

**Agenda Item 6****CX/MAS 14/35/6****JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING****Thirty-fifth Session
Budapest, Hungary, 3 - 7 March 2014****DISCUSSION PAPER ON ELABORATION OF PROCEDURES
FOR REGULAR UPDATING OF METHODS***(Prepared by eWG chaired by Brazil)***BACKGROUND**

At the 34th CCMAS Session, in 2013, updating the references of methods of analysis and related texts was discussed.

The Committee agreed that there should be harmonization in how methods of analysis were mentioned in Codex Standards; Commodity Codex Standards could just make reference to a general document with all the methods of analysis, which allows permanent and dynamic revision. The decision to have one up to date list of recommended methods of analysis is important because more authorities are referring to the “Codex accepted list of methods” they use for compliance testing. If these methods are different from methods generally used outside and inside authority laboratories disputes may occur. In addition, the credibility of Codex’s recommendations could be jeopardized.

The Committee also generally agreed with the following recommendation: “before each CCMAS, the Codex Secretariat would issue a list of all methods with an endorsement date older than 5 years from the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) for consideration during the method endorsement session. For each method in this list, CCMAS should re-endorse, withdraw or suggest an alternative method. Where a commodity committee is still active, the CCMAS will either propose to the committee an appropriate new method or motivate the committee to make a proposal; where the commodity committee is already adjourned, CCMAS will perform the update under its responsibility”.

The Committee noted that the IAM had worked on the update of methods in the Standard and would continue playing a significant role in the process; that a procedure for the work should be clearly defined; that a unified database for methods of analysis in Codex system should be elaborated to facilitate this work (updating); and that the 5 year period to review methods was consistent with the current practices of ISO.

The Secretariat indicated that proposals which affected the standards developed by other committees may require some consultation with these committees and amendments to the format of Codex standards or any other section in the Procedural Manual would need to be referred to the Committee on General Principles.

The Committee agreed to establish an eWG on the elaboration of procedures for regular updating of methods, chaired by Brazil and working in English, to facilitate the discussion on the matter with the following mandate:

- Propose a format for a single source (document, database) to capture all methods in the scope of CCMAS
- Propose a process to update the reference to methods of analysis. Include work to be done by commodity committees, IAM and Codex Secretariat
- Propose a plan to prioritize the (re)endorsement of current methods in the CODEX STAN 234 list and commodity committees. (e.g. methods of adjourned/abolished committee first).

Brazil prepared the discussion paper with comments from AACC International, AOCS, Argentina, Australia, Canada, IDF and Switzerland . A list of countries and NGOs that joined the EWG can be found in the Appendix.

SOME ISSUES RAISED BY THE ELECTRONIC WORKING GROUP

- a) It was discussed the use of Probability of Detection (POD) instead Limit of Detection (LOD) for qualitative methods. In the case of POD the confidence interval of the detection limit is calculated using the prediction interval of the probability curve, while for LOD this interval is directly determined by the probability curve. Thus the interval defined by POD is more reliable than the LOD. Although this concept has already been developed by ISO and AOAC, it has not yet been discussed by CCMAS. Following suggestions made by many EWG participants, the POD was included in the discussion paper as necessary information for qualitative methods, but the CCMAS should decide about it.
- b) It was noted that some additives covered in the “all food” section of STAN 234 have only limited applications and might not be used in all foods. Some suggestions were made about protocol to consider a method of analysis appropriate to be used for “all foods”. The AOAC International had developed a food composition triangle with 9 separate sectors for different foods based on their fat/carbohydrate/protein composition. A method could be considered applicable to all foods if it was demonstrated that the method performed adequately for a food from each of the 9 sectors. However there should also be a qualifier for methods for “all foods” that alerts users to the fact that although the methods have been validated for a broad range of foods, it is the responsibility of the users to verify the performance of the method for new or previously untested foods. Alternatively another point of view is not to qualify a method applicable to ‘all foods’, just identify the matrices validated. Every new matrix analyzed with a given method has to be verified. There may be an exception for methods that analyze elements. In this case the matrix is fully destroyed, and validation may be done per matrix category as for example defined in the ‘AOAC food triangle’. For other analytes it is necessary to know the parameters influencing the quantification for all matrices, in order to recommend a method suitable for all foods. For this reason, the status "applicable to all food" is seldom appropriate. A solution would be to replace it by the wording used by ISO /IDF: "horizontal methods".
- c) It was suggested that the Committee responsible could be removed from the columns (TABLE I – Information required in the methods of analysis standard document) and included in the existing headers for each section in STAN 234. E.g. Natural Mineral Waters CCNMW (adjourned sine die), but considering the proposal of all information will be part of a database in Codex website such as veterinary drugs database or an excel file such as a working document to the CCMAS, the headers may complicate the work at this stage. So there are two different formats to present the information, the first is the Codex / STAN 234 and the second is in a database or excel file format with the information necessary for decision-making by CCMAS.
- d) Another issue discussed was the necessity to have the information of the number of laboratories in the collaborative study available. Many EWG participants see no need for this information in table I, because Codex methods should be fully validated and this process requires a minimum number of labs in the study. Methods that do not meet this requirement would not be considered fully validated and would only be considered Type IV. On the other hand, all the information mentioned in Table I may be necessary for CCMAS to take a decision in a transparent traceable way . The information at this stage is submitted to the CCMAS for further discussion.
- e) Another much discussed question was what to do when there are no performance characteristics available for a method already approved. An evaluation procedure for CCMAS was proposed, considering the importance of having the information to take a decision, but opening the possibility of maintaining a method without that information.
- f) It was also suggested to replace “provision” with “analyte” in the Table II. The term provision was retained because Codex/STAN 234 contains the term “provision”. CCMAS may assess if this change is appropriate.

