CODEX ALIMENTARIUS COMMISSION E

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Agenda Item 5 **CX/MAS 12/33/5**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Thirty-third Session

Budapest, Hungary, 5 - 9 March 2012

PROVISIONS ON THE USE OF PROPRIETARY METHODS IN CODEX STANDARDS

(Prepared by an Electronic Working Group)

BACKGROUND

At the thirty-second Session of CCMAS there was discussion on the use of methods of analysis involving proprietary aspects within the Codex system. That Session had before it a paper which had been prepared within the Inter-Agency Meeting (IAM), the partcipants to that meeting also being concerned because of the potential impact on methods publiched by the Standard Development Organisations. The rationale for and concerns about this topic are given in the paper CX/MAS 11/32/6.

The Report of the thirty-second Session of CCMAS states:

> 73. The Committee recalled that its last session had noted that the Inter-Agency Meeting (IAM) would proceed with its consideration of proprietary methods, invited wider contribution than only IAM members and would provide an update to the current session.
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> 74. The Delegation of the United Kingdom introduced the discussion paper and pointed out that the problems of endorsing a proprietary method were mostly limited to Type I as for the "alternative" proprietary methods of analysis, which would be endorsed as Type III, there appeared to be little advantage in specifying such methods in national legislation or in Codex Standards. The discussion paper proposed to consider including in the Codex Procedural Manual a definition of proprietary methods and criteria for the selection of such methods, whether it would be necessary to define additional characteristics that a proprietary method should meet. The situation in which no alternative methods existed was also discussed, including a possibility to define the proprietary chemical used in the method or other alternatives.
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> 75. Some delegations, noting that a proprietary method was easy to use for industry and competent authorities, were of the opinion that several potential problems resulted from the endorsement of proprietary methods in Codex: availability to end-users; potential risk to stop developing new methods of analysis; a "black box method" in which key information would not be disclosed; significant financial advantages for some manufacturers, which would distort competition; and difficulties for governments when using such methods for enforcement purposes.
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> 76. Some delegations pointed out that if CCMAS would endorse a proprietary method as Type I, CCMAS should define a procedure, criteria to assess the need for the method, information requirements about the method such as performance characteristics, validation status, cross reaction, and they should be clearly stated in the Procedural Manual. The Committee noted that a proprietary method without such information would be endorsed as Type IV only.

77. Some delegations and observers drew the attention of the Committee to the fact that the term "proprietary method" should be clearly defined as there was no internationally recognized definition, and that confusion should be avoided with intellectual property rights related to method development in general.

78. After some discussion, the Committee agreed to initiate new work on the development of provisions for proprietary methods in the Procedural Manual and agreed that an electronic working group, led by the United Kingdom and Germany and working in English, would define the term "proprietary method" and prepare a draft version of the criteria to be included in the Procedural Manual. The Committee further agreed that the definition and the draft should be circulated to invite comments from Members and Observers and it would be discussed at the next session.

Other matters

In associated discussion there was comment about the possibility of extending the use of the criteria approach for methods of analysis to Type I methods. The reported discussion here is:

79. The Observer from EURACHEM introduced the discussion paper that had been presented in the IAM concerning the extension of the criteria approach in Codex to Type I methods (CRD 19 and CRD 24), and proposed to discuss how to apply the criteria approach, at least partially, for Type I methods.

80. The discussion paper considered the criteria that could be applied and concluded that, while trueness was not relevant, it may be useful to set additional performance criteria, particularly for precision for establishing Type I methods when the intended use is for calibration. It was proposed to note in Codex guidance that Type I methods define a measurand that could in principle be estimated using alternative methods of measurement, subject to demonstration of adequate performance as defined by the Criteria Approach.

81. Some delegations pointed out that calibration was carried out internally in laboratories but in the framework of Codex and for enforcement purposes there was no need to consider alternative methods to Type I methods, and they did not support further consideration of this approach.

82. The Committee noted that discussion on this question would proceed in the IAM and that the next session would be informed of any further development in the organisations concerned.

ELECTRONIC WORKING GROUP

A general invitation was made to Codex member countries and organizations, associated members of FAO and WHO and international observer organisations to participate in the work. In the event the following countries and organisations agreed to participate in the work:

AACC International, Argentina, Australia, Brazil, Canada, Chile, Denmark, European Commission, Food and Drink Europe, France, Germany, IDF, ISO, Japan, New Zealand, Norway, Panama, The Netherlands, UK and USA.

An early draft of a possible text for inclusion in the Procedural Manual was circulated with a final text for discussion given at the Appendix to this paper. As ever it should be noted that there are differences in the comments submitted by participants to the coordinator of the Working Group. However, there was substantial agreement with the Working Group that care should be taken when introducing proprietary methods of analysis into the Codex system.

CONCLUSIONS FROM INITIAL CIRCULATION

A substantial number of comments were received from the circulation of the paper in January 2012, which is pleasing. The following conclusions/actions may be drawn from the comments made, which, as may be expected, are often sometimes in conflict with each other.

- The scope of General Principles for the Establishment of Codex Methods of Analysis should be clarified, in particular whether they apply to methods for pesticide residues, veterinary drugs and hygiene and thus whether it may then be assumed that proprietary methods should be taken to have the same applicability as the General Principles (comment – the General Principles for the selection of Codex methods are not generally taken to refer to the work of these committees).

