmonization should be carried out in close cooperation with the SDOs owning the methods for the specific commodities and provisions. The IUPAC color books, specifically the “Orange book” (currently under revision), may also be a good reference for the harmonization of principles in annex 3. *Category : SUBSTANTIVE*
Annex 2: LIST OF PROVISIONS	**Canada** Would it be possible to provide additional context to aid in the understanding of each provision? *Category : EDITORIAL*
Annex 3: LIST OF THE PRINCIPLES OF THE METHODS	**Mexico** We believe that it is necessary to have harmonized principles, but these principles should not be simplified so much , that they do not provide relevant information in the selection of a method. *Category : TECHNICAL*