INTRODUCTION

Codex methods of analysis are primarily intended as international methods for the verification of provisions in Codex standards. They should be used for reference, in calibration of alternative methods in use or to be introduced for routine examination and control purposes.

According to the Procedural Manual, there number of criteria used in the selection of a method of analysis that is fit for purpose, such as:

- Official methods of analysis elaborated by international organizations occupying themselves with a food or group of food;
- Methods with reliability established considering the selectivity, accuracy, precision (repeatability and reproducibility), limit of detection and sensitivity;
- Practicability and applicability under normal laboratory conditions;
- Methods of analysis have direct pertinence to the Codex Standard to which they are directed;
- Methods of analysis applicable uniformly to a various group of commodities.

SINGLE SOURCE (DOCUMENT, DATABASE) FOR METHODS OF ANALYSIS

A single document or a single database is critical to keep methods of analysis updated. It is essential to develop a plan for updating the references to methods of analysis. This approach would allow for a simple and effective method search as well as a permanent and dynamic revision system.

For this proposal all methods from Codex Standards within the oversight of CCMAS should migrate to CODEX STAN 234-1999 and the Procedural Manual should be amended accordingly. The methods administered by CCFH Food Hygiene (microbiological methods), CCPR Pesticide Residues and CCRVDF Residues of Veterinary Drugs in Food are not included in the single document.

The following actions are needed to prepare a single document:

- The section of methods of analysis in Codex Commodity Standards should just mention the reference to see the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) and the methods should be incorporated into this single document;
- Revoke the Codex Standards dealing with general methods of analysis for food additives (CODEX STAN 239-2003), for the detection of irradiated foods (CODEX STAN 231-2001) and for contaminants (CODEX STAN 228-2001) and include these general methods in the single CODEX STAN 234-1999;
- Include into the single document the performance criteria of methods of analysis from the CODEX STAN 193-1995.

The new CODEX STAN 234-1999 should have 3 sections with the following content, depending on how the methodologies are currently mentioned in the Codex documents: standardized methods published by international organizations; performance criteria required for provision determination and complete description of the method of analysis.

I - All Codex Methods of analysis, including standardized methods published by international organizations and methods of the Tables II and III.

In order to permit an evaluation and reevaluation, the single document or database (CODEX STAN 234-1999) should have information mentioned in Table I for methods from international organizations.

Quantitative methods should include the following performance information: Limit of Detection (LOD), Limit of Quantification (LOQ), Recovery (R), Repeatability Relative Standard Deviation (RSD_r) and Reproducibility Standard Deviation (RSD_R). Depending upon the analyte concentration range, it may be not necessary to determine POD or LOQ though it is necessary to consider the minimum applicable range (Range).

Qualitative methods should include at least Probability of Detection (POD).

All information mentioned in the table I is required for Type II and III Methods . Type IV methods may not have all necessary performance data from a collaborative study. A method with incomplete precision data will be automatically classified as Type IV.

