

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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TO: Codex Contact Points
Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme

SUBJECT: Distribution of the Report of the 33rd Session of the Codex Committee on Methods of Analysis and Sampling (REP12/MAS)

A. MATTERS FOR ADOPTION BY THE 35th SESSION OF THE COMMISSION:

Draft Guidelines Step 5 of the Procedure

1. Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (section on Principles) (para. 20, Appendix IV).

Methods of Analysis and Sampling

2. Methods of Analysis in Codex Standards at different steps, including methods of analysis for food grade salt (paras 23 - 60, Appendix III)

Governments and interested international organizations wishing to comments on items 1, 2 and 3 above should do so in writing, in conformity with the *Procedure for the Elaboration of Codex Standards and Related Texts* (Procedural Manual of the Codex Alimentarius Commission), to the above address, before **15 May 2012**.

Appendix II**STATUS OF ENDORSEMENT OF METHODS OF ANALYSIS AND SAMPLING**

- A. Fish and Fishery Products
- B. Food Additives
- C. Processed Fruits and Vegetables
- D. Coordinating Committee for the Near East
- E. Milk and Milk Products
- F. Nutrition and Foods for Special Dietary Uses
- G. Fats and Oils
- H. Natural Mineral Waters
- I. Methods that are no longer available

A. COMMITTEE ON FISH AND FISHERY PRODUCTS

Standard for Fish Sauce

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Fish sauce	total nitrogen	AOAC 940.25	digestion	type I
Fish sauce	amino acid nitrogen	AOAC 920.04 and AOAC 920.03	determining formaldehyde titration method subtracting by ammoniacal nitrogen (magnesium oxide method)	type I
Fish sauce	pH	AOAC 981.12	electrometry	type III The pH shall be measured in a sample of fish sauce diluted with water to 1:10 using a pH meter. The dilution of fish sauce is necessary because of the high ionic strength in the undiluted sauce.
Fish sauce	sodium chloride	AOAC 937.09	Titrimetry	type IV
Fish sauce	sodium chloride	AOAC 976.18	potentiometry	type II
Fish sauce	sodium chloride	AOAC 976.19	Indicating strip method	Not endorsed as this is a “proprietary method” and alternative methods are available
Fish sauce	histamine	AOAC 977.13	Fluorimetry	type II

Note: Consequential amendment to the methods for sodium chloride in Boiled Dried Salted Anchovies (AOAC 937.09)

B. COMMITTEE ON FOOD ADDITIVES

Draft Revision of the Standard for Food Grade Salt

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
food grade salt	sulphate	ISO 2480:1972	gravimetric	type II
food grade salt	sulphate	EuSalt/AS 015-2007	ICP-OES	type III
food grade salt	sulphate	EuSalt/AS 018-2005	Ion chromatography	type III
food grade salt	halogens	ISO 2481:1973	mercurimetry	Not endorsed. Refer back to CCFA due to no provision for halogen in the Standard and safety concerns with a reagent in the method
food grade salt	halogens	EuSalt/AS 016-2005	potentiometry	Not endorsed. Refer back to CCFA due to no provision for halogen in the Standard
food grade salt	halogens	EuSalt/AS 018-2005	ion chromatography	Not endorsed. Refer back to CCFA due to no provision for halogen in the Standard

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
food grade salt	calcium and magnesium	ISO 2482:1973	complexometric titrimetry	type II
food grade salt	calcium and magnesium	EuSalt/AS 009-2005	Flame atomic absorption spectrometry	type III
food grade salt	calcium and magnesium	EuSalt/AS 015-2007	ICP-OES	type III
food grade salt	potassium	EuSalt/AS 007-2005	volumetry	Not endorsed. Refer back to CCFA due to safety concerns with a reagent in the method
food grade salt	potassium	EuSalt/AS 008-2005	Flame atomic absorption spectrometry	type II
food grade salt	potassium	EuSalt/AS 015-2007	ICP-OES	type III
food grade salt	copper	EuSalt/AS 005-2005	photometry	Not endorsed. Concern on availability of carbon tetrachloride; See annex
food grade salt	copper	EuSalt/AS 015-2007	ICP-OES	type III; See annex
food grade salt	arsenic	EuSalt/AS 011-2005	photometry	Not endorsed. Refer back to CCFA due to safety concern on the use of pyridine in the method; See annex
food grade salt	arsenic	EuSalt/AS 015-2007	ICP-OES	type IV; See annex
food grade salt	mercury	EuSalt/AS 012-2005	cold vapour atomic absorption spectrometry	type IV; See annex
food grade salt	lead	EuSalt/AS 013-2005	flame atomic absorption spectrometry	type IV; See annex
food grade salt	lead	EuSalt/AS 015-2007	ICP-OES	type III; See annex
food grade salt	cadmium	EuSalt/AS 014-2005	flame atomic absorption spectrometry	type IV; See annex
food grade salt	cadmium	EuSalt/AS 015-2007	ICP-OES	type III; See annex
food grade salt	iodine	EuSalt/AS 002-2005	Titrimetry using sodium thiosulphate	type II
food grade salt	iodine	WHO/UNICEF/ICCIDD method ¹	Titrimetry using sodium thiosulphate	type IV Only applicable to a product which has been fortified with iodate
food grade salt	iodine	EuSalt/AS 019-2009	ICP-OES	type III

