Codex Committee on Methods of Analysis and Sampling  
(33rd Session)  
Budapest, Hungary (5 - 9 March 2012)  

European Union comments on the  
Provisions on the Use of Proprietary Methods in Codex Standards  

(Agenda item 5, CX/MAS 12/33/5)  

Mixed Competence  
European Union Vote  

The European Union and its Member States (EUMS) wish to commend the United Kingdom and Germany for taking the lead in an electronic working group tasked with the development of a discussion paper on the introduction of proprietary methods of analysis into the Codex system.

Proprietary methods and their relationship to the Codex system were discussed at previous meetings of CCMAS and delegates acknowledged the increasing importance of such methods for the food industry as well as for competent authorities. At the same time concerns have been expressed regarding *inter alia* a proper definition of proprietary methods and the lack of provisions for proprietary methods in the Procedural Manual. More specifically, questions were raised related to the classification of proprietary methods, their validation requirements, and distorted market competition due to preferential treatment of proprietors of endorsed proprietary methods.

The EUMS welcomes and supports the proposed additional text to the Principles for the Establishment of Codex Methods of Analysis for inclusion in the Procedural Manual as it clarifies what proprietary methods are, under what conditions they can be brought into the Codex system, and which validation requirements have to be fulfilled. In particular, the EUMS supports the notion that only methods validated by a collaborative study can by of Type I, II or III.

It is suggested:

1. To move the definition of proprietary methods, which now appears at the end of the additional text, to appear below the heading *Proprietary Methods of Analysis.*

2. To add the words "*and comparably performing*" to (a). This is important because for instance in the case of GMOs almost all event specific methods validated are proprietary, but often there are no valid alternatives; therefore CCMAS should not reject a proprietary method simply because there is a “suitable” (too generic) alternative, but only of a method providing the same performance is available and validated.

3. To add in (d), If appropriate, information on lot-to-lot variability of the proprietary method to the method performance criteria should be provided.
The text would then be as follows:

Proprietary Methods of Analysis

**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.

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 and comparably performing 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. **If appropriate, information on lot-to-lot variability of the proprietary method to the method performance criteria should be provided.**

(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.

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