In some cases, where no data are available for some performance characteristics, one possible solution is to obtain this information from the historical series data of proficiency tests¹ when filling table I. If additional information is not available other methods may be identified or the method may be endorsed for 5 more years, depending on the CCMAS evaluation, and the entries left blank. However the information should be available to the fullest extent possible, so that CCMAS can make a call for data for consideration in subsequent endorsement meetings. Where information is not available for the next review and CCMAS considers them important, the method can be revoked and another method identified.

Table I should also mention the Committee responsible for the endorsement and the date of endorsement or (re)endorsement, which is essential in the updating process.

Where Performance criteria exist a Methods of Analysis for a particular provision in the Commodity Standard, Table I should contain commodity, provision, ML, Committee Responsible for revision and Year of Endorsement or (Re) Endorsement. In the field "Identification" list "See table II".

For Methods of Analysis where there is a complete description of the method of analysis in the Commodity standard the information in Table I is required and should be provided by the Commodity Committee. In the field "Identification" list "See table III".

II- Performance criteria required for provision determination

Table II of the single document or database (CODEX STAN 234-1999 should contain the following information (Table II): Commodity, Provision, Maximum level (ML), Minimum applicable level, Limit of Detection (LOD), Limit of Quantification (LOQ), Reproducibility Standard Deviation (RSD_R) and Recovery. Methods of analysis that achieve the performance required and their principles can also be identified in table II. To evaluate whether a method is fit for purpose all the data required to approve a standard method (Table I) is also necessary.

III- Complete description of the method of analysis

This section is designed to cover the situation where a complete description of methods of analysis is found in Codex Commodities Standards, however all the methods to be included in the single document or database (CODEX STAN 234-1999) should meet the same criteria used in the other two tables.

¹ Although some data on reproducibility can be derived from proficiency test data, its value could only be determined if it is derived from use of the method in question. Proficiency test providers do not require use of a single method in many cases and thus any data would require careful consideration.

TABLE I – Information required in the methods of analysis standard document

Commodity	Provision	ML	METHOD								Number of Labs in collaborative study	Committee Responsible for revision	Year of Endorsement or (Re) Endorsement	applicabl e standard (s)	
			Identification	Principle	Type	Range	METHOD CRITERIA								
							POD	LOQ	Rec	RSDR					RSDr

TABLE II- Performance criteria required for provision determination

Commodity	Provision	ML (mg/kg)	Min. applicable level (mg/kg)	LOD/POD (mg/kg)	LOQ (mg/kg)	RSDR (%)	Recovery (%)	Suggested methods meeting the criteria	Principle
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UPDATING METHODS OF ANALYSES AND THEIR TYPES

According to the Procedural Manual, the *Codex Alimentarius Commission* and its subsidiary bodies are committed to revise, as necessary, Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information. When required, a standard or related text shall be revised or removed in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts. Each member of the *Codex Alimentarius Commission* is responsible for identifying and presenting to the appropriate committee any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts.

The Commission decides whether a standard should be elaborated and also which subsidiary body or other body should undertake the work. Decisions to elaborate standards may also be taken by subsidiary bodies of the Commission and subsequently be approved by the Commission.

CCMAS is responsible for carrying out the steps of the elaboration procedures of the methods of analysis and sampling of general application to foods.

Methods of analysis for specific commodities were originally assigned by commodity committees or ad hoc Intergovernmental Task Forces. However, some of these committees and Task Forces have been adjourned, abolished or dissolved as shown in Table III. In these cases, CCMAS might perform the update.

TABLE III- List of Codex Committees and Task Forces whose methods of analysis may be submitted to CCMAS and their status