¹ Assessment of iodine deficiency disorders and monitoring their elimination. A guide for programme managers. Third edition, Annex 1: Titration method for determining salt iodate and salt iodine content. World Health Organization, Geneva, 2007. The report is available from http://www.who.int/nutrition/publications/micronutrients/iodine_deficiency/WHO_NHD_01.1/en/index.html

C. COMMITTEE ON PROCESSED FRUITS AND VEGETABLES

Standard for Canned bamboo Shoots

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Canned Bamboo Shoots	Tin	NMKL 126:1988 ISO 17240:2004	Flame atomic absorption spectrometry	type III

Note: The 24th CCFFV (2006) agreed to delete method ISO 2447:1998 in the Standard for Pickled Fruits and Vegetables following the request from CCMAS to clarify why this method was used and to consider using the General Codex Method AOAC 980.19 (Type II) (ALINORM 07/30/27, Appendix II)

D. COORDINATING COMMITTEE FOR THE NEAR EAST

Regional Standard for Harissa

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
harissa	acidity	ISO 750:1998	titrimetry	type I
harissa	dry extract – soluble solids	ISO 2173:2003	refractometry	type I
harissa	acid insoluble ash	ISO 763:2003	gravimetry	type I
harissa	colour	“Hunter” method		Not endorsed. CCNEA to be asked to propose an appropriately referenced method

Regional Standard for Halwa Tehenia

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
halwa tehena	moisture	AOAC 925.45 AACC Intl 44.60.01	gravimetry	type I
halwa tehena	fat	AOAC 963.15	gravimetry	type I
halwa tehena	ash	AOAC 900.02 AACC Intl 8.14.01	gravimetry	type I
halwa tehena	sugars (estimated as sucrose)	AOAC 930.15		Method proposed not endorsed. CCNEA to be asked to propose an appropriate method
halwa tehena	acidity	AOAC 900.02		Method proposed not endorsed. CCNEA to be asked to propose an appropriate method

E. COMMITTEE ON MILK AND MILK PRODUCTS

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type proposed
Fermented milks	total acidity expressed as percentage of lactic acid	ISO/TS 11869 IDF/RM 150: 2012	Potentiometry, titration to pH 8.30	type I
Blend of sweetened condensed skimmed milk and vegetable fat	Milk solids-not-fat (MSNF) ²	ISO 6734 IDF 15:2010	Calculation from total solids content, fat content and sugar content	type IV
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	MSNF ²	ISO 6734 IDF 15:2010	Calculation from total solids content, fat content and sugar content	type IV

F. COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Methods of analysis for dietary fibre: Guidelines for Use of Nutrition and Health Claims: Table of Conditions for Claims

Other methods ⁽²⁾ that have not been subjected to interlaboratory evaluation				
Yeast cell wall	Insoluble glucans and mannans of yeast cell wall (for yeast cell wall only)	Eurasymp (European association for specialty yeast product) – LM Bonanno. Biospringer- 2004 – online version : http://www.eurasymp.org/public.technique.home.screen .	Chemical & HPAEC-PAD	Type IV

² Milk total solids and Milk solids-not-fat content include water of crystallization of lactose.