- A decision will have to be made as to whether it is better to endorse a proprietary method which is "superior" to a conventional non-proprietary method or better to endorse the non-proprietary method (comment – if there is a choice then the methods concerned must be Type II/III so method criteria should be used).
- It has been suggested that proposed clause (e) identifies another key issue but is not unique to proprietary methods. However, there are a substantial number of commercial approval procedures/certification and it is to emphasise that validation using these procedures is not sufficient that this clause has been included (comment this is a major issue of applicability).
- It has been suggested that the "Definition of a Proprietary Method of Analysis" could be more focused, e.g. is a "party" the same as a "commercial company"? Is it intended that the definition embraces methods that, for instance, specify a proprietary brand of culture medium or HPLC column? If it is, then many methods, including some already adopted, may be covered by these rules (comment – the definition is difficult to formulate without being over-restrictive!).

RECOMMENDATIONS

It is recommended that CCMAS:

- Considers the additional text to the Principles for the Establishment of Codex Methods of Analysis dealing proprietary methods of analysis with principles of the establishment of Codex Methods of Analysis as outlined in the Appendix to this paper.
- Approves the text for inclusion in the Procedural Manual.
- Considers updating the current Principles, particularly with respect to the examples of the different Types of methods of analysis and the method criteria.

APPENDIX: PRINCIPLES FOR THE ESTABLISHMENT OF CODEX METHODS OF ANALYSIS

Current Text in the Procedural Manual to remain as is:

Purpose of Codex Methods of Analysis

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

Methods of Analysis

Definition of types of methods of analysis

(a) **Defining Methods (Type I)**

Definition: A method which determines a value that can only be arrived at in terms of the method per se and serves by definition as the only method for establishing the accepted value of the item measured.

Examples: Howard Mould Count, Reichert-Meissl value, loss on drying, salt in brine by density.

(b) **Reference Methods (Type II)**

Definition: A Type II method is the one designated Reference Method where Type I methods do not apply. It should be selected from Type III methods (as defined below). It should be recommended for use in cases of dispute and for calibration purposes.

Example: Potentiometric method for halides.

(c) **Alternative Approved Methods (Type III)**

Definition: A Type III Method is one which meets the criteria required by the Codex Committee on Methods of Analysis and Sampling for methods that may be used for control, inspection or regulatory purposes.

Example: Volhard Method or Mohr Method for chlorides

(d) **Tentative Method (Type IV)**

Definition: A Type IV Method is a method which has been used traditionally or else has been recently introduced but for which the criteria required for acceptance by the Codex Committee on Methods of Analysis and Sampling have not yet been determined.

Examples: chlorine by X-ray fluorescence, estimation of synthetic colours in foods.

General Criteria for the Selection of Methods of Analysis

(a) Official methods of analysis elaborated by international organizations occupying themselves with a food or group of foods should be preferred.

(b) Preference should be given to methods of analysis the reliability of which have been established in respect of the following criteria, selected as appropriate:

(i) selectivity

(ii) accuracy

(iii) precision; repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within laboratory and between laboratories)

(iv) limit of detection

(v) sensitivity

(vi) practicability and applicability under normal laboratory conditions

(vii) other criteria which may be selected as required.

(c) The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use.

(d) All proposed methods of analysis must have direct pertinence to the Codex Standard to which they are directed.

(e) Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

Additional text for Procedural Manual:

Proprietary Methods of Analysis

Codex Committees may occasionally submit methods of analysis which are proprietary, or are based on proprietary aspects, to the Codex Committee on Methods of Analysis and Sampling for endorsement. CCMAS supports the protection of confidential information in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and encourages the willingness of method sponsors to provide data for CCMAS assessment. When a proprietary method is submitted CCMAS should:

(a) Not endorse a proprietary method if there is available a suitable non-proprietary method of analysis which could be endorsed.

(b) Ensure that preference should be given to endorsing those methods of analysis where the reagents and/or apparatus are described in the method to the degree that either laboratories or other manufacturers could produce them themselves.

(c) Ensure that no approach is taken which appears as if the method is endorsed by Codex to the detriment of other potential methods; if possible preference should be given to adopting appropriate method criteria rather than endorsing a specific proprietary method of analysis. If suitable non-proprietary methods become available and endorsed, the status of the previously endorsed proprietary method may be reviewed and revised.

(d) Ensure that method performance criteria established for proprietary methods are the same as those for non-proprietary methods. Performance criteria should be those stipulated above.

(e) A proprietary method should either be fully collaboratively validated or be validated and reviewed by an independent third party according to internationally recognised protocols. If a proprietary method has not been validated by a full collaborative trial, it may be eligible for adoption into the Codex system as a Codex Type IV method, but not as a Type I, II or III method.

(f) Ensure that any information considered proprietary in a submitted method is minimised to only protect the essential components of the proprietary property.

(g) Ensure that proprietary methods brought into the Codex system are accessible to all competent authorities.

(h) Ensure that proprietary methods brought into the Codex system do not restrict research into determining their properties, scope of claim and validity or development of improvements to the technology.

Definition of a Proprietary Method of Analysis

For Codex purposes a proprietary method of analysis is one that contains protected intellectual property preventing full disclosure of information about the method and/or restricting or limiting the use or distribution of the method or materials for its performance without express permission or licensing. It does not extend to a method which is subject only to copyright.