Commodity Committees		
<u>CCCPC</u>	Codex Committee on Cocoa Products and Chocolate	Adjourned sine die
<u>CCCLPL</u>	Codex Committee on Cereals, Pulses and Legumes	Adjourned sine die
<u>CCFFP</u>	Codex Committee on Fish and Fishery Products	Active
<u>CCFFV</u>	Codex Committee on Fresh Fruits and Vegetables	Active
<u>CCFO</u>	Codex Committee on Fats and Oils	Active
<u>CCIE</u>	Codex Committee on Edible Ices	Abolished
<u>CCM</u>	Codex Committee on Meat	Abolished
<u>CCMMP</u>	Codex Committee on Milk and Milk Products	Adjourned sine die
<u>CCNMW</u>	Codex Committee on Natural Mineral Waters	Adjourned sine die
<u>CCPFV</u>	Codex Committee on Processed Fruits and Vegetables	Active
<u>CCPMPP</u>	Codex Committee on Processed Meat and Poultry Products	Abolished
<u>CCS</u>	Codex Committee on Sugars	Active
<u>CCSB</u>	Codex Committee on Soups and Broths	Abolished
<u>CCSCH</u>	Codex Committee on Spices and Culinary Herbs	Active
<u>CCVP</u>	Codex Committee on Vegetable Proteins	Adjourned sine die
ad hoc Intergovernmental Task Forces		
<u>CGECPMMP</u>	Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products	Renamed and reestablished
<u>GEFJ</u>	Joint ECE/Codex alimentarius groups of experts on standardization: Fruit Juices	Abolished
<u>GEQFF</u>	Joint ECE/Codex alimentarius groups of experts on standardization: Quick Frozen Foods	Abolished
<u>TFFBT</u>	Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology	Dissolved
<u>TFFJ</u>	Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices	Dissolved
<u>TFFHQFF</u>	Ad hoc Codex Intergovernmental Task Force on the Processing and Handling of Quick Frozen Foods	Dissolved

FAO /WHO Coordinating Committees		
<u>CCAFRICA</u>	FAO/WHO Coordinating Committee for Africa	Active
<u>CCASIA</u>	FAO/WHO Coordinating Committee for Asia	Active
<u>CCEURO</u>	FAO/WHO Coordinating Committee for Europe	Active
<u>CCLAC</u>	FAO/WHO Coordinating Committee for Latin America and the Caribbean	Active
<u>CCNASWP</u>	FAO/WHO Coordinating Committee for North America and South West Pacific	Active
<u>CCNEA</u>	FAO/WHO Coordinating Committee for Near East	Active
General Subject Committees		
CCCF	Codex Committee on Contaminants in Foods	Active
CCFA	Codex Committee on Food Additives	Active
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses	Active

Source: *Codex Alimentarius* website

PROCESS TO UPDATE CODEX METHODS OF ANALYSIS

There is a concern to keep Codex' recommended methods of analysis up to date. For example, all ISO standards are reviewed at least every 5 years. A majority of the Participating-members of the ISO Technical Committees (TC) or Subcommittee (SC) decides whether an International Standard should be confirmed, revised or withdrawn (www.iso.org).

Similar review processes are also undertaken by other SDOs. The purpose of the review may be to include a new method, to withdraw a method, or to amend or change the type of the method.

The review to include, withdraw or amendment a method is necessary when:

- The provision or the maximum/minimum levels are changed and the method does not meet the required performance;
- Method contains incorrect information;
- Method is not used because it does not meet the performance criteria or it use reagents with safety concerns for the analyst or for the environment;
- Organization responsible for the method revoked, replaced or updated the methodology;
- The Committee responsible for the establishment of the provision propose a revision;
- Every 5 years.

A revision to change the type of the method may occur when:

- A type II method does not meet the current required performance under normal laboratory conditions and/or it is not practical and applicable;
- Performance criteria are established for Type IV methods;
- A Type III method has superior precision data or attributes than the type II method example.g. better equipment, speed, accessibility, affordability;
- Type I method defined for a parameter that currently can be assessed by validated methods that use other principle of determination, for example, protein determination by Kjeldahl or Dumas;
- The method was misclassified.

How to proceed

The procedure should be divided into 3 steps:

1. Put all the methods into one single workable list

2. Select the methods to examine first using prioritization criteria

3. Divide the methods into workable packages

a) Put all the methods into one single workable list

The currently endorsed methods amount to several hundreds and they are listed in numerous Codex documents. This situation makes it very difficult to have a complete overview. The first move should be to put all the methods into a single Excel list where they could be sorted according to the following criteria: Commodity, Provision, Type (I-IV), Responsible, Committee, Year of endorsement and Remarks (any inaccuracies related of the method information, such as two Type II method for the same provision, method not available, wrong provision, not validated for the specific commodity, not identified - just a journal reference).