G. COMMITTEE ON FATS AND OILS

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Fats and oils	Butylhydroxy-anisole, butylhydroxy-toluene, tert-butylhydroquinone, & propyl gallate	AOAC 983.15; or AOCs Ce 6-86 (09)	Liquid chromatography	type II
Fats and oils not covered by individual standards	Acid Value	ISO 660:2009; or AOCs Cd 3d-63 (09)	Titrimetry	type I
Fats and oils not covered by individual standards	Copper and Iron	AOAC 990.05 ISO 8294:2007 or AOCs Ca 18b-91 (09) (Codex general method)	Atomic absorption Spectrophotometry (direct graphite furnace)	type II
Fats and oils not covered by individual standards	Peroxide value	AOCs Cd 8b-90 (11) ISO 3961:1996	Titrimetry using <i>iso</i> -octane	type I
Named Animal Fats	Iodine value (IV)	ISO 3961: 1996; or AOAC 993.20; or AOCs Cd 1d-92 (09)	Wijs-Titrimetry	type I
Named Animal Fats	Peroxide value	AOCs Cd 8b-90 (11) ISO 3961:1996	Titrimetry using <i>iso</i> -octane	type I
Named Animal Fats	Saponification value	ISO 3657:2002; or AOCs Cd 3-25 (11)	Titrimetry	type I
Named Animal Fats	Unsaponifiable matter	ISO 3596:2000 or ISO 18609: 2000; or AOCs Ca 6b-53 (11)	Titrimetry after extraction with diethyl ether	type I
Named Vegetable Oils	Acidity	ISO 660: 2009 or AOCs Cd 3d-63 (09)	Titrimetry	type I
Named Vegetable Oils	Apparent density	ISO 6883: 2007, with the appropriate conversion factor; or AOCs Cc 10c-95 (09)	Pycnometry	type I

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Named Vegetable Oils	Crismet value	AOCS Cb 4-35 (09) and AOCS Ca 5a-40 (12)	Turbidity	type I
Named Vegetable Oils	GLC ranges of fatty acid composition	ISO 5508: 1990 and ISO 12966-2:2011; or AOCS Ce 2-66 (09) and Ce 1-62 (09) or Ce 1h-05 (09)	Gas chromatography of methyl esters	type II
Named Vegetable Oils	Insoluble impurities	ISO 663:2007	Gravimetry	type I
Named Vegetable Oils	Iodine value (IV)	Wijs - ISO 3961:2009; or AOAC 993.20; or AOCS Cd 1d-92 (09); or NMKL 39 (2003)	Wijs-Titrimetry ³	type I
Named Vegetable Oils	Peroxide value (PV)	AOCS Cd 8b-90 (11); or ISO 3960: 2007	Titrimetry	type I
Named Vegetable Oils	Saponification value (SV)	ISO 3657: 2002; or AOCS Cd 3-25 (11)	Titrimetry	type I
Named Vegetable Oils	Sterol content	ISO 12228: 1999; or AOCS Ch 6-91 (11)	Gas chromatography	type II
Named Vegetable Oils	Unsaponifiable matter	ISO 3596: 2000; or ISO 18609: 2000; or AOCS Ca 6b-53 (11)	Gravimetry	type I
Olive Oils and Olive Pomace Oils	Acidity, free (acid value)	ISO 660:2009 or AOCS Cd 3d-63 (09)	Titrimetry	type I
Olive Oils and Olive Pomace Oils	Difference between the actual and theoretical ECN 42 triglyceride content	COI/T.20/Doc. no. 20 or AOCS Ce 5b-89 (11)	Analysis of triglycerides of HPLC and calculation	type I
Olive Oils and Olive Pomace Oils	Fatty acids in the 2-position of the triglycerides	ISO 6800:1997 or AOCS Ch 3-91 (11)	Gas chromatography	type I

³ It is possible to calculate the Iodine Value from fatty acid composition data obtained by gas chromatography e.g. using AOCS Cd 1b-87 (09)

COMMODITY	PROVISION	METHOD	PRINCIPLE	Notes and Type
Olive Oils and Olive Pomace Oils	Insoluble impurities in light petroleum	ISO 663:2007	Gravimetry	type I
Olive Oils and Olive Pomace Oils	Iodine value	ISO 3961:2009 or AOAC 993.20 or AOCS Cd 1d-92 (97) or NMKL 39 (2003)	Wijs-Titrimetry	type I
Olive Oils and Olive Pomace Oils	Peroxide value	ISO 3960:2007 or AOCS Cd 8b-90 (11)	Titrimetry	type I
Olive Oils and Olive Pomace Oils	Saponification value	ISO 3657:2002 or AOCS Cd 3-25 (11)	Titrimetry	type I
Olive Oils and Olive Pomace Oils	Sterol composition and total sterols	COI/T.20/Doc. no. 10 or ISO 12228:1999 or AOCS Ch 6-91 (11)	Gas chromatography	type I
Olive Oils and Olive Pomace Oils	<i>trans</i> fatty acids content	COI/T.20/Doc no. 17 or ISO 15304:2002 or AOCS Ch 2a-94 (11)	Gas chromatography of methyl esters	type II
Olive Oils and Olive Pomace Oils	Unsapoifiable matter	ISO 3596:2000 or ISO 18609:2000 or AOCS Ca 6b-53 (11)	Gravimetry	type I
Olive Oils and Olive Pomace Oils	Wax content	COI/T.20/Doc. no. 18 or AOCS Ch 8-02 (11)	Gas chromatography	type II

H. NATURAL MINERAL WATERS

Criteria applicable to health-related substances in the Standard for Natural Mineral Waters

Provision	ML (mg/L)	Min. applicable range (mg/L)	LOD (mg/L)	LOQ (mg/L)	Precision RSDR (%) No more than	Recovery (%)	Suggested methods meeting the criteria	Principle
Borate	5	3.1	0.5	1	25	97-103	ISO 9390:1990 ISO 11885:2007 ISO 17294-2:2003	Spectrophotometry ICP-OES ICP-MS ⁴
Fluoride	1.0	0.52	0.1	0.2	32	97-103	ISO 10304-1:2007 ISO 10359-1:1992 (dissolved fluoride) ISO 10359-2:1994 (inorganic bound)	LC of ions Electrochemical probe Digestion, distillation
Nitrate	50	37	5	10	18	98-102	ISO 10304-1:2007 ISO 13395:1996 ISO 7890-3:1988	LC of ions CFA, FIA, Spectrophotometry Spectrophotometry
Nitrite	0.1	0.03	0.01	0.02	44	95-105	ISO 10304-1:2007 ISO 13395:1996 ISO 6777:1984	LC of ions UV CFA, FIA, Spectrophotometry Spectrophotometry

I. METHODS TO BE REVOKED FROM CODEX STAN 234

COMMODITY	PROVISION	METHOD	PRINCIPLE	Note
Milk fat products	Milk fat	IDF 24:1964	Gravimetry (calculation from solids-not-fat content and water content)	
Fruit juices and Nectars	Vitamin C	EN 14130:2004	HPLC	
Infant Formula	Vitamin C	EN 14130:2003	HPLC	

⁴ Total Boron is determined

Method Criteria Values for Copper, Arsenic, Mercury, Lead and Cadmium in Food Grade Salt

Table 1: Criteria approach including appropriate methods

Provision	ML (mg/kg)	Min. applicable level (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	Precision RSD _R (%)	Recovery (%)	Suggested methods meeting the criteria	Principle
Copper	2	1.1	0.2	0.4	29	80-110	EuSalt/AS 015-2007	ICP-OES
Arsenic	0.5	0.2	0.05	0.1	36	80-110		
Mercury	0.1	0.03	0.01	0.02	45	80-110		
Lead	2	1.1	0.2	0.4	29	80-110	EuSalt/AS 015-2007	ICP-OES
Cadmium	0.5	0.2	0.05	0.1	36	80-110	EuSalt/AS 015-2007	ICP-OES

Table 2: Methods, suggested for endorsement, but for which further documentations/validations are needed:

Provision	Method	Principle	Results from the collaborative study	Comments
Copper	EuSalt/AS 005-2005	Photometry Note: use of carbon tetrachloride is restricted	13 laboratories 4 <u>low</u> levels: 0.02 – 0.054 mg/kg thus RSD _R high (43-77%)	The collab study is not valid as it has been performed on too low levels, and thus the precision is poor. The method might be ok, however, documentation is needed for the levels around ML.
Arsenic	EuSalt/AS 011-2005	Photometry	17 laboratories 3 <u>low</u> levels: 0.005-0.0024 mg/kg thus RSD _R high (210-680%)	See above.
Arsenic	EuSalt/AS 015-2007	ICP-OES	16 laboratories 5 levels: 0.08 – 20.76 mg/kg RSD _R : 5.4-270% Lowest validated level with ok prec. 0.84 mg/kg	The precision is not satisfactory for the levels around ML.
Mercury	EuSalt/AS 012-2005	cold vapour AAS	Several laboratories 3 levels below LOQ thus RSD _R very high (>350%)	The collab study is not valid as it has been performed on too low levels, and thus the precision is poor. The method might be ok, however, documentation is needed for the levels around ML.
Lead	EuSalt/AS 013-2005	Flame AAS	15 laboratories 3 levels below LOQ, thus RSD _R very high (>125%)	See above.
Cadmium	EuSalt/AS 014-2005	Flame AAS	15 laboratories 3 levels below LOQ (highest 0.011mg/kg) RSD _R : > 93%	See above.

APPENDIX IV

PROPOSED DRAFT PRINCIPLES FOR THE APPLICATION OF SAMPLING AND TESTING ACTIVITIES IN INTERNATIONAL FOOD TRADE

(Step 5 of the procedure)

SECTION 1 - INTRODUCTION

1. Sampling and testing procedures are utilized to determine if foods in trade are compliant with particular specifications. These procedures establish the level of protection afforded to exporters and producers, and importers and consumers. The procedures used should be such as to ensure that Consumers' Risk and Producers' Risk are both considered. The absence of defined, scientifically valid procedures could lead to *ad hoc* practices being used, resulting in inconsistent decisions and an increased occurrence of disputes.
2. To ensure the sampling and testing procedures are valid, they should be based upon scientific, internationally accepted principles, and it is necessary to ensure that they can be applied fairly. In regard to sampling, the *General Guidelines on Sampling* states that "Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard." As for methods of analysis, those endorsed by Codex should be considered first.
3. Sampling and testing procedures in international food trade are often used for the purpose of risk management related to safety. For this purpose, sampling and testing procedures should be established as an integral part of a national food control system to the extent possible.
4. Risk management decisions should be commensurate to the assessed risk, and should take into account the economic consequences and feasibility of risk management options. Risks due to conditions during storage and transport should be considered by all business operators in the food distribution chain. In order to achieve this there should be an understanding of the impacts of sampling and testing options on all affected parties. Risk management itself should be a continuing process that takes into account all new information, including scientific information, in the evaluation and review of risk management decisions based on sampling and testing.
5. It should be recognised that end-product sampling and testing is only one of the methods by which an exporter can validly claim confidence that product meets specifications.
6. This document does not affect existing Codex limits or the current way of setting those limits. These responsibilities are set out in committees' terms of reference.

SECTION 2 - SCOPE

7. These principles are intended to assist governments in the establishment and use of sampling and testing procedures for determining, on a scientific basis, whether foods in international trade are in compliance with particular specifications. Compliance with these principles will also assist in avoiding potential disputes.
8. These principles do not :
 - a) address other uses of sampling and testing;
 - b) address other means of establishing that foods in trade meet specifications;
 - c) give guidance on choosing appropriate levels of Consumers' Risk and Producers' Risk.

SECTION 3 - DEFINITIONS**Testing**

Process to examine the specified characteristics of a sample.

Testing procedure

Operational requirements and/or instructions relating to the testing; i.e. preparation of sample and method of analysis to yield knowledge of the characteristic(s) of the sample.

Sampling procedure

Operational requirements and/or instructions relating to the use of a particular sampling plan; i.e. the planned method of selection, withdrawal and transport to the laboratory of sample(s) from a lot or consignment to yield knowledge of its characteristic(s).

Other definitions relevant to these principles include:

Consignment¹**Lot¹****Sample¹****Sampling¹****Sampling plan¹****Result²****Measurement uncertainty³****Consumers' Risk and Producers' Risk¹***Note 1*

The definitions of Consumers' Risk and Producers' Risk refer to the probabilities of wrongly accepting or wrongly rejecting a lot or consignment, respectively.

Note 2

The word “probability” should be interpreted as the proportion or percentage of times that lots or consignments identical to the given lot or consignment would be incorrectly decided by the specified sampling and testing procedures.