Once this has been done, it would be feasible to start with the prioritization criteria.

b) Select the method to examine first using prioritization criteria

As the time and resources that can be allocated by the national administrations and by the CCMAS itself to handle this issue is by nature limited, this asks for clear prioritization criteria.

According to the Codex procedure manual general prioritization criteria, the items that should be handled first are those involving "Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries".

Methods of analysis can be categorized according to several parameters: Responsible Codex Committee; Commodity; Provision (analytical parameter) involved; Type (I, II, III or IV); Year of endorsement and methods with inaccurate information.

The prioritization criteria must consider the provision, the type and the method status e.g. absent, inaccurate, inappropriate performance data. The provision gives a hint about relevance for food safety, the type and the accurate information related with the method are relevant for both fair practices and needs of developing countries.

According to these general criteria, the suggestion is to set priority for consideration using the following specific criteria: analytical methods directly linked with food safety (e.g. because they are dealing with chemical, microbiological or physical hazards), type II methods (as these are needed to avoid disputes), methods with inaccurate information and number of years since endorsement (the oldest first).

c) Divide the methods into workable packages

The methods listed/published more than 5 years ago will be divided into first priority and second priority methods. These groups will be divided themselves into packages that could be handled during one CCMAS session. A package contains a group of first priority methods that would be examined in all cases and a group of second priority methods, that would be looked at in the remaining time.

An excel file will be developed for CCMAS that will include all methods approved for the provisions of a Committee, from all sources CCMAS (CODEX STAN 234-1999; CODEX STAN 239-2003; CODEX STAN 231-2001; CODEX STAN 228-2001) and standards belonging to the specific Committee. The file can be the starting document to follow the procedures proposed in this section.

Following prioritization, the packages should be submitted to the IAM Members for comments on the inconsistencies and errors, inclusion of any additional information defined in the new single document and identification of updated methodology to replace the old ones. After this evaluation, methods will be forwarded for review by the responsible committee and subsequent endorsement by CCMAS.

The CCMAS will take the responsibility to revise general methods and those from inactive Committees.

In addition, the Codex Secretariat should prepare every year a list of methods to be revised according the same procedure described in the previous paragraph.

At any time, CCMAS, other Codex Committees, IAM Member Organizations or Members Countries may request revision of methods of analysis if they meet the criteria for revision mentioned in this document. In this case, a document should be prepared with the necessary information to justify the change.

RECOMENDATIONS The CCMAS agreed, in its last session, on the necessity to collect all methods of analysis into a single document. In order to implement this decision, the CCMAS should:

1. Suggest to CCGP to revise the Procedural Manual , Section II, Elaboration of Codex text – Format for Codex Commodity Standards, Methods of Analysis and Sampling (page 54 in English version. The first proposal is to split the section Methods of Analysis and Sampling in two separate sections. The second proposal is regarding the Methods of Analysis section that should be read as follow:

This section should contain only the reference to see the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999). The methods of analysis considered necessary should be prepared in accordance with the guidance given in the section on Methods of Analysis and Sampling in the Relations between Commodity Committees and General Subject Committees. Preference should be given to set performance criteria according to the guidance established in the General Criteria for the Selection of Methods of Analysis using the Criteria Approach. If two or more methods have been accepted as equivalent by the Codex Committee on Methods of Analysis and Sampling, these could be regarded as alternatives.

Original Text from Procedural Manual for comparison:

This section should include, either specifically or by reference, all methods of analysis and sampling considered necessary and should be prepared in accordance with the guidance given in the section on Methods of Analysis and Sampling in the Relations between Commodity Committees and General Subject Committees. If two or more methods have been proved to be equivalent by the Codex Committee on Methods of Analysis and Sampling, these could be regarded as alternatives and included in this section either specifically or by reference.

2. decide about the necessary information for:
 - a. Codex Stan 234
 - b. for a database,
 - c. use of POD instead of LOD for qualitative methods,
 - d. the necessity to replace the term “provision” for “analyte” and
 - e. when the method of analysis is appropriate to “all foods”.
3. agree on the Process to update Codex Methods of Analysis as suggested in this document, including the reasons for the revision.
4. address the revision of the Methods of Analysis, according to the criteria to prioritize the revision and the role performed by CCMAS, IAM Members Organizations and other Codex Committees.
5. agree that CODEX STAN 234-1999 should be revised to include information proposed in this document for the format of a single source of methods of analysis.

ANNEX

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