SECTION 4 - PRINCIPLES**Principle 1: Agreements before initiating trade**

Before starting trading activities, the parties concerned should reach agreement related to the sampling and testing procedures that will be applied to determine whether the food in trade meets the specifications of the importing country and also on the sampling and testing procedures to be followed in the case of a dispute.

Principle 2: Transparency

The selection of sampling and testing procedures and the process for comparing test results to specifications should be documented, communicated and agreed upon by all parties. All relevant information should be shared between governments using mutually agreed upon format and language(s).

Principle 3: Components of a product assessment procedure

Sampling and testing of food in trade to determine whether the food meets specifications involves three components, and all three of these should be considered when an assessment procedure is selected:

- Selection of samples from a lot or consignment as per the sampling plan;
- Examination or analysis of these samples to produce test results (sample preparation and test method(s)); and
- Criteria upon which to base a decision using the results.

Principle 4: Consumers' Risk and Producers' Risk

Whenever food is sampled and tested, the probability of wrongly accepting or wrongly rejecting a lot or consignment affects both exporters and importers and can never be entirely eliminated. The Consumers'

¹ *General Guidelines on Sampling (CAC/GL 50)*

² *Guidelines on Analytical Terminology (CAC/GL 72)*

³ *Guidelines on Measurement Uncertainty (CAC/GL 54)*

Risk and Producers' Risk should be evaluated and controlled, preferably using methodology described in internationally recognized standards.

Principle 5: Selecting appropriate sampling and testing procedures

The sampling and testing procedures selected should be scientifically based and appropriate to the commodity and lot or consignment to be sampled and tested, fit for intended purposes and applied consistently.

Principle 6: Practical considerations

The selection of sampling and testing procedures should take into account practical matters such as cost and timeliness of the assessment and access to lots or consignments, provided that Consumers' Risk is not compromised.

Principle 7: Taking account of analytical measurement uncertainty and its implications

The selection of the product assessment procedure should take into account analytical measurement uncertainty.

Principle 8: Product variation

The selection of sampling and testing procedures should take into account the potential variations within a lot or consignment.

Principle 9: Fitness for purpose

A testing procedure is fit for purpose in a given product assessment procedure, if, when used in conjunction with the sampling plan and the decision criteria, it has accepted probabilities of wrongly accepting or wrongly rejecting a lot or consignment.

Principle 10: Review procedures

Sampling and testing procedures should be reviewed periodically to ensure they take into account new science and information.

SECTION 5 - REFERENCES

- *Guidelines for Food Import Control Systems* (CAC/GL 47-2003)
- Publications and resources of the ISO Committee on Conformity Assessment (ISO CASCO) at http://www.iso.org/iso/resources/conformity_assessment.htm.

APPENDIX V

PROVISIONS ON THE USE OF PROPRIETARY METHODS IN CODEX STANDARDS

(To be added to the procedural manual)

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 where the intellectual property owner restricts the use or distribution of the method or materials for its performance such that no alternative source of these would be available. It does not extend to a method which is subject only to copyright.

Requirements

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 encourages the method sponsors to provide data for CCMAS assessment.

- a) A proprietary method should not be endorsed if there is available a suitable non-proprietary method of analysis which has been or could be endorsed and which has similar or better performance characteristics. This should ensure that no approach is taken such that it appears as if a proprietary 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.
- b) 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) 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 the effect of manufacturing variability of the proprietary method on the method performance should be provided.
- d) After endorsing, any changes that influence performance characteristics must be reported to CCMAS for consideration.
- e) A proprietary method should be either fully collaboratively validated or validated and reviewed by an independent third party according to internationally recognised protocols. The results of such studies should be made available for CCMAS. 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) Whilst respecting the necessity for reasonable protection of intellectual property, sufficient information should be available to enable reliable use of the method by analysts and to enable evaluation of the performance of the method by CCMAS. In any particular case this may extend beyond performance data, for example to include details of operating principle, at the sole discretion of CCMAS.
- g) The supplier or submitter of a proprietary method should demonstrate to CCMAS's satisfaction that the method will be readily available to all interested parties.
- h) CCMAS may decline to endorse a proprietary method if restrictions by intellectual property unduly restrict research into determining the method properties, scope of claim and validity or development of improvements to the technology.
- i) If suitable nonproprietary methods become available and endorsed, the status of the previously endorsed proprietary method should be reviewed and may